Table of Contents

As filed with the Securities and Exchange Commission on August 11, 2014.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

TOKAI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	20-1000967
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

One Broadway, 14th floor
Cambridge, MA 02142
(617) 225-4305
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jodie P. Morrison
President and Chief Executive Officer
Tokai Pharmaceuticals, Inc.
One Broadway, 14th floor
Cambridge, MA 02142
(617) 225-4305
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Stuart M. Falber, Esq. **Glenn J. Luinenburg, Esq.** **Wilmer Cutler Pickering Hale and Dorr LLP** **60 State Street** **Boston, Massachusetts 02109** **(617) 526-6000**	**Mitchell S. Bloom, Esq.** **Lawrence S. Wittenberg, Esq.** **Goodwin Procter LLP** **Exchange Place** **53 State Street** **Boston, Massachusetts 02109** **(617) 570-1000**

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act") please check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

CALCULATION OF REGISTRATION FEE

Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.001 par value per share	$75,000,000	$9,660

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, and includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price and includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated August 11, 2014

PRELIMINARY PROSPECTUS

Shares

Common Stock

Tokai Pharmaceuticals, Inc.

This is the initial public offering of shares of common stock of Tokai Pharmaceuticals, Inc. We anticipate that the initial public offering price will be between $ and $ per share.

We have granted the underwriters the option to purchase up to an additional shares of common stock on the same terms and conditions set forth above within 30 days from the date of this prospectus if the underwriters sell more than shares of common stock in this offering.

We are offering all of the shares of common stock offered by this prospectus. No public market currently exists for our common stock.

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "TKAI."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to Tokai Pharmaceuticals, Inc. (before expenses)	$	$

(1) We refer you to "Underwriting" beginning on page 153 for additional information regarding underwriter compensation.

The underwriters expect to deliver the shares on or about , 2014.

BMO Capital Markets • Stifel • William Blair

Janney Montgomery Scott

Prospectus dated , 2014.

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. We are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

Until , 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside the United States: Neither we nor any of the underwriters have taken any action to permit a public offering of the shares of our common stock or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Prospectus Summary

This summary highlights selected information included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the "Risk Factors" section beginning on page 12 and our consolidated financial statements and the related notes appearing at the end of this prospectus before making an investment decision. Unless the context otherwise requires, we use the terms "Tokai," "our company," "we," "us" and "our" in this prospectus to refer to Tokai Pharmaceuticals, Inc.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Our lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies. We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone was well tolerated and in multiple prostate cancer populations showed clinically meaningful reductions in levels of prostate specific antigen, or PSA, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy. Subject to discussions with the U.S. Food and Drug Administration, or FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015.

We are focusing our initial development of galeterone on the treatment of patients with castration resistant prostate cancer, or CRPC, whose prostate tumor cells express an altered androgen receptor that is truncated. We intend to conduct our planned pivotal clinical trial in these patients who we believe may not be effectively treated by the therapies approved by the FDA in recent years. We believe that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provides an opportunity to treat this population of patients. In our ongoing Phase 2 clinical trial of galeterone, which we refer to as our ARMOR2 trial, four patients were identified as having altered androgen receptors that were truncated, all of whom showed clinically meaningful PSA reductions of at least 50%. Although our initial development focus is on galeterone for the treatment of this population of patients, we are conducting our Phase 2 ARMOR2 trial of galeterone in multiple CRPC patient populations.

Galeterone acts by disrupting the androgen receptor signaling pathway, which is the primary pathway that drives prostate cancer growth. The pathway is ordinarily activated by the binding of male hormones, or androgens, such as testosterone and the more potent androgen dihydrotestosterone, or DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. Galeterone disrupts the activation of the pathway through multiple mechanisms of action:

- inhibition of the enzyme CYP17, which blocks the synthesis of testosterone;
- androgen receptor antagonism, which blocks the binding of testosterone or DHT with the androgen receptor; and
- androgen receptor degradation, which reduces the amount of androgen receptor protein in the tumor cells.

We believe that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments.

The truncated androgen receptors for which we are developing galeterone are missing the end of the receptor that contains the ligand binding domain. We describe patients with these truncated androgen receptors as having C-terminal loss. An example of one such truncated androgen receptor with C-terminal loss is the splice

variant AR-V7, which is the most prevalent of the splice variants that cause C-terminal loss. In these patients, the lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. In clinical studies conducted by researchers at MD Anderson Cancer Center and Johns Hopkins University, the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga® (abiraterone acetate) and Xtandi® (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2013 sales of more than $2.1 billion. We believe that these studies indicate that there is a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7. We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone based on this unmet need in CRPC patients and the design of our planned pivotal clinical trial.

In addition to our planned pivotal clinical trial, we are conducting our ARMOR2 trial of galeterone for the treatment of multiple CRPC populations. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We have exclusive worldwide development and commercialization rights to galeterone.

Prostate Cancer. According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States during 2014, approximately 233,000 new cases of prostate cancer will be diagnosed, and approximately 29,000 men will die from the disease. Prostate cancer drugs represent a large and growing market. According to Decision Resources Group, an independent research firm, sales of prostate cancer drugs are expected to increase from $6.0 billion in 2013 to more than $9.0 billion in 2021, due to a growing aged population, a rising incidence of cancer and the introduction of new drugs for the treatment of prostate cancer. These new drugs include Zytiga and Xtandi, which are approved for the treatment of CRPC. Although Zytiga was only approved in 2011 and Xtandi in 2012, both of these drugs have experienced rapid sales growth, with reported worldwide 2013 sales of $1.7 billion for Zytiga and $445 million for Xtandi. Despite their success, the need for new treatment options remains as each of these drugs has treatment limitations in CRPC patients generally and may not be effective in CRPC patients with C-terminal loss, including AR-V7.

ARMOR2 Trial. In December 2012, we initiated a two-part Phase 2 open label clinical trial of galeterone for the treatment of CRPC, which we refer to as our ARMOR2 trial. Part 1 of the trial was a dose escalation phase designed to confirm the dose of galeterone to be evaluated in Part 2 of the trial. We are currently evaluating the 2550 mg/day dose for safety and efficacy in Part 2 of the trial in a total of up to 108 patients, in four distinct CRPC patient populations.

In May 2014, we announced interim data from our ARMOR2 trial at The American Society of Clinical Oncology 2014 Annual Meeting, or ASCO. The interim data included patients who had not previously undergone chemotherapy and had not received treatment with Zytiga or Xtandi, whom we refer to as CRPC treatment-naïve patients, and patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga- refractory patients. We reported that in 51 evaluable CRPC treatment-naïve patients, galeterone showed clinically meaningful reductions in levels of PSA. Specifically, we reported the following:

- *Non-metastatic and metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 82% of patients showed maximal reduction in PSA levels of at least 30%, and 75% of patients showed maximal reduction in PSA levels of at least 50%.
- *Metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 85% of patients showed maximal reduction in PSA levels of at least 30%, and 77% of patients showed maximal reduction in PSA levels of at least 50%.

We also reported 12-week data for 15 Zytiga-refractory patients, two of whom had a maximal reduction in PSA levels of at least 30%.

In addition, we presented data from a retrospective subset analysis in which four treatment-naïve CRPC patients in ARMOR2 were identified as having truncated androgen receptors with C-terminal loss. All four of these patients had maximal reductions in PSA levels of at least 50%. These data are consistent with galeterone's mechanism of action of androgen receptor degradation, which does not require a functional ligand binding domain.

In June 2012, the FDA designated galeterone for the treatment of CRPC for fast track review. The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have more frequent interactions with the FDA, and the FDA may initiate review of sections of a fast track product's new drug application, or NDA, on a rolling basis before the application is complete. In addition, sponsors may request and be granted priority review of their application.

Mechanisms of Action. The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. Ordinarily, the pathway and tumor growth are activated by the binding of testosterone and DHT to the ligand binding domain of androgen receptors. As a result, therapies that block this binding can be effective in disrupting the pathway and tumor cell growth. Zytiga blocks this binding by reducing the synthesis of testosterone through the inhibition of the enzyme CYP17. Xtandi blocks the binding of testosterone or DHT with the androgen receptor through androgen receptor antagonism. However, the effectiveness of Zytiga, Xtandi and other therapies based solely on one of these mechanisms of action requires a functional ligand binding domain. In the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, including AR-V7, there is no functional ligand binding domain, which causes the truncated androgen receptor to be constitutively active. As a result, we believe that patients with truncated androgen receptors with C-terminal loss may not be effectively treated by these therapies.

In contrast, galeterone disrupts the androgen receptor signaling pathway at multiple points by combining the mechanisms of action of CYP17 inhibition and androgen receptor antagonism with the mechanism of androgen receptor degradation. Unlike CYP17 inhibition and androgen receptor antagonism, androgen receptor degradation does not require a functional ligand binding domain to disrupt the activation of the pathway and tumor growth. As a result, we believe that, based on galeterone's multiple mechanisms of action, data from the subset of patients in our ARMOR2 trial and data from preclinical studies conducted by us and independent laboratories, galeterone may have the ability to treat both patients with full-length androgen receptors and patients with C-terminal loss. To our knowledge, there are no approved drugs or drugs in clinical development, other than galeterone, that disrupt the androgen receptor signaling pathway through androgen receptor degradation.

The following figure shows a comparison of the mechanisms of action of Zytiga, Xtandi and galeterone:

	Mechanisms of Action		
	CYP17 Inhibition	Androgen Receptor Antagonism	Androgen Receptor Degradation
Zytiga (abiraterone acetate)	✓		
Xtandi (enzalutamide)		✓	
Galeterone	✓	✓	✓

Advantages of Galeterone. Although Zytiga and Xtandi have improved survival of CRPC patients, they have limitations in terms of safety, dosing, patient compliance and the development of resistance. In addition, Zytiga and Xtandi may not be effective in treating CRPC patients with prostate cancer tumors that express altered androgen receptors with C-terminal loss. As a result, there remains an unmet medical need for therapies that address populations that are resistant to therapy and will further improve overall survival while providing a more favorable risk benefit profile.

We believe that galeterone has advantages over Zytiga and Xtandi because of the following key differentiating attributes:

- ***Potential for improved efficacy.*** We believe that galeterone, which combines the mechanism of action of androgen receptor degradation with the mechanisms of action of CYP17 inhibition and androgen receptor antagonism, may further improve progression-free survival and overall survival beyond that of products that depend on only a single mechanism of action.
- ***Potential for lower risk of resistance.*** We believe that galeterone may reduce the risk of or delay the development of resistance to therapy because galeterone addresses multiple mechanisms of action simultaneously.
- ***Potential for broad utility in prostate cancer.*** We believe that galeterone may be well suited to treat different prostate cancer patient populations, from early-stage prostate cancer patients to end-stage salvage metastatic CRPC patients, because of its efficacy, safety and tolerability.
- ***Potential for efficacy in CRPC patients with C-terminal loss, including AR-V7.*** Because galeterone's distinct mechanism of androgen receptor degradation does not require an intact ligand binding domain for efficacy, we believe galeterone may be effective in prostate cancer tumors that express altered androgen receptors with C-terminal loss, including AR-V7. In contrast, the mechanisms of action of Zytiga and Xtandi and other similar drugs in development all require the presence of a functional ligand binding domain in order to be effective.
- ***Favorable safety profile.*** We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone demonstrated a favorable safety and tolerability profile.
- ***No requirement for steroids.*** Zytiga must be co-administered with the steroid prednisone to minimize the risk of mineralocorticoid excess, a potentially fatal syndrome characterized by hypertension, hypokalemia, fluid retention and edema. Unlike Zytiga, galeterone has not been shown in clinical trials to cause mineralocorticoid excess and, as a result, does not require co-administration of steroids.
- ***No associated seizure risk.*** Xtandi has shown a risk of grand mal seizures in clinical trials. Unlike Xtandi, galeterone is not in a class of therapeutics that has shown a risk of seizures. We have not had any reports of seizures in clinical trials of galeterone.
- ***Ease of dosing.*** Galeterone is dosed orally once per day, does not require the co-administration of steroids and can be taken with or without food. We believe that this convenient dosing regimen will enhance patient compliance. In contrast, Zytiga must be taken in a fasted state to avoid large increases in absorption, which may cause side effects. Zytiga must also be co-administered with steroids. The steroid co-administered with Zytiga must be taken with food, resulting in a staggered dosing regimen of pills three times per day.
- ***Potential for use as part of combination therapy.*** We believe that galeterone may prove to be well suited for use in combination with other therapies used across all patient populations of prostate cancer because of its favorable safety profile, ease of administration and highly selective, multiple mechanisms of action.

Our Strategy

Our goal is to become a leading biopharmaceutical company that develops and commercializes products for the treatment of prostate cancer and other hormonally-driven diseases. Our strategy includes the following components:

- ***Complete the clinical development of and seek marketing approval for galeterone for the treatment of CRPC patients with prostate cancer tumors that express altered androgen receptors with C-terminal loss.*** Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in CRPC patients with C-terminal loss generally or AR-V7 specifically in the first half of 2015. We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone in these patients and the design of our planned pivotal clinical trial.
- ***Develop galeterone for other prostate cancer indications and patient populations***. Although our initial development focus is on galeterone for the treatment of prostate cancer in CRPC patients with altered androgen receptors, we are conducting our ARMOR2 trial of galeterone for the treatment of multiple CRPC patient populations. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We also plan to develop galeterone for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents.
- ***Explore the use of galeterone for other hormonally-driven diseases***. We plan to explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway.
- ***Maximize the commercial potential of galeterone.*** We have worldwide development and commercialization rights to galeterone. If galeterone is approved in the United States, we intend to build a urology- and oncology-focused specialty sales organization in the United States to support the commercialization of galeterone. We intend to commercialize galeterone outside the United States through collaborations with third parties.
- ***Advance the development of our platform of androgen receptor degradation agents.*** We plan to identify and develop novel compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under an exclusive license from the University of Maryland, Baltimore. We believe that such compounds may have utility as monotherapies or in combination with existing therapies in treating patients with androgen receptor signaling diseases, including prostate cancer patients with primary or acquired resistance to existing therapies.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- We depend heavily on the success of our lead product candidate, galeterone, which is in clinical development for the treatment of CRPC patients. Any failure to successfully develop galeterone for these patients or for other indications or patient populations, or any future product candidates, or significant delays in doing so, would compromise our ability to generate revenue and become profitable.
- If clinical trials of galeterone and our future product candidates, including our ongoing Phase 2 clinical trial and our planned pivotal clinical trial of galeterone, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or are not otherwise successful, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of galeterone and our future product candidates.

- We will need substantial additional funding to complete our development of, and to commercialize, galeterone for the treatment of CRPC patients with C-terminal loss generally or AR-V7 specifically, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce, terminate or eliminate product development programs, including our commercialization efforts for galeterone for the treatment of these patients and other indications and patient populations and our future product candidates.
- We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- Fast track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures or that we will ultimately obtain regulatory approval of galeterone. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.
- If an *in vitro* companion diagnostic test or a laboratory developed test for the use of galeterone in the patients who we determine to evaluate in our planned pivotal clinical trial is unable to be developed, or if there are significant delays in doing so, our planned pivotal clinical trial may be delayed and we may not achieve marketing approval or realize the full commercial potential of galeterone.
- Even if galeterone receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing galeterone or any of our future product candidates if they are approved.
- We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Our Company

We were incorporated under the laws of the State of Delaware on March 26, 2004 under the name Tokai Pharmaceuticals, Inc. Our executive offices are located at One Broadway, 14th Floor, Cambridge, Massachusetts 02142 and our telephone number is (617) 225-4305. Our website address is www.tokaipharma.com. The information contained in, or accessible through, our website does not constitute part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

The Tokai logo is our trademark. The trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

Implications of Being an Emerging Growth Company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure and other requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of some or all these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates or we issue more than $1 billion of non-convertible debt over a three-year period. We have taken advantage of certain reduced reporting obligations in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

The Offering

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares (shares in the event the underwriters elect to exercise in full their over-allotment option to purchase additional shares from us)
Over-allotment option	The underwriters have an option for a period of 30 days to purchase up to additional shares of our common stock to cover over-allotments.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $ million, or approximately $ million if the underwriters exercise their over-allotment option to purchase additional shares from us in full, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. We plan to use the net proceeds of this offering, together with our existing cash and cash equivalents, to fund our planned pivotal clinical trial of galeterone and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone, to fund our ongoing ARMOR2 trial and to fund our initial research of other compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation and for working capital and other general corporate purposes. See "Use of Proceeds" for more information.
Risk factors	You should read the "Risk Factors" section starting on page 12 of this prospectus and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Global Market symbol	"TKAI"

The number of shares of common stock to be outstanding after this offering is based on 5,251,501 shares of common stock outstanding as of July 31, 2014 and gives effect to the conversion of all outstanding shares of our redeemable convertible preferred stock into 155,586,141 shares of common stock upon the closing of this offering.

The number of shares of common stock to be outstanding after this offering excludes:

- 17,111,343 shares of common stock issuable upon the exercise of stock options outstanding as of July 31, 2014, at a weighted average exercise price of $0.27 per share;
- 459,555 shares of common stock available for future issuance under our equity compensation plan as of July 31, 2014; and

- an additional shares of common stock that will be made available for future issuance under our equity compensation plans upon the closing of this offering.

Except as otherwise noted, all information in this prospectus:

- assumes no exercise of the outstanding options described above;
- assumes no exercise by the underwriters of their over-allotment option to purchase up to additional shares of common stock from us; and
- gives effect to the restatement of our certificate of incorporation and bylaws upon the closing of this offering.

Summary Consolidated Financial Data

The following table summarizes our consolidated financial data. We have derived the consolidated statement of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the six months ended June 30, 2013 and 2014 and for the cumulative period from inception (March 26, 2004) through June 30, 2014 and the consolidated balance sheet data as of June 30, 2014 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. Our historical results are not necessarily indicative of results that should be expected in the future, and results for the six months ended June 30, 2014 are not necessarily indicative of the results that should be expected for the full year ending December 31, 2014.

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period from Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014	
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	7,370	12,201	5,148	7,948	57,314
General and administrative	2,279	3,548	1,687	2,829	16,286
Total operating expenses	9,649	15,749	6,835	10,777	73,600
Loss from operations	(9,649)	(15,749)	(6,835)	(10,777)	(73,600)
Other income (expense):					
Interest income	—	—	—	—	216
Interest expense	—	—	—	—	(302)
Other income (expense), net	—	24	—	79	342
Total other income, net	—	24	—	79	256
Net loss	(9,649)	(15,725)	(6,835)	(10,698)	(73,344)
Accretion of redeemable convertible preferred stock to redemption value	(34)	(94)	(79)	—	(3,359)
Accrual of dividend on redeemable convertible preferred stock	—	—	—	—	(347)
Modifications of redeemable convertible preferred stock	—	—	—	—	9,925
Net loss attributable to common stockholders	$ (9,683)	$ (15,819)	$(6,914)	$ (10,698)	$ (67,125)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (2.97)	$ (3.63)	$ (1.96)	$ (2.05)	
Weighted average common shares outstanding, basic and diluted[1]	3,261	4,356	3,534	5,215	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		$ (0.12)		$ (0.07)	
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)[1]		128,050		160,801	

	As of June 30, 2014		
	Actual	Pro Forma[2]	Pro Forma As Adjusted[3][4]
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 21,150	$ 21,150	$
Working capital[5]	18,051	18,051	
Total assets	23,420	23,420	
Redeemable convertible preferred stock	85,345	—	
Total stockholders' equity (deficit)	(65,613)	19,732	

(1) See Note 10 to our consolidated financial statements for further details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

(2) Pro forma consolidated balance sheet data give effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 155,586,141 shares of common stock upon the closing of this offering.

(3) Pro forma as adjusted consolidated balance sheet data give effect to the pro forma adjustment described in footnote 2 above as well as the sale by us of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted data above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

(5) We define working capital as current assets less current liabilities.

Risk Factors

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $9.6 million for the year ended December 31, 2012, $15.7 million for the year ended December 31, 2013 and $10.7 million for the six months ended June 30, 2014. As of June 30, 2014, we had an accumulated deficit of $73.8 million. To date, we have financed our operations primarily through private placements of our redeemable convertible preferred stock and convertible promissory notes, none of which are currently outstanding. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of any product candidate and it may be several years, if ever, before we have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- conduct our planned pivotal clinical trial of galeterone for castration-resistant prostate cancer, or CRPC, patients with C-terminal loss generally or AR-V7 specifically, and conduct other clinical trials and preclinical studies to support the submission of a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for galeterone for this indication;
- continue to conduct our ongoing ARMOR2 trial for the treatment of multiple CRPC patient populations;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test to identify CRPC patients with C-terminal loss or AR-V7;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies for the treatment of hormonally-driven diseases; and
- operate as a public company following this offering.

We have never generated any revenue from product sales and may never be profitable. To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential and market acceptance. This development and commercialization will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of galeterone for the treatment of CRPC patients with truncated androgen receptors and other indications and patient populations, as well as preclinical testing and clinical trials of any of our future product candidates, obtaining marketing and regulatory approval for these product candidates, contracting with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test to identify CRPC patients with C-terminal loss or AR-V7, partnering with third parties to manufacture our product candidates in commercial quantities, marketing and selling those products for which we may obtain regulatory approval and obtaining reimbursement from third-party payors. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our share price to decline. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding to complete our development of, and to commercialize, galeterone for the treatment of CRPC patients with C-terminal loss generally or AR-V7 specifically, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce, terminate or eliminate product development programs, including our commercialization efforts for galeterone for the treatment of these patients and other indications and patient populations and for our future product candidates.

As of June 30, 2014, we had cash and cash equivalents of $21.2 million and working capital of $18.1 million. We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will only be sufficient to enable us to continue our ongoing ARMOR2 trial, conduct our planned pivotal clinical trial of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically, and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone for these patients, as well as to continue to fund our operating expenses and capital expenditure requirements through . We will need to obtain substantial additional funding in order to submit an NDA to the FDA for galeterone for the treatment of CRPC patients with C-terminal loss generally or AR-V7 specifically, complete the development of, and commercialize, galeterone for these patients and other indications and patient populations and develop or commercialize any future product candidates. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, terminate or eliminate our product development programs and our commercialization efforts.

Our future capital requirements will depend on many factors, including:

- the progress and results of our planned pivotal clinical trial of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically, and our efforts to complete the clinical development of galeterone and submit an NDA to the FDA for this indication;
- the progress and results of our ongoing ARMOR2 trial and any additional clinical trials of galeterone that we decide to conduct for the treatment of other indications and patient populations in prostate cancer, including for early-stage prostate cancer, and for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;

- the timing and outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically and other indications and patient populations, and of any other future product candidates;
- the costs under agreements with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test for identifying CRPC patients with C-terminal loss or AR-V7;
- the cost of commercialization activities, including product sales, marketing, manufacturing and distribution, for galeterone and our future product candidates for which we receive regulatory approval;
- the development of future product candidates, including our plans to seek to acquire or in-license additional compounds or technologies for the treatment of hormonally-driven diseases;
- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States; and
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, galeterone and any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Additional financing may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, require us to relinquish rights to our technologies or product candidates or divert our management's attention from our operating activities.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We will require substantial funding in addition to the net proceeds of this offering to fund our development and commercialization efforts, operating expenses and other activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. Additional fundraising efforts may also divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates.

Risks Related to the Development and Regulatory Approval of Galeterone and Our Future Product Candidates

We depend heavily on the success of our lead product candidate, galeterone, which is in clinical development for the treatment of CRPC patients. Any failure to successfully develop galeterone for these patients or for other indications or patient populations, or any future product candidates, or significant delays in doing so, would compromise our ability to generate revenue and become profitable.

We currently have no products approved for sale and have only one product candidate, galeterone, in clinical development. We have invested substantially all of our efforts and financial resources in the development of galeterone for the treatment of CRPC. Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and commercialization of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically. We also may develop galeterone for other indications or patient populations in prostate cancer or for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway and compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation. The success of galeterone or other product candidates will depend on several factors, including the following:

- successfully completing clinical trials, including obtaining clinical results that are statistically significant as well as clinically meaningful in the context of the indications for which we are developing galeterone and our future product candidates;
- receiving marketing approvals for our products from the FDA and similar regulatory authorities outside the United States;
- successfully developing an *in vitro* companion diagnostic test or a laboratory developed test to identify CRPC patients with C-terminal loss or AR-V7;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for galeterone or other product candidates, both in the United States and internationally;
- establishing successful sales and marketing arrangements and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtaining commercial acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining adequate reimbursement;
- effectively competing with other therapies;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of our products following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize galeterone and our future product candidates, which would materially harm our business.

If clinical trials of galeterone and our future product candidates, including our ongoing Phase 2 clinical trial and our planned pivotal clinical trial of galeterone, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or are not otherwise successful, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of galeterone and our future product candidates.

Before obtaining regulatory approval for the sale of galeterone and our future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates.

We are currently finalizing our plans for our pivotal clinical trial of galeterone. Subject to discussions with the FDA, we anticipate initiating our planned pivotal clinical trial in the first half of 2015. However, there can be no assurance that we will initiate the trial when we anticipate.

For drug and biological products, the FDA typically requires the successful completion of two adequate and well-controlled clinical trials to support marketing approval. In the case of galeterone, we intend to seek approval based upon the results of a single pivotal clinical trial. If the results of the trial are not robust, are subject to confounding factors, or are not adequately supported by other study endpoints, the FDA may refuse to approve galeterone based upon a single clinical trial. Thus there can be no guarantee that the FDA will not require additional pivotal clinical trials as a condition for approving galeterone.

We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone for the treatment of CRPC patients with C-terminal loss generally or AR-V7 specifically. Even if the FDA agrees to an expedited development pathway, such agreement may not result in a faster development process, review or approval compared to drugs considered for approval under the conventional FDA procedures and does not assure ultimate approval by the FDA.

If the FDA does not agree to an expedited development pathway, if we are required to conduct additional clinical trials or other testing of galeterone or of our future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for galeterone or our future product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- have the product removed from the market after obtaining marketing approval.

If we experience any of a number of possible unforeseen events in connection with our preclinical studies or clinical trials, our ability to conduct further clinical trials of, obtain regulatory approval of or commercialize galeterone or our future product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, preclinical studies or clinical trials that could delay or prevent our ability to conduct further clinical trials, obtain regulatory approval or commercialization of galeterone or our future product candidates. For instance, we experienced delays following our open label, dose escalation Phase 1 clinical trial of galeterone, which we refer to as our ARMOR1 trial, due to the exposure variability associated with the food effect of administering galeterone in capsule formulation and our efforts to reformulate galeterone, which resulted in the development of the spray dried dispersion formulation of galeterone and required us to conduct additional Phase 1 clinical trials. Unforeseen events that could delay or prevent our ability to conduct clinical trials, obtain regulatory approval or commercialize galeterone and our future product candidates include:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- preclinical studies and clinical trials of galeterone or our future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical or clinical trials or abandon product development programs;
- the number of patients required for clinical trials of galeterone or our future product candidates may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our failure to conduct our clinical trials in accordance with the FDA's good clinical practices or applicable regulatory requirements in other countries;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or institutional review boards may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements,
- a finding that the participants are being exposed to unacceptable health risks or the occurrence of serious adverse events associated with galeterone or our future product candidates;
- the cost of clinical trials of galeterone and our future product candidates may be greater than we anticipate; and
- the supply or quality of galeterone or our future product candidates or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate.

In addition, the patients recruited for clinical trials of our product candidates may have characteristics that are different than we expect and different than the clinical trials were designed for, which could adversely impact the results of the clinical trials. For example, our patients could develop genetic mutations that are not responsive or are otherwise resistant to galeterone.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. In addition to additional costs, significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates.

Galeterone could ultimately prove to be ineffective or unsafe.

We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. We are currently conducting our ARMOR2 trial. As of May 12, 2014, we had enrolled 101 patients in the trial and expect to enroll a total of approximately 136 patients in the trial. However, we have yet to fully explore the safety and efficacy of galeterone. Ultimately, the results of our clinical trials to date, in which galeterone has been well tolerated and showed clinically meaningful reductions in levels of prostate specific antigen, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy, may prove to be incorrect. No assessment of the efficacy, safety or side effects of a product candidate can be considered complete until all clinical trials needed to support a submission for marketing approval are complete, and success in early-stage clinical trials does not mean that subsequent trials will confirm the earlier findings, or that experience with use of a product in large-scale commercial distribution will not identify additional safety or efficacy issues. If we find that galeterone is not safe, or if its efficacy cannot be consistently demonstrated, we may not be able to commercialize, or may be required to cease distribution, of the product. Galeterone may also prove to be substantially identical or inferior to drugs already available, in which case the market for galeterone would be reduced or eliminated.

Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in CRPC patients with C-terminal loss generally or AR-V7 specifically in the first half of 2015. We believe that patients' prostate tumor cells may not be responsive to treatment with Zytiga and Xtandi in the presence of C-terminal loss, including AR-V7, but that galeterone, with its mechanism of androgen receptor degradation, may effectively treat these patients. There can be no assurance, however, that our beliefs and assumptions about the effectiveness of galeterone, Zytiga (abiraterone acetate) or Xtandi (enzalutamide) in the treatment of CRPC patients with C-terminal loss or AR-V7 are accurate. Our belief that patients' prostate tumor cells may not be responsive to treatment with Zytiga and Xtandi in the presence of C-terminal loss or AR-V7 is based on our understanding of the mechanisms of action of these products, data from clinical studies conducted by MD Anderson Cancer Center, or MD Anderson, and Johns Hopkins University, or Johns Hopkins, and data from preclinical studies conducted by us and independent laboratories. However, the clinical studies conducted by MD Anderson and Johns Hopkins only involved a limited number of patients with C-terminal loss or AR-V7 and were conducted in different patient populations, using different protocols and using different and unvalidated assays to identify patients with C-terminal loss or AR-V7. The patient populations, protocols and assays used in the MD Anderson and Johns Hopkins studies may also differ from the patient populations, protocols and assays used in our planned pivotal clinical trial. In addition, it is possible that other factors were present that caused, or contributed to, the poor responsiveness of Zytiga and Xtandi in the presence of C-terminal loss and AR-V7 in the clinical studies. The outcome of preclinical testing and clinical studies may not be predictive of the success of later clinical trials and is often susceptible to varying interpretations and analyses. If Zytiga and Xtandi are found to be more responsive to C-terminal loss or AR-V7 than we anticipate, any clinical trial designed to compare galeterone to Zytiga and Xtandi for this patient population would be less likely to succeed.

Our belief that galeterone may be effective in CRPC patients with C-terminal loss, including AR-V7, is based on data from preclinical studies and a retrospective subset analysis in which four treatment-naïve CRPC patients in our ARMOR2 trial were identified as having truncated androgen receptors with C-terminal loss pursuant to an unvalidated assay. We believe that these data support our view that galeterone may be effective in patients without an intact ligand binding domain. However, there can be no assurance that these data will be predictive of the success of our planned pivotal clinical trial of galeterone. While we are still finalizing the design of the planned pivotal clinical trial, the trial will be the first clinical trial to evaluate galeterone in prospectively identified patients with C-terminal loss or AR-V7 and will have a design that is different than the design of our ARMOR2 trial, including primary endpoints that, unlike our ARMOR2 trial, are not based on PSA. The failure of our planned pivotal clinical trial of galeterone in this patient population would have a material adverse impact on our ability to obtain approval for galeterone and on our business, financial condition and prospects.

If we experience delays or difficulties in the enrollment of patients in our clinical trials, or patients discontinue their participation in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to continue our ARMOR2 trial or conduct our planned pivotal clinical trial, or any other clinical trials, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Our competitors may have ongoing clinical trials for product candidates that could be competitive with galeterone and our future product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- trials of other products for similar indications;
- efforts to facilitate timely patient enrollment in clinical trials;
- patient referral practices of physicians;
- alternative products for similar indications;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, because we expect that our planned pivotal clinical trial of galeterone will be focused on CRPC patients with C-terminal loss generally or AR-V7 specifically, which we expect represents a small percentage of CRPC patients, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment delays in our planned pivotal clinical trial or any of our other future clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for our planned pivotal clinical trial would result in significant delays. Any significant delays or increases in costs of our planned pivotal clinical trial could result in the need for us to obtain additional funding to complete the trial.

In addition, patients enrolled in our clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including experiencing adverse clinical events that may or may not be associated with our product candidates under evaluation. The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial or may lead to negative or insufficient results to support a filing for marketing and regulatory approval of the applicable product candidate.

If serious adverse or unforeseen side effects are identified during the development of galeterone or our future product candidates, we may need to abandon or limit our development of some or all of our product candidates.

If galeterone or our future product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less

severe or more acceptable from a risk-benefit perspective. Adverse or unexpected side effects or characteristics of galeterone, whether discovered by us or independently publicized by third parties during clinical trials, could cause an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of galeterone or our future product candidates, require us to conduct additional clinical trials or other tests or studies, and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities.

In our ARMOR2 trial, there were three unexpected serious adverse events that were assessed by the investigators as possibly related to treatment with galeterone. These treatment-related serious adverse events involved a case of angioedema in a patient who was taking a medication associated with angioedema, an episode of dizziness and fainting in a patient with a history of nausea, diabetes and hypertension who had discontinued treatment with galeterone four days prior to the episode, and a case of hypocalcemia and hyperparathyroidism in a patient with a history of hypocalcemia and hyperparathyroidism. In our ARMOR1 trial, there was only one unexpected serious adverse event assessed by the investigator as possibly related to treatment with galeterone. This treatment-related serious adverse event involved a 77-year old patient who developed rhabdomyolysis, an acute disintegration of muscle tissue, and acute renal failure that occurred while receiving simvastatin, a statin known to be associated with rhabdomyolysis. In addition, the patient had underlying chronic renal insufficiency, renal artery stenosis and hydronephrosis requiring stents and presented after a fall, all of which are risk factors for either acute renal failure or rhabdomyolysis. To date, none of these events resulted in interruptions or delays of our clinical trials.

If an in vitro companion diagnostic test or a laboratory developed test for the use of galeterone in CRPC patients with C-terminal loss or AR-V7 is unable to be developed, or if there are significant delays in doing so, our planned pivotal clinical trial may be delayed and we may not achieve marketing approval or realize the full commercial potential of galeterone.

We will need to develop assays that sensitively detect C-terminal loss or AR-V7 in order to proceed with our planned pivotal clinical trial and seek approval of, and commercialize, galeterone for patients with these types of truncated androgen receptors. We plan to contract with third parties to develop the assay and to use widely available methodologies and technologies, if possible, in order to minimize development and regulatory risks. We are currently finalizing our strategy for developing this assay and may develop it as an *in vitro* companion diagnostic test or a laboratory may develop it as a conventional laboratory developed test. We expect to discuss with the FDA our development strategy and plans for identifying C-terminal loss or AR-V7 in our pivotal clinical trial, including our plans to develop the assay as an *in vitro* companion diagnostic test or a conventional laboratory developed test.

We may decide to develop the assay as an *in vitro* companion diagnostic test. We do not have experience or capabilities in developing, obtaining regulatory approval, or commercializing companion diagnostic tests and would need to rely in large part on third parties to perform these functions. Companion diagnostic tests are subject to regulation by the FDA and similar regulatory authorities outside of the United States as medical devices and require separate regulatory approval prior to commercialization. We and these third parties may encounter difficulties in developing and obtaining approval for the *in vitro* companion diagnostic test, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation.

Alternatively, we may rely on a third-party laboratory to develop a laboratory developed test to identify prostate cancer patients with C-terminal loss or AR-V7. Although the FDA maintains that it has authority to regulate the development and use of laboratory developed tests as medical devices, it has not exercised its authority with respect to most laboratory developed tests as a matter of enforcement discretion. Under this policy, we or the third party would not be required to obtain FDA approval for a laboratory developed test. However, in July 2014, the FDA notified Congress of its intent to take a risk-based approach to determining the level of regulation to which laboratory developed tests will be subject. The FDA intends to phase in enforcement of regulatory requirements over time. If the FDA requires approval or clearance of a laboratory developed test for the use of galeterone in CRPC patients with C-terminal loss or AR-V7, we could incur additional costs and time delays associated with meeting requirements for pre-market clearance or approval of the laboratory developed test or approval of galeterone.

If we or any of the third parties we engage to assist us are unable to successfully develop and obtain approval of an *in vitro* companion diagnostic test or a laboratory developed test, or experience delays in doing so:

- the development of galeterone for use by CRPC patients with C-terminal loss generally or AR-V7 specifically will be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- galeterone may not receive marketing approval on a timely basis or at all; and
- we will not realize the full commercial potential of galeterone if, among other reasons, we are unable to appropriately identify patients with C-terminal loss or AR-V7.

If any of these events were to occur, our business would be materially harmed.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize galeterone, and our ability to generate revenue will be materially impaired.

Failure to obtain regulatory approval for galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically or other indications and patient populations will prevent us from commercializing galeterone for those indications. Although our management team has experience filing and supporting applications necessary to gain regulatory approvals, we have yet to file for or obtain regulatory approval to market galeterone in any jurisdiction. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish galeterone's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Galeterone may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of galeterone. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render galeterone commercially unviable.

If we experience delays in obtaining approval or if we fail to obtain approval of galeterone, the commercial prospects for galeterone may be harmed and our ability to generate revenues will be materially impaired.

Even if we complete the necessary clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize galeterone or our future product candidates or the approval may be for a more narrow indication than we expect.

Even if galeterone or our future product candidates demonstrate safety and efficacy in clinical trials, regulatory agencies may not complete their review processes in a timely manner or grant regulatory approval at all. Additional delays may result if a regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a treatment candidate

for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

We have obtained fast track designation from the FDA for galeterone for the treatment of metastatic CRPC. However, fast track designation may not actually lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA fast track designation. If the fast track designation is obtained, the FDA may initiate review of sections of an NDA, before the application is complete. This "rolling review" is available if the applicant provides, and the FDA approves, a schedule for submission of the individual sections of the application. In June 2012, the FDA notified us that we had obtained fast track designation for galeterone for the treatment of metastatic CRPC. Fast track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures or that we will ultimately obtain regulatory approval of galeterone. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

In the event we receive FDA approval for galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically, we will not be able to expand the indications for which galeterone is approved unless we receive FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for galeterone.

We are focusing our initial development of galeterone on the treatment of CRPC patients with C-terminal loss and plan to seek marketing and regulatory approvals for galeterone for this patient population. We also plan to develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents. In addition, we plan to explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway. In order to market and sell galeterone in the U.S. for these additional indications, we will need to conduct additional clinical trials and obtain FDA approval for each proposed indication. There can be no assurance that we will be successful in obtaining FDA approval for additional indications for the use of galeterone. If we are unsuccessful in expanding the approved indications for the use of galeterone, the size of the commercial market for galeterone will be limited.

Failure to obtain regulatory approval in international jurisdictions would prevent galeterone or our future product candidates from being marketed abroad.

In order to market and sell our products in jurisdictions outside the United States, we or third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain foreign approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be separately approved for reimbursement before the product can be approved for sale in that country. We intend to enter into arrangements with third parties under which they would market our products outside the United States. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to the Commercialization of Our Product Candidates

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We have never commercialized a product candidate. Our operations to date have been limited to financing and staffing our company, developing our product candidates and conducting our preclinical studies and clinical trials. We have not completed a pivotal clinical trial, obtained marketing approvals or conducted sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We may also encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. In the future, we will need to transition from a company with a preclinical and clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Even if galeterone receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if galeterone receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If galeterone does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of galeterone or any of our future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer galeterone and our future product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the strength of sales, marketing and distribution support;
- the approval of other products for the same indications;
- combinations of existing or newly approved products that alter the standard of care;
- availability and amount of reimbursement from government payors, managed care plans and other third- party payors;
- adverse publicity about the product or favorable publicity about competitive products;
- clinical indications for which the product is approved; and
- the prevalence and severity of any side effects.

Even if a potential product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community, patients and third-party payors on the benefits of galeterone or our other future product candidates may require significant resources and may never be successful.

If galeterone or any of our future product candidates receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product

candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy, or REMS;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing galeterone or any of our future product candidates if they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either outsource these functions to third parties or develop an internal sales and marketing organization. If galeterone is approved in the United States, we intend to build a urology and oncology focused, specialty sales organization in the United States to support the commercialization of galeterone. We intend to commercialize galeterone outside the United States through collaborations with third parties. Such reliance on third parties to market our products, if approved, is risky as these parties may not perform satisfactorily or at all.

There are risks involved with both entering into arrangements with third parties to perform these services and establishing our own sales and marketing capabilities, neither of which we have pursued previously. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retrain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these products are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market galeterone or our future product candidates or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing galeterone or our future product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. Research and discoveries by others may result in breakthroughs which may render our products obsolete even before they generate any revenue. We face competition with respect to our lead product candidate, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing galeterone. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Many marketed therapies for the indications that we are currently pursuing, or indications that we may in the future seek to address, are widely accepted by physicians, patients and payors, which may make it difficult for us to replace them with any products that we successfully develop and are permitted to market.

We are focusing our initial development of galeterone on the treatment of CRPC patients whose prostate tumor cells express an altered androgen receptor that is truncated. Based on their mechanisms of action, preclinical data and the data from the MD Anderson and Johns Hopkins trials, we believe that Zytiga and Xtandi may be less responsive in this patient population and do not expect that other drugs in development with similar mechanisms of action will be responsive in this patient population. However, we expect that other drugs with alternative mechanisms of action may be developed for the treatment of this patient population.

We believe that galeterone may be well suited to treat other prostate cancer patient populations. If galeterone is approved for additional indications, it may compete with other secondary hormonal treatments currently being marketed, such as Zytiga and Xtandi, or with secondary hormonal treatment drug candidates currently in development, such as ARN-509 and ODM-201. Galeterone could compete in the future with products, including secondary hormonal treatments, some of which are marketed by several of the world's largest and most experienced pharmaceutical companies, who have substantially more financial resources than us and greater flexibility to engage in aggressive price competition to gain revenues and market share. Approved secondary hormonal treatments in the United States for CRPC include Zytiga, marketed by Janssen Biotech, Inc. and Xtandi, marketed by Astellas Pharma US, Inc. and Medivation, Inc. Approved non-hormonal agents for CRPC include Taxotere® (docetaxel) and Jevtana® (cabazitaxel), marketed by sanofi-aventis U.S. LLC;

Provenge® (sipuleucel-T), marketed by Dendreon Corporation; and Xofigo® (radium-223), marketed by Bayer HealthCare Pharmaceuticals, Inc. It is uncertain whether we could compete with such products, and our failure to compete or decision to reduce the price of galeterone or other future products we may develop in order to compete could severely impact our business.

In addition, there are numerous prostate cancer products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these are in late stage development. These include secondary hormonal treatments such as Johnson and Johnson's ARN-509 and Orion Corporation's ODM-201. Other compounds that are not secondary hormonal treatments in clinical development include Exelixis, Inc.'s Cometriq and Bavarian Nordic A/S's Prostvac. If a therapy for prostate cancer were developed that targeted the C-terminal loss or AR-V7 patient populations or altered the standard of care for the treatment of CRPC, such therapy could render galeterone irrelevant.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render galeterone or any future product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, medical and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize galeterone or any other future product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in galeterone or our future product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the

demand for, or the price of, any product candidate for which we receive marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we receive marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of galeterone and our future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Galeterone has not been widely used over an extended period of time, and therefore our safety data are limited.

If we cannot successfully defend ourselves against claims that galeterone or future product candidates or products we may develop caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $5 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when we begin commercializing galeterone and our future product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical

investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for galeterone or other product candidates we may develop in the future and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We may enter into collaborations with third parties for the development and commercialization of galeterone and future product candidates we may develop. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may enter into collaborations with third parties for the development and commercialization of galeterone and future product candidates we may develop. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. We will likely have limited control under any additional arrangements we may enter into with third parties over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products
- are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may have the right to conduct clinical trials of our product candidates without our consent and could conduct trials with flawed designs that result in data that adversely affect our clinical trials, our ability to obtain marketing approval for our product candidates or market acceptance of our product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

We will face significant competition in seeking appropriate collaborators if we determine to do so. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Such factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for galeterone. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are not able to obtain such funding or enter into collaborations for galeterone, we may have to curtail the development of galeterone, reduce or delay our development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop galeterone or other future candidates or bring these product candidates to market and generate product revenue.

Failure of third parties to successfully develop or commercialize an in vitro companion diagnostic test or a laboratory developed test to prospectively identify prostate cancer patients with C-terminal loss or AR-V7 could harm our ability to commercialize galeterone.

We do not plan to internally develop an *in vitro* companion diagnostic test or a laboratory developed test to prospectively identify prostate cancer patients with C-terminal loss or AR-V7 and, as a result, we will be dependent on the efforts of the third parties that we engage to successfully develop and commercialize these tests. The third parties:

- may not perform their obligations as expected;
- may encounter production difficulties that could constrain the supply of the *in vitro* companion diagnostic test or the laboratory developed test;
- may have difficulties gaining acceptance of the use of the *in vitro* companion diagnostic test or the laboratory developed test in the clinical community;

- may not pursue commercialization of the *in vitro* companion diagnostic test or the laboratory developed test even if they receive any required regulatory approvals;
- may elect not to continue the development of the *in vitro* companion diagnostic test or the laboratory developed test based on changes in the third parties' strategic focus or available funding, or external factors such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of the *in vitro* companion diagnostic test or the laboratory developed test; and
- may terminate their relationship with us.

If the *in vitro* companion diagnostic test or the laboratory developed test that is developed to prospectively identify prostate cancer patients with C-terminal loss or AR-V7 fail to gain market acceptance, our ability to derive revenues from sales from galeterone would be harmed. If the third parties we engage fail to commercialize the *in vitro* companion diagnostic test or the laboratory developed test, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative test for use in connection with galeterone or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of galeterone.

If galeterone is approved, we intend to rely on third parties to perform many necessary services related to the sale and distribution of galeterone, and expect to do so for any future product candidates.

If galeterone is approved, we intend to retain third-party service providers to perform a variety of functions related to the sale and distribution of galeterone, key aspects of which are out of our direct control. For example, we intend to rely on third parties to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management, and storage, including entrusting our inventories of galeterone to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver galeterone to meet commercial demand would be significantly impaired. In addition, we intend to utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to market galeterone could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

Risks Related to the Manufacturing of Galeterone and Our Future Product Candidates

We contract with third parties for the manufacture of galeterone for clinical trials and expect to continue to do so in connection with the commercialization of galeterone and for clinical trials and commercialization of any other product candidates that we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have nor do we plan to build the internal infrastructure or capability to manufacture galeterone. We currently rely on and expect to continue to rely on third-party contract manufacturers to manufacture clinical supplies of galeterone and any other product candidates we may develop. We expect to continue to rely upon third-party contract manufacturers to manufacture commercial quantities of galeterone and any other product candidates that we commercialize following approval for marketing by applicable regulatory authorities. Reliance on third-party manufacturers entails risks, including:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We currently rely on a small number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our clinical trials. We do not have long-term agreements with any of these third parties. If any of our existing manufacturers should become unavailable to us for any reason, we may incur some delay in our clinical trials as we identify or qualify replacements.

We currently rely on a single third-party contract manufacturer, with which we do not have a long-term agreement, to supply us with the spray dried dispersion formulation of galeterone. If this third-party manufacturer fails to fulfill orders or should become unavailable to us for any reason, we likely would incur some delay in our clinical trials for galeterone and added costs and delays in identifying or qualifying such replacements. In addition, we may be unable to establish any agreements with such a replacement manufacturers or to do so on acceptable terms or at all. Even if we could transfer manufacturing to a different third party, the shift would likely be expensive and time-consuming.

If galeterone or any other product candidate that we may develop in the future is approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under current good manufacturing practices, or cGMPs, that are capable of manufacturing our product candidates. As a result, we may be unable to reach agreement with third-party manufacturers on satisfactory terms or at all, which could delay our commercialization.

Our current and anticipated future dependence upon others for the manufacture of galeterone and any other product candidate that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If our third-party manufacturing facilities are damaged or destroyed, or production at one of these facilities is otherwise interrupted, our business and prospects would be negatively affected.

If any manufacturing facilities owned by third parties who manufacture galeterone or any of our future product candidates are damaged or destroyed, we likely would not be able to quickly or inexpensively replace our manufacturing capacity and possibly would not be able to replace it at all. Any new facility needed to replace these facilities would need to comply with the necessary regulatory requirements and need to be tailored to our specialized manufacturing requirements. We would need FDA approval before selling any products manufactured at a new facility. Such an event could delay our clinical trials or, if any of our product candidates are approved by the FDA, reduce or eliminate our product sales.

While we maintain insurance coverage to cover damage to our property and equipment and to cover business interruption and research and development restoration expenses, if we have underestimated our insurance needs with respect to an interruption in our clinical manufacturing of our product candidates, we may not be able to adequately cover our losses.

We rely on our third-party manufacturers for compliance with applicable regulatory requirements. This may increase the risk of sanctions being imposed on us or on a manufacturer of our products or product candidates, which could result in our inability to obtain sufficient quantities of these products or product candidates.

Our manufacturers may not be able to comply with cGMPs, regulations or other regulatory requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including:

- fines;
- injunctions;
- civil penalties;
- failure of regulatory authorities to grant marketing approval of our product candidates;
- delays, suspension or withdrawal of approvals;
- suspension of manufacturing operations;
- license revocation;
- seizures or recalls of products or product candidates;
- operating restrictions; and
- criminal prosecutions.

Any of these sanctions could significantly and adversely affect supplies of our products and product candidates.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our technology, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our product candidates.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a Master License Agreement with UMB under which we license certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen compounds, including galeterone. We may enter into additional license agreements in the future. Our license agreement with UMB imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could materially adversely affect the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms.

Restrictions on our patent rights relating to our drug candidates may limit our ability to prevent third parties from competing against us.

As of July 31, 2014, we owned two issued U.S. patents, ten U.S. provisional and non-provisional patent applications, one issued foreign patent and 34 foreign applications in our galeterone patent portfolio. We also had exclusive rights under our license agreement with UMB to five issued U.S. patents and 44 issued foreign patents as well as three U.S. patent applications and 13 foreign applications. Our success will depend, in part, on our ability to obtain and maintain patent protection for galeterone and other product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the intellectual property for which we have submitted patent applications or in-license issued patents and applications, were the first to conceive of the inventions covered by such patents and pending patent applications or that we and those inventors were the first to file patent applications covering such inventions. Also, the patent protection of our numerous issued and pending patent applications may lapse before we manage to obtain commercial value from them, which might result in increased competition and materially affect our position in the market.

We have an exclusive license from UMB for a U.S. patent covering compositions and methods of use of a class of compounds encompassing galeterone, which expires in 2017. Given its expiration date and the anticipated timing of development and commercialization of galeterone, we do not believe this patent will provide significant protection for galeterone. We have no patent protection specifically covering the chemical structure of galeterone. As a result, a third party that obtains regulatory approval of a product with the same active ingredient as galeterone may be able to market such product so long as the third party does not infringe any other patents owned or licensed by us with respect to galeterone. For this reason, we have filed for or licensed patents and patent applications relating to galeterone covering methods of use, pharmaceutical compositions, combination treatments, prodrugs, metabolites and analogs of galeterone and their use.

Our owned and licensed patents and patent applications, if issued, are expected to expire on various dates from 2017 through 2034. Upon the expiration of these patents, we and UMB will lose the right to exclude others from practicing the inventions claimed by such patents. As a result, the expiration of these patents could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and UMB's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and UMB have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development efforts before it is too late to obtain patent protection. Moreover, prior to April 10, 2012, we did not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from UMB, and we were and still are reliant on UMB. Therefore, we cannot be certain that these patents and applications were prosecuted in a manner consistent with the best interests of our business. If we or UMB fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and UMB's patent rights are highly uncertain. Our and UMB's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Third parties could practice our inventions in territories where we do not have patent protection. Furthermore, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. A U.S. patent may be infringed by anyone who, without authorization, practices a patented process in the United States or imports a product made by a process covered by the U.S. patent. In foreign countries, however, importation of a product made by a process patented in that country may not constitute an infringing activity, which would limit our ability to enforce process patents against importers in that country. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement or misappropriation of our intellectual property rights. If competitors are able to use our technologies, our ability to compete effectively could be harmed.

Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act, or AIA, enacted in September 2011, the United States moved to a first inventor to file system in March 2013. The United States Patent and Trademark Office recently finalized the rules relating to these changes and courts have yet to address the new provisions. These changes could increase the costs and uncertainties surrounding the prosecution of patent applications and the enforcement or defense of patent rights. Furthermore, we may become involved in interference proceedings, opposition proceedings, or other post-grant proceedings, such as reexamination or *inter partes* review proceedings, challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us

with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges, including through opposition or other post-grant proceedings, may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to or stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to galeterone but that are not covered by the claims of our patents;
- the galeterone compound may become generic, and no patent protection will be available without regard to formulation or method of use;
- we or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulations;
- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- this may be especially likely for manufacturing processes or formulations;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that our owned or in-licensed issued patents or pending patent applications are not Orange-Book eligible;
- it is possible that there are dominating patents to galeterone of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' inventions, as the case may be, or parts of our or their inventions of which we or they are not aware;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that the U.S. government may exercise any of its statutory rights to our owned or in-licensed patents or patent applications that was developed with government funding;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal challenges by third parties; or
- we may not develop additional proprietary technologies for which we can obtain patent protection.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time- consuming and unsuccessful.

Competitors may infringe our patents. To counter such infringement or unauthorized use, we may be required to file infringement claims against third parties, which can be expensive and time-consuming. In addition, during an infringement proceeding, a court may decide that the patent rights we are asserting are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims, and we are reliant on them.

Claims that galeterone or the manufacture, use or sale of galeterone infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that galeterone, its manufacture, use or sale, does not and will not infringe third-party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future.

It is also possible that we failed to identify relevant third-party patents or applications. For example, certain U.S. patent applications that will not be filed outside the United States may remain confidential until patents issue. Furthermore, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering galeterone, its manufacture, use or sale, could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover galeterone or its use.

We are aware of two issued U.S. patents having broad claims relating to a composition of matter or its use in regulating cellular differentiation or proliferation. We are also aware of certain third-party pending U.S. patent applications that have broad generic disclosures and disclosure of certain compounds possessing structural similarities to galeterone. Although we believe that it is unlikely that such applications will lead to issued claims that would cover galeterone and its use and still be valid, patent prosecution is inherently unpredictable and an application could be allowed. Based on our analyses, if any of the above third-party patents or patent applications, if issued, were asserted against us, we do not believe our proposed products or activities would be found to infringe any valid claims of these patents. If we were to challenge the validity of an issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

In order to avoid or settle potential claims with respect to any patent rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing galeterone, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent or

trade secret litigation longer than we could. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Legal Compliance Matters

Any product candidate for which we receive marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, if any of them are approved.

Any product candidate for which we receive marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have adverse consequences, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we

market, sell and distribute our products for which we receive marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, require manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize galeterone or other future products candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of galeterone or other future products candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we receive marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this and other more recent legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act or other more recent legislation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of galeterone or our other future products candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Jodie Morrison, our President and Chief Executive Officer, John McBride, our Chief Operating Officer and Chief Financial Officer, and Karen Ferrante, our Chief Medical Officer and Head of Research and Development, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our research and development, manufacturing and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, manufacturing and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock and this Offering

After this offering, our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers, directors and our existing stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately % of our common stock (% if the underwriters exercise in full

their option to purchase additional shares). As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

In addition, upon the closing of this offering, our two largest stockholders, Apple Tree Partners and Novartis BioVentures, will beneficially own shares representing approximately % and % of our common stock, respectively. Each stockholder acting individually, as well as together, will exercise significant control over our management and affairs.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the

extent outstanding options are exercised, you will incur further dilution. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid for all purchases of our stock but the shares purchased in this offering will represent an aggregate of only approximately % of our total common stock outstanding after this offering. In addition, future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we plan to apply to have our common stock approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of galeterone and our future product candidates or those of our competitors;
- the success of competitive products or technologies;
- potential approvals of galeterone or other future product candidates for marketing by the FDA or equivalent foreign regulatory authorities or our failure to obtain such approvals;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize galeterone or other future products candidates;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to galeterone or any of our future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, pharmaceutical companies have experienced significant share price volatility in recent years, and securities class action litigation often follows a decline in the market price of a company's securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business and stock price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, once we are a public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, will require, among other things, that we assess the effectiveness of our disclosure controls and procedures quarterly and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's annual report on internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act, in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2015.

In connection with the preparation of our consolidated financial statements as of and for the year December 31, 2012 and with the audit of those financial statements, a material weakness in internal control was identified relating to our accounting for complex stockholders' equity transactions. During 2013, we engaged resources with significant financial and accounting technical experience. These additional resources have enabled us to remediate the material weakness. Based on our assessment of the impact of the additional resources, our management concluded that, as of December 31, 2013, we had remediated the material weakness in our internal control over financial reporting described above.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company. If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and our stock price may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our common stock.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. Overall, we estimate that our incremental costs resulting from operating as a

public company may be between $2.0 million and $4.0 million per year. The rules and regulations associated with being a public company are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of galeterone and our future product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of July 31, 2014. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of our common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

If equity research analysts do not publish research reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. The price of our common stock could decline if we do not obtain research analyst coverage, or one or more securities analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Cautionary Note Regarding Forward-Looking Statements and Industry Data

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the anticipated timing, cost and conduct of our ongoing ARMOR2 trial and our planned pivotal clinical trial and our efforts to complete the clinical development of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically;
- the outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically or other indications or patient populations and any other future product candidates;
- the development of future product candidates, including compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- our plans to enter into collaborations for the commercialization of galeterone and any other future product candidates;
- the potential benefits of any future collaboration;
- the rate and degree of market acceptance and clinical utility of our products;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our expectations related to the use of proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this prospectus, the documents that we reference in this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

Use of Proceeds

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $ million.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2014, we had cash and cash equivalents of $21.2 million. We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to fund our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone for this indication;
- approximately $ million to fund our ongoing ARMOR2 trial;
- approximately $ million to fund our initial research of compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- the greater of $0.5 million and 1% of the gross proceeds of this offering to pay a fee to a financial advisor in connection with strategic and financial advisory services unrelated to this offering; and
- the remainder for working capital and other general corporate purposes.

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to complete our ongoing ARMOR2 trial, conduct our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements through . We do not expect that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to enable us to submit an NDA to the FDA for galeterone for this indication, complete the development of galeterone for this indication, commercialize galeterone for this indication and develop or commercialize any future product candidates.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay any cash dividends to the holders of our common stock in the foreseeable future.

Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2014:

- on an actual basis;
- on a pro forma basis, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 155,586,141 shares of common stock upon the closing of this offering; and
- on a pro forma as adjusted basis, after giving effect to the pro forma adjustment listed above as well as the sale by us of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and the filing and effectiveness of our restated certificate of incorporation upon the closing of this offering.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the following table in conjunction with the sections of this prospectus entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 21,150	$ 21,150	$
Redeemable convertible preferred stock (Series A, B-1, B-2, C, D-1, D-2, D-3 and E), $0.001 par value; 155,586,141 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$ 85,345	$ —	$ —
Stockholders' equity (deficit):			
Preferred stock, $0.001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value; 178,408,438 shares authorized, 5,251,501 shares issued and outstanding, actual; shares authorized, 160,837,642 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	5	161	
Additional paid-in capital	8,135	93,324	
Deficit accumulated during the development stage	(73,753)	(73,753)	
Total stockholders' equity (deficit)	(65,613)	19,732	
Total capitalization	$ 19,732	$ 19,732	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease)

of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' equity and total capitalization by $ million, assuming the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock shown as issued and outstanding on a pro forma as adjusted basis in the table above is based on 5,251,501 shares of common stock outstanding as of June 30, 2014 and excludes:

- 17,111,343 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2014, at a weighted average exercise price of $0.27 per share;
- 459,555 shares of our common stock available for future issuance under our equity compensation plan as of June 30, 2014; and
- an additional shares of common stock that will be made available for future issuance under our equity compensation plans upon the closing of this offering.

Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2014 was $(67.1) million, or $(12.78) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and redeemable convertible preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of June 30, 2014.

Our pro forma net tangible book value as of June 30, 2014 was $18.2 million, or $0.11 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 155,586,141 shares of common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the pro forma number of shares of our common stock outstanding as of June 30, 2014, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 155,586,141 shares of common stock upon the closing of this offering.

After giving effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma as adjusted net tangible book value as of June 30, 2014 would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders. The initial public offering price per share will significantly exceed the pro forma as adjusted net tangible book value per share. Accordingly, new investors who purchase shares of common stock in this offering will suffer an immediate dilution of their investment of $ per share. The following table illustrates this per share dilution to the new investors purchasing shares of common stock in this offering, without giving effect to the over-allotment option granted to the underwriters:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2014	$(12.78)	
Increase per share attributable to the conversion of all shares of redeemable convertible preferred stock outstanding	12.89	
Pro forma net tangible book value per share as of June 30, 2014	0.11	
Increase in pro forma as adjusted net tangible book value per share attributable to sale of shares of common stock in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma net tangible book value by $ million, the pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution to investors in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

An increase of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by

$ and decrease the dilution per share to new investors participating in this offering by $, assuming the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution per share to new investors participating in this offering by $, assuming the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share after this offering will increase to $ per share, representing an immediate increase in pro forma as adjusted net tangible book value per share to existing stockholders of $ per share and an immediate dilution of $ per share to new investors.

The following table summarizes, as of June 30, 2014, on a pro forma as adjusted basis as described above, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid to us by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					$
Total		100%	$	100%	

The table above assumes no exercise of the underwriters' over-allotment option to purchase additional shares in this offering. If the underwriters exercise their over-allotment option to purchase additional shares from us in full, the number of shares of our common stock held by new investors will increase to , or % of the total number of shares of common stock outstanding after this offering, and the percentage of shares held by existing stockholders will decrease to % of the total shares outstanding number of shares of common stock outstanding after this offering.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The above discussion and tables are based on 5,251,501 shares of common stock outstanding as of June 30, 2014, gives effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 155,586,141 shares of common stock upon the closing of this offering, assumes no exercise of any outstanding stock options and excludes:

- 17,111,343 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2014, at a weighted average exercise price of $0.27 per share;
- 459,555 shares of our common stock available for future issuance under our equity compensation plan as of June 30, 2014; and

- an additional shares of common stock that will be made available for future issuance under our equity compensation plans upon the closing of this offering.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

Selected Consolidated Financial Data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2012 and 2013 and the consolidated balance sheet data as of December 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the six months ended June 30, 2013 and 2014 and for the cumulative period from inception (March 26, 2004) through June 30, 2014 and the consolidated balance sheet data as of June 30, 2014 have been derived from our unaudited consolidated financial statements and the related notes appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future, and results for the six months ended June 30, 2014 are not necessarily indicative of the results that should be expected for the full year ending December 31, 2014.

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period from Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014	
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	7,370	12,201	5,148	7,948	57,314
General and administrative	2,279	3,548	1,687	2,829	16,286
Total operating expenses	9,649	15,749	6,835	10,777	73,600
Loss from operations	(9,649)	(15,749)	(6,835)	(10,777)	(73,600)
Other income (expense):					
Interest income	—	—	—	—	216
Interest expense	—	—	—	—	(302)
Other income (expense), net	—	24	—	79	342
Total other income, net	—	24	—	79	256
Net loss	(9,649)	(15,725)	(6,835)	(10,698)	(73,344)
Accretion of redeemable convertible preferred stock to redemption value	(34)	(94)	(79)	—	(3,359)
Accrual of dividend on redeemable convertible preferred stock	—	—	—	—	(347)
Modifications of redeemable convertible preferred stock	—	—	—	—	9,925
Net loss attributable to common stockholders	$(9,683)	$ (15,819)	$(6,914)	$ (10,698)	$ (67,125)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (2.97)	$ (3.63)	$ (1.96)	$ (2.05)	
Weighted average common shares outstanding, basic and diluted[1]	3,261	4,356	3,534	5,215	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		$ (0.12)		$ (0.07)	
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)[1]		128,050		160,801	

	As of December 31,		As of June 30,
	2012	2013	2014
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 11,691	$ 31,753	$ 21,150
Working capital(2)	9,908	29,969	18,051
Total assets	11,962	32,287	23,420
Redeemable convertible preferred stock	49,845	85,345	85,345
Total stockholders' deficit	(39,901)	(55,267)	(65,613)

(1) See Note 10 to our consolidated financial statements for further details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

(2) We define working capital as current assets less current liabilities.

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of financial condition and results of operations together with the section entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. The information contained in this discussion and analysis or set forth elsewhere in this prospectus contains forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from the results described in or implied by these forward-looking statements as a result of many important factors, including those factors set forth in the "Risk Factors" section of this prospectus.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Our lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies. We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone was well tolerated and, in multiple prostate cancer populations, showed clinically meaningful reductions in levels of prostate specific antigen, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy. Subject to discussions with the U.S. Food and Drug Administration, or FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015.

We are focusing our initial development of galeterone on the treatment of patients with castration resistant prostate cancer, or CRPC, whose prostate tumor cells express an altered androgen receptor that is truncated. These truncated androgen receptors are missing the end of the receptor that contains the ligand binding domain. We describe patients with these truncated androgen receptors as having C-terminal loss. An example of one such truncated androgen receptor with C-terminal loss is the splice variant AR-V7, which is the most prevalent of the splice variants that cause C-terminal loss. We intend to conduct our planned pivotal clinical trial of galeterone in these patients.

In addition to our planned pivotal clinical trial, we are conducting a Phase 2 clinical trial of galeterone for the treatment of multiple CRPC populations, which we refer to as our ARMOR2 trial. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. In June 2012, the FDA designated galeterone for fast track review. We have exclusive worldwide development and commercialization rights to galeterone.

Since our inception in March 2004, we have devoted substantially all of our resources to developing our product candidates, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Prior to 2007, we focused our efforts on the development of women's health products. In 2007, we changed our focus and began developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases, including our lead drug candidate, galeterone. To date, we have funded our operations primarily through private placements of redeemable convertible preferred stock and, to a lesser extent, through the issuances of convertible promissory notes, none of which are currently outstanding. From our inception through June 30, 2014, we have received aggregate gross proceeds of $92.5 million from such transactions.

We are a development stage company and have not generated any revenue. We have incurred net losses in each year since our inception, and we have an accumulated deficit of $73.8 million as of June 30, 2014. Our net loss was $9.6 million for the year ended December 31, 2012, $15.7 million for the year ended December 31, 2013 and $10.7 million for the six months ended June 30, 2014. These losses have resulted principally from costs incurred in connection with research and development activities, general and administrative costs associated with

our operations and in-licensing our product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We expect our expenses will increase substantially in connection with our ongoing activities, if and as we:

- conduct our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of a new drug application, or NDA, to the FDA for galeterone for this indication;
- continue to conduct our ongoing ARMOR2 trial for the treatment of multiple CRPC patient populations;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test to identify CRPC patients with C-terminal loss or AR-V7;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies for the treatment of hormonally-driven diseases; and
- operate as a public company following this offering.

Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of galeterone and other product candidates that we may develop in the future. As a result, we will need additional financing to support our continuing operations. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We may be unable to raise capital when needed or on acceptable terms, which would force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of June 30, 2014, we had cash and cash equivalents of $21.2 million. We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to continue our ongoing ARMOR2 trial, conduct our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements through . See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for galeterone or other product candidates

that we may develop in the future are successful and result in regulatory approval or license or collaboration agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

The majority of our operating expenses since inception have consisted primarily of research and development activities and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- personnel costs, including salaries, related benefits and stock-based compensation for personnel engaged in research and development functions;
- consulting fees paid to third parties;
- costs related to compliance with regulatory requirements; and
- payments made under our third-party licensing agreements.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, payments made under our licensing agreements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses in the table below.

The following table summarizes our research and development expenses by program:

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period from Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014	
			(in thousands)		
Galeterone for prostate cancer	$ 5,417	$10,257	$ 4,185	$ 6,481	$ 39,476
Other early-stage development programs and additional indications for galeterone	18	40	17	49	2,371
Unallocated research and development expenses	1,935	1,904	946	1,418	15,467
Total research and development expenses	$ 7,370	$12,201	$ 5,148	$ 7,948	$ 57,314

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we pursue later stages of clinical development of galeterone and other product candidates that we may develop in the future.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our ongoing clinical trials as well as any additional clinical trials and other research and development activities that we may conduct;
- future clinical trial results;

- uncertainties in clinical trial design and patient enrollment rate;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in patient enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We are currently conducting a Phase 2 clinical trial of galeterone for the treatment of CRPC, which we refer to as our ARMOR2 trial. Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015. Our current estimate for the external costs associated with completing our ARMOR2 trial is between $ million and $ million and for conducting our planned pivotal clinical trial is between $ million and $ million.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including salaries, related benefits and stock-based compensation expense, of our executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property, travel expenses and facility-related costs.

We expect that our general and administrative expenses will increase in future periods as we continue the development and potential commercialization of galeterone for the treatment of CRPC and any future product candidates and as a result of increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with being a public company and costs incurred to seek collaborations with respect to galeterone and any other product candidates that we may develop in the future.

Other Income (Expense)

Interest Income. Interest income consists of interest earned on our cash and cash equivalents and, for years prior to 2012, marketable securities. Our interest income has not been significant due to nominal investment balances and low interest earned on those balances. We anticipate that our interest income will increase in the future due to anticipated cash proceeds from this offering.

Interest Expense. Interest expense consists of interest expense on our convertible promissory notes at the stated interest rates and interest expense related to the amortization of deferred financing costs associated with our issuances of the convertible promissory notes. Prior to 2012, all of our convertible promissory notes and accrued interest had been converted into shares of our redeemable convertible preferred stock. As a result, we no longer incur interest expense related to this debt.

Other Income (Expense), Net. Other income (expense), net, primarily consists of other income for the year ended December 31, 2010 related to the Qualifying Therapeutic Discovery Project, or QTDP, reimbursement program of the United States government, which provided for reimbursement of certain qualifying costs. We do not anticipate any further income related to the QTDP program. Other income (expense), net also consists of small amounts of miscellaneous income and expense unrelated to our core operations.

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2013, we had federal and state net operating loss carryforwards of $10.5 million and $8.1 million respectively. Our federal and state net operating loss carryforwards begin to expire in 2024 and 2014, respectively. We also had federal and state research and development tax credit carryforwards of $0.6 million and $0.4 million, respectively, as of December 31, 2013, which begin to expire in 2025 and 2023, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of $49.0 million that we have capitalized for income tax purposes as of December 31, 2013. See "—Liquidity and Capital Resources—Net Operating Loss Carryforwards and Other Deferred Tax Assets."

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also Note 2 of our consolidated financial statements included elsewhere in this prospectus for information about these critical accounting policies as well as a description of our other significant accounting policies.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- clinical research organizations in connection with clinical trials;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple clinical research organizations and investigative sites that manage and conduct clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be

materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure the fair value of stock-based awards granted to employees and directors on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Our stock-based awards typically vest over four years. Generally, we issue stock options and restricted stock awards with service-based vesting conditions and record the expense for these awards using the straight-line method. We have historically granted stock options with exercise prices equivalent to the fair value of our common stock as of the date of grant.

We measure the fair value of stock-based awards granted to non-employees on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such non-employee consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is re-measured using, for options, the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model and using, for restricted stock, the then-current fair value of our common stock.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions for volatility, expected term, risk-free interest rate and dividend yield, determined as follows:

- *Fair Value of Common Stock*. Because our common stock is not publicly traded, we must estimate its fair value, as discussed in "—Determination of the Fair Value of Common Stock" below.
- *Volatility*. We historically have been a private company and lack company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of our publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price.
- *Expected Term*. We use the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of options granted to employees and directors, and we determine the expected term of options granted to non-employees based on the contractual term of the options.
- *Risk-Free Interest Rate*. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.
- *Dividend Yield*. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The following table sets forth the assumptions we used to determine the fair value of stock options granted, presented on a weighted average basis:

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
Risk-free interest rate	0.79%	1.72%	1.71%	1.87%
Expected term (in years)	6.07	5.98	5.99	5.89
Expected volatility	65.5%	79.7%	79.6%	79.2%
Expected dividend yield	0%	0%	0%	0%

The assumptions used in determining the fair value of stock-based awards represent our best estimates, which involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different in the future.

We recognize compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate for pre-vesting forfeitures, we have considered our historical experience of actual forfeitures. If our future actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

The following table summarizes the classification of our stock-based compensation expenses recognized in our consolidated statements of operations:

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(in thousands)			
Research and development	$ 87	$ 91	$ 41	$ 136
General and administrative	123	147	49	204
	$ 210	$ 238	$ 90	$ 340

Determination of the Fair Value of Common Stock

We are a privately held company with no active public market for our common stock. Therefore, our board of directors has estimated the fair value of our common stock at various dates, with input from management, considering our most recently available third-party valuations of common stock and its assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options.

In the absence of a public trading market for our common stock, our determination of the fair value of our common stock was performed using methodologies, approaches and assumptions consistent with the *American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, which we refer to as the Practice Aid. We performed these contemporaneous valuations, with the assistance of a third-party specialist, as of December 31, 2012, May 13, 2013, December 1, 2013, February 12, 2014 and April 3, 2014, which resulted in valuations of our common stock of $0.13, $0.15, $0.35, $0.40 and $0.62 per share, respectively, as of those dates. In addition, our board of directors considered various objective and subjective factors, along with input from management, to determine its best estimate of the fair value of our common stock as of each grant date, including the following:

- the prices of shares of our preferred stock that we had sold and the rights, preferences and privileges of that preferred stock relative to our common stock;
- the progress of our research and development programs, including the status of clinical trials for our product candidates;
- our stage of development and business strategy;
- our financial condition, including cash on hand;
- our historical and forecasted performance and operating results;
- the composition of, and changes to, our management team and board of directors;
- the lack of an active public market for our common stock as a private company;

- the likelihood of achieving a liquidity event, such as a sale of our company or an initial public offering, or IPO, given prevailing market conditions;
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry; and
- external market conditions affecting the biopharmaceutical industry.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our product candidates, the timing of a potential IPO or other liquidity event and the determination of the appropriate valuation methodology at each valuation date. If we had made different assumptions, our stock-based compensation expense, net loss attributable to common stockholders and net loss per share attributable to common stockholders could have been significantly different.

Valuation Methodologies

Our common stock valuations as of December 31, 2012 and May 13, 2013 were prepared utilizing the option-pricing method, or OPM, as described in the Practice Aid, to determine the estimated fair value of our common stock. Our common stock valuations as of December 1, 2013, February 12, 2014 and April 3, 2014 were prepared utilizing the probability-weighted expected return method, or PWERM, as described in the Practice Aid, to determine the estimated fair value of our common stock. The method selected was based on availability and the quality of information to develop the assumptions for the methodology.

OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preference at the time of a liquidity event, such as a strategic sale or merger. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock liquidation preference is paid.

The OPM uses the Black-Scholes option-pricing model to price the call options. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

We estimated enterprise value used in the OPM using either the guideline public company method and the guideline transaction method or the OPM backsolve method. The guideline public company method includes comparisons to companies with several years of trading history as well as recent IPOs. The guideline transaction method evaluates market multiples indicated by recent acquisitions of companies in the relevant industry. The OPM backsolve method uses the OPM to calculate the implied equity value for one type of security based on recent sales transaction involving another type of the company's equity securities. In the OPM, the assumed volatility factor was based on the historical trading volatility of our publicly traded peer companies. At each valuation date, a determination was made by us as to the appropriate volatility to be used, considering such factors as the expected time to a liquidity event and our stage of development.

To derive the fair value of the common stock using the OPM, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock, including the participation features of certain series of the preferred stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market. The aggregate value of the common stock derived from the OPM is then divided by the number of shares of common stock outstanding to arrive at a per-share value.

PWERM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. We considered four scenarios for the valuation of our common stock determined using the PWERM methodology: an IPO scenario, a longer-term strategic sale scenario, a near-term sale scenario and a low-value sale scenario.

For the IPO, near-term and low-value sale scenarios, the enterprise value was determined using the guideline public company method, which considered the pricing of recent IPOs by comparable clinical-stage biopharmaceutical companies. In determining the enterprise value for these scenarios, we considered the multiples of paid-in capital indicated by these IPOs as well as the pricing of each IPO relative to the pricing of the most recent preferred round preceding comparable biopharmaceutical companies that were acquired from 2011 through January 2014.

The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. We applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

Option Grants

The following table summarizes by grant date the number of shares subject to options granted between January 1, 2013 and July 31, 2014, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options[1]	Fair Value of Common Stock on Date of Option Grant	Per Share Estimated Fair Value of Options[2]
June 26, 2013 (non-employee award)	86,509	$ 0.15	$ 0.15	$ 0.12[3]
June 26, 2013	7,502,713	$ 0.15	$ 0.15	$ 0.10
December 11, 2013	645,960	$ 0.35	$ 0.35	$ 0.24
February 25, 2014	2,190,107	$ 0.40	$ 0.40	$ 0.27
March 17, 2014	25,000	$ 0.40	$ 0.40	$ 0.27
April 8, 2014	3,272,613	$ 0.62	$ 0.62	$ 0.42

(1) The per share exercise price of options represents the fair value of our common stock on the date of grant, as determined by our board of directors after taking into account our most recently available contemporaneous valuations of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuation through the date of grant.

(2) The per share estimated fair value of options reflects the weighted average fair value of options granted on each grant date as estimated at the date of grant using the Black-Scholes option-pricing model. This model estimates the fair value using as inputs the exercise price of the option and assumptions of the risk-free interest rate, expected term of the option, expected share price volatility of the underlying common stock, expected dividends on the underlying common stock and the per share fair value of the underlying common stock.

(3) For the purposes of recording stock-based compensation, we measure the fair value of options on the service completion date (vesting date). At the end of each reporting period prior to completion of the services, we re-measure the value of the unvested portion of the outstanding options at the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company," as defined in the JOBS Act. As an emerging growth company, we have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if we choose to rely on such exemptions, for so long as we remain an emerging growth company, we will not be required to, among other things:

- provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002;
- provide all of the compensation disclosure that may be required of non-emerging growth companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- comply with certain disclosure obligations regarding executive compensation.

We may take advantage of some or all these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates or we issue more than $1 billion of non-convertible debt over a three-year period.

Results of Operations

Comparison of Six Months Ended June 30, 2013 and 2014

The following table summarizes our results of operations for the six months ended June 30, 2013 and 2014:

	Six Months Ended June 30,		Increase (Decrease)
	2013	2014	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	5,148	7,948	2,800
General and administrative	1,687	2,829	1,142
Total operating expenses	6,835	10,777	3,942
Loss from operations	(6,835)	(10,777)	(3,942)
Other income (expense):			
Other income	—	79	79
Total other income, net	—	79	79
Net loss	$ (6,835)	$(10,698)	$(3,863)

Research and development expenses

	Six Months Ended June 30,		Increase (Decrease)
	2013	2014	
	(in thousands)		
Galeterone for prostate cancer	$ 4,185	$ 6,481	$ 2,296
Other early-stage development programs and additional indications for galeterone	17	49	32
Unallocated research and development expenses	946	1,418	472
Total research and development expenses	$ 5,148	$ 7,948	$ 2,800

Research and development expenses for the six months ended June 30, 2013 were $5.1 million, compared to $7.9 million for the six months ended June 30, 2014. The increase was primarily due to increased costs of $2.3 million associated with our galeterone for prostate cancer program and an increase in unallocated research and development expenses of $0.5 million. The increase in costs of our galeterone for prostate cancer program consisted primarily of increased costs of clinical trials of $2.6 million, partially offset by decreased manufacturing costs of $0.5 million. The increase in clinical trial costs was due to an increased number of patients and sites in our ARMOR2 trial in the six months ended June 30, 2014 as compared to the six months ended June 30, 2013. The decrease in manufacturing costs primarily consisted of decreased drug product cost, reflecting the purchase of raw materials in the three months ended June 30, 2013, partially offset by increased manufacturing costs as we increased our manufacturing of galeterone in the six months ended June 30, 2014 for our ARMOR2 trial and in anticipation of our planned pivotal clinical trial of galeterone. The increase in unallocated research and development costs of $0.5 million for the six months ended June 30, 2014 from the six months ended June 30 2013 was due to increased personnel related costs as a result of increased headcount in our research and development function, including the additions of our Chief Medical Officer and our Vice President of Medical Affairs in the three months ended June 30, 2014.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2013 were $1.7 million, compared to $2.8 million for the six months ended June 30, 2014. The increase of $1.1 million in general and administrative expenses was primarily due to an increase in professional fees of $0.8 million as well as an increase in personnel related costs of $0.2 million. The increase in professional fees primarily consisted of a $0.8 million increase in accounting, audit and legal fees associated with ongoing business activities and our preparations to operate as a public company. Personnel related costs increased by $0.2 million primarily due to an increase in headcount in our general and administrative function in the six months ended June 30, 2014, including the addition of our Chief Operating Officer in the three months ended March 31, 2014, partially offset by a decrease in personnel related costs due to severance paid to our former Chief Executive Officer in the six months ended June 30, 2013.

Comparison of Year Ended December 31, 2012 and 2013

The following table summarizes our results of operations for the year ended December 31, 2012 and 2013:

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	7,370	12,201	4,831
General and administrative	2,279	3,548	1,269
Total operating expenses	9,649	15,749	6,100
Loss from operations	(9,649)	(15,749)	(6,100)
Other income (expense):			
Other income	—	24	24
Total other income, net	—	24	24
Net loss	$ (9,649)	$(15,725)	$(6,076)

Research and development expenses

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
Galeterone for prostate cancer	$ 5,417	$10,257	$ 4,840
Other early-stage development programs and additional indications for galeterone	18	40	22
Unallocated research and development expenses	1,935	1,904	(31)
Total research and development expenses	$ 7,370	$12,201	$ 4,831

Research and development expenses for the year ended December 31, 2012 were $7.4 million, compared to $12.2 million for the year ended December 31, 2013. The increase was primarily due to increased costs of $4.8 million associated with our galeterone for prostate cancer program, consisting primarily of increased manufacturing costs of $2.8 million and increased costs of clinical trials of $2.0 million. These increases were due to the higher costs associated with our ARMOR2 trial of galeterone, manufacturing galeterone for use in our ARMOR2 trial and further developing the manufacturing process for our spray dried dispersion formulation. During 2012, we focused our research and development efforts on the reformulation of galeterone from our product in capsule formulation to our spray dried dispersion formulation and a bridging Phase 1 clinical trial.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2012 were $2.3 million, compared to $3.5 million for the year ended December 31, 2013. The increase of $1.2 million in general and administrative expenses was primarily due to an increase in professional fees of $0.6 million and an increase in personnel related costs of $0.5 million year over year. The increase in professional fees consisted of a $0.4 million increase in accounting, audit and legal fees due to ongoing business activities and our preparations to operate as a public company as well as an increase of $0.2 million related to business development activities. Personnel related costs increased by $0.5 million year over year primarily due to severance costs of $0.4 million in 2013 paid to our former Chief Executive Officer.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred recurring net losses. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

We have funded our operations since inception primarily through private placements of redeemable convertible preferred stock and, to a lesser extent, through the issuances of convertible promissory notes, none of which are currently outstanding. From our inception through June 30, 2014, we have received aggregate gross proceeds of $92.5 million from such transactions.

As of June 30, 2014, we had cash and cash equivalents of $21.2 million. We invest our cash equivalents in money market accounts in order to preserve principal.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented below:

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(in thousands)			
Cash used in operating activities	$ (9,333)	$(15,476)	$ (5,674)	$(10,197)
Cash used in investing activities	(8)	(53)	(33)	(18)
Cash provided by (used in) financing activities	18,779	35,591	20,136	(388)
Net increase (decrease) in cash and cash equivalents	$ 9,438	$ 20,062	$14,429	$(10,603)

Net cash used in operating activities. During the six months ended June 30, 2013, cash used in operating activities was $5.7 million, resulting primarily from our net loss of $6.8 million, partially offset by net cash provided by changes in our operating assets and liabilities of $1.1 million. Our net loss was primarily attributable to research and development activities related to galeterone and our general and administrative expenses, as we had no revenue in the period. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2013 consisted primarily of a $1.0 million increase in accounts payable and accrued expenses. Our accounts payable and accrued expenses balances were affected by the timing of vendor invoicing and payments.

During the six months ended June 30, 2014, cash used in operating activities was $10.2 million, resulting from our net loss of $10.7 million, partially offset by net non-cash charges of $0.3 million and by net cash provided by changes in our operating assets and liabilities of $0.2 million. Our net loss was primarily attributable to research and development activities related to galeterone and our general and administrative expenses, as we had no revenue in the period. Our net non-cash charges during the period consisted primarily of stock-based compensation expense of $0.3 million. Cash provided by changes in our operating assets and liabilities consisted primarily of a net increase in accounts payable and accrued expenses of $0.5 million, partially offset by an increase in prepaid expenses and other current assets of $0.2 million. Our prepaid expenses and other current assets and accounts payable and accrued expense balances were affected by the timing of vendor invoicing and payments.

During the year ended December 31, 2012, cash used in operating activities was $9.3 million, primarily resulting from our net loss of $9.6 million, partially offset by non-cash charges of $0.2 million and by cash provided from changes in our operating assets and liabilities of $0.1 million. Our net loss was primarily

attributable to research and development activities related to galeterone and our general and administrative expenses, as we had no revenue in the period. Our net non-cash charges during the year ended December 31, 2012 consisted primarily of stock-based compensation expense of $0.2 million.

During the year ended December 31, 2013, cash used in operating activities was $15.5 million, resulting from our net loss of $15.7 million, partially offset by non-cash charges of $0.2 million. Our net loss was primarily attributable to research and development activities related to galeterone and our general and administrative expenses, as we had no revenue in the period. Our net non-cash charges during the year ended December 31, 2013 consisted primarily of stock-based compensation expense of $0.2 million.

Net cash used in investing activities. We used a small amount of cash during the years ended December 31, 2012 and 2013 and the six months ended June 30, 2014 related to purchases of property and equipment.

Net cash provided by (used in) financing activities. During the six months ended June 30, 2013, cash provided by financing activities was $20.1 million, consisting of the net proceeds from the sale and issuance of our Series E redeemable convertible preferred stock of $19.9 million and proceeds of $0.2 million from the exercise of stock options.

During the six months ended June 30, 2014, cash used in financing activities was $0.4 million, consisting primarily of payments of deferred offering costs of $0.5 million related to our anticipated initial public offering of common stock, partially offset by the collection of cash related to our outstanding note receivable from a stockholder.

During the year ended December 31, 2012, net cash provided by financing activities was $18.8 million, resulting from net proceeds from the sale and issuance of our Series D-3 redeemable convertible preferred stock.

During the year ended December 31, 2013, net cash provided by financing activities was $35.6 million, resulting from net proceeds of $35.4 million from the sale and issuance of our Series E redeemable convertible preferred stock, as well as $0.2 million received from the exercise of stock options.

Funding Requirements

Galeterone is still in clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- conduct our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone for this indication;
- continue to conduct our ongoing ARMOR2 trial for the treatment of multiple CRPC patient populations;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test to identify CRPC patients with C-terminal loss or AR-V7;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;

- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies for the treatment of hormonally-driven diseases; and
- operate as a public company following this offering.

As of June 30, 2014, we had cash and cash equivalents of $21.2 million. We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to continue our ongoing ARMOR2 trial, conduct our planned pivotal clinical trial of galeterone for CRPC patients with C-terminal loss generally or AR-V7 specifically and conduct other clinical trials and preclinical studies to support the submission of an NDA to the FDA for galeterone for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of galeterone and because the extent to which we may enter into collaborations with third parties for development of this product candidate is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidate. Our future capital requirements for galeterone will depend on many factors, including:

- the progress and results of our planned pivotal clinical trial of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically and the completion of the clinical development of galeterone for this indication;
- the progress and results of our ongoing ARMOR2 trial and any additional clinical trials of galeterone that we decide to conduct for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- the cost, timing and outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with C-terminal loss generally or AR-V7 specifically and other indications and patient populations, and of any other future product candidates;
- the costs under agreements with third parties to develop an *in vitro* companion diagnostic test or a laboratory developed test for identifying CRPC patients with C-terminal loss or AR-V7;
- the cost of commercialization activities, including product sales, marketing, manufacturing and distribution, for galeterone and our future product candidates for which we receive regulatory approval;
- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States;
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the extent to which we expand our product pipeline by acquiring or in-licensing additional compounds or technologies for the treatment of hormonally-driven diseases.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect

your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs of galeterone or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market galeterone that we would otherwise prefer to develop and market ourselves.

Net Operating Loss Carryforwards and Other Deferred Tax Assets

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2013, we had federal net operating loss carryforwards of $10.5 million, which begin to expire in 2024. As of December 31, 2013, we had state net operating loss carryforwards of $8.1 million, which began to expire in 2014. As of December 31, 2013, we also had federal and state research and development tax credit carryforwards of $0.6 million and $0.4 million, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of $49.0 million that we have capitalized for income tax purposes. We expect to begin to amortize this capitalized asset for tax purposes, which will increase our net operating loss carryforwards, over a period of five years, commencing once we begin to recognize product or collaboration revenue. Ownership changes, as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, limit the amount of net operating loss carryforwards and research and development credit carryforwards we can use each year to offset future taxable income and taxes payable. We have not completed a study to assess whether a change in ownership, as defined under Section 382 of the Code, has occurred or whether there have been multiple changes in ownership since our inception due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. federal and state tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may be unable to take full advantage of these carryforwards for U.S. federal and state tax purposes.

Contractual Obligations and Commitments

As of June 30, 2014, we did not have any significant contractual obligations or commitments.

We lease office space and obtain office support services in Cambridge, Massachusetts under a 30-day cancelable operating service agreement under which a small minimum monthly amount is required.

We are party to a license agreement with UMB. In consideration for the rights granted to us, we made an upfront payment to UMB of $20,000 following the execution of the license agreement and a payment of $10,000 following the execution of each of the March 2009, April 2012 and October 2013 amendments. We are obligated to pay UMB an annual maintenance fee of $10,000 each year until the first commercial sale. In addition, we paid UMB a $50,000 milestone payment upon the submission of our investigational new drug application, or IND, for galeterone and a $40,000 milestone payment upon the issuance of the first patent related to UMB's prodrug patent application. We are obligated to make an additional $50,000 milestone payment to UMB for each additional IND we file for a licensed product and a $100,000 milestone payment upon the approval of each NDA for a licensed product by the FDA. We must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by our sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. Our royalty obligations are subject to specified reductions in the event that we are required to obtain additional licenses from third parties or in the event of specified competition from third-party products licensed by UMB. Our minimum annual royalty payment to UMB is $50,000 beginning in the year following the year in

which the first commercial sale occurs. We must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, as of April 10, 2012, we assumed responsibility for all patent expenses related to the prosecution and maintenance of the licensed patents. As of June 30, 2014, we have not yet developed a commercial product using the licensed technologies and we have not entered into any sublicense agreements for the technologies.

In November 2010, we assigned rights to develop and commercialize certain compounds that were unrelated to our core operations to Diotima Pharmaceuticals, Inc., or Diotima, which was then our wholly owned subsidiary, and then spun off Diotima to our existing stockholders. In connection with various agreements between us and Diotima, we funded certain license and license maintenance fees during the period from the spin-off in 2010 through June 30, 2014. In February and April 2014, we terminated the license agreements relating to these compounds on behalf of Diotima and believe that no further payments are due to these licensors. In April 2014, the board of directors and stockholders of Diotima approved the dissolution of Diotima, and Diotima was dissolved.

We enter into contracts in the normal course of business with contract research organizations for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

We previously agreed to pay a fee to a financial advisor upon the closing of this offering equal to the greater of $0.5 million and 1% of the gross proceeds of this offering for strategic and financial advisory services unrelated to this offering.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission rules.

Recently Issued Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this guidance remove all incremental financial reporting requirements for development stage entities. Among other changes, this guidance will no longer require development stage entities to present inception-to-date information about income statement line items, cash flows, and equity transactions. These presentation and disclosure requirements will no longer be required for the first annual period beginning after December 15, 2014 for public companies. Early application is permitted for interim and annual periods for which financial statements have not yet been issued or made available for issuance. Effective upon our adoption of this guidance, we will no longer disclose inception-to-date information currently included in our consolidated statements of operations and comprehensive loss, of cash flows, and of redeemable convertible preferred stock and stockholders' deficit and the related notes thereto.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of June 30, 2014 consisted of cash and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

Business

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Our lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies. We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone was well tolerated and in multiple prostate cancer patient populations showed clinically meaningful reductions in levels of prostate specific antigen, or PSA, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy. Subject to discussions with the U.S. Food and Drug Administration, or FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015.

We are focusing our initial development of galeterone on the treatment of patients with castration resistant prostate cancer, or CRPC, whose prostate tumor cells express an altered androgen receptor that is truncated. We intend to conduct our planned pivotal clinical trial in these patients who we believe may not be effectively treated by the therapies approved by the FDA in recent years. We believe that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provides an opportunity to treat this population of patients. In our ongoing Phase 2 clinical trial of galeterone, which we refer to as our ARMOR2 trial, four patients were identified as having altered androgen receptors that were truncated, all of whom showed clinically meaningful PSA reductions of at least 50%. Although our initial development focus is on galeterone for the treatment of this population of patients, we are conducting our Phase 2 ARMOR2 trial of galeterone in multiple CRPC patient populations.

Galeterone acts by disrupting the androgen receptor signaling pathway, which is the primary pathway that drives prostate cancer growth. The pathway is ordinarily activated by the binding of male hormones, or androgens, such as testosterone and the more potent androgen dihydrotestosterone, or DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. Galeterone disrupts the activation of the pathway through multiple mechanisms of action:

- inhibition of the enzyme CYP17, which blocks the synthesis of testosterone;
- androgen receptor antagonism, which blocks the binding of testosterone or DHT with the androgen receptor; and
- androgen receptor degradation, which reduces the amount of androgen receptor protein in the tumor cells.

We believe that, in comparison to therapies that act solely through CYP17 inhibition or androgen receptor antagonism, galeterone's unique combination of mechanisms of action may provide galeterone with advantages in efficacy in the treatment of CRPC and may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments.

The truncated androgen receptors for which we are developing galeterone are missing the end of the receptor that contains the ligand binding domain. We describe patients with these truncated androgen receptors as having C-terminal loss. An example of one such truncated androgen receptor with C-terminal loss is the splice variant AR-V7, which is the most prevalent of the splice variants that cause C-terminal loss. In patients with truncated androgen receptors, the lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. In clinical studies conducted by researchers at MD Anderson Cancer Center, or MD Anderson, and Johns Hopkins University, or Johns Hopkins, the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide

2013 sales of more than $2.1 billion. We believe that these studies indicate that there is a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7. We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone based on this unmet need in CRPC patients with C-terminal loss generally and AR-V7 specifically and the design of our planned pivotal clinical trial.

In addition to our planned pivotal clinical trial, we are conducting our ARMOR2 trial of galeterone for the treatment of multiple CRPC populations. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We have exclusive worldwide development and commercialization rights to galeterone.

In June 2012, the FDA designated galeterone for the treatment of CRPC for fast track review. The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have more frequent interactions with the FDA, and the FDA may initiate review of sections of a fast track product's new drug application, or NDA, on a rolling basis before the application is complete. In addition, sponsors may request and be granted priority review of their application.

According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States during 2014, approximately 233,000 new cases of prostate cancer will be diagnosed, and approximately 29,000 men will die from the disease. Prostate cancer drugs represent a large and growing market. According to Decision Resources Group, an independent research firm, sales of prostate cancer drugs are expected to increase from $6.0 billion in 2013 to more than $9.0 billion in 2021, due to a growing aged population, a rising incidence of cancer and the introduction of new drugs for the treatment of prostate cancer. These new drugs include Zytiga and Xtandi, which are approved for the treatment of CRPC. Although Zytiga was only approved in 2011 and Xtandi in 2012, both of these drugs have experienced rapid sales growth, with reported worldwide 2013 sales of $1.7 billion for Zytiga and $445 million for Xtandi. Despite their success, the need for new treatment options remains as each of these drugs has treatment limitations in CRPC patients generally and may not be effective in CRPC patients with C-terminal loss, including AR-V7.

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. Ordinarily, the pathway and tumor growth are activated by the binding of testosterone and DHT to the ligand binding domain of androgen receptors. As a result, therapies that block this binding can be effective in disrupting the pathway and tumor cell growth. Zytiga blocks this binding by reducing the synthesis of testosterone through the inhibition of the enzyme CYP17. Xtandi blocks the binding of testosterone or DHT with the androgen receptor through androgen receptor antagonism. However, the effectiveness of Zytiga, Xtandi and other therapies based solely on one of these mechanisms of action requires a functional ligand binding domain. In the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, including AR-V7, there is no functional ligand binding domain, which causes the truncated androgen receptor to be constitutively active. As a result, we believe that patients with truncated androgen receptors with C-terminal loss may not be effectively treated by these therapies.

In contrast, galeterone disrupts the androgen receptor signaling pathway at multiple points by combining the mechanisms of action of CYP17 inhibition and androgen receptor antagonism with the mechanism of androgen receptor degradation. Unlike CYP17 inhibition and androgen receptor antagonism, androgen receptor degradation does not require a functional ligand binding domain to disrupt the activation of the pathway and tumor growth. As a result, we believe that, based on galeterone's multiple mechanisms of action, data from a subset of patients in our ARMOR2 trial and data from preclinical studies conducted by us and independent laboratories, galeterone may have the ability to treat both patients with full-length androgen receptors and

patients with C-terminal loss. To our knowledge, there are no approved drugs or drugs in clinical development, other than galeterone, that disrupt the androgen receptor signaling pathway through androgen receptor degradation.

Interim Clinical Trial Results. In May 2014, we announced interim data from our ARMOR2 trial at The American Society of Clinical Oncology 2014 Annual Meeting, or ASCO. The interim data included patients who had not previously undergone chemotherapy and had not received treatment with Zytiga or Xtandi, whom we refer to as CRPC treatment-naïve patients, and patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga-refractory patients. We reported that in 51 evaluable CRPC treatment-naïve patients, galeterone showed clinically meaningful reductions in levels of PSA. Specifically, we reported the following:

- *Non-metastatic and metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 82% of patients showed maximal reduction in PSA levels of at least 30%, and 75% of patients showed maximal reduction in PSA levels of at least 50%.
- *Metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 85% of patients showed maximal reduction in PSA levels of at least 30%, and 77% of patients showed maximal reduction in PSA levels of at least 50%.

We also reported 12-week data for 15 Zytiga-refractory patients, two of whom had a maximal reduction in PSA levels of at least 30%.

In addition, we presented data from a retrospective subset analysis in which four treatment-naïve CRPC patients in ARMOR2 were identified as having truncated androgen receptors with C-terminal loss. All four of these patients had maximal reductions in PSA levels of at least 50%. These data are consistent with galeterone's mechanism of action of androgen receptor degradation, which does not require a functional ligand binding domain.

Advantages of Galeterone. Although Zytiga and Xtandi have improved survival of CRPC patients, they have limitations in terms of safety, dosing, patient compliance and the development of resistance. In addition, Zytiga and Xtandi may not be effective in treating CRPC patients with prostate tumors that express altered androgen receptors with C-terminal loss. As a result, there remains an unmet medical need for therapies that address populations that are resistant to therapy and will further improve overall survival while providing a more favorable risk benefit profile.

We believe that galeterone has advantages over Zytiga and Xtandi because of the following key differentiating attributes:

- ***Potential for improved efficacy.*** We believe that galeterone, which combines the mechanism of action of androgen receptor degradation with the mechanisms of action of CYP17 inhibition and androgen receptor antagonism, may further improve progression-free survival and overall survival beyond that of products that depend on only a single mechanism of action.
- ***Potential for lower risk of resistance.*** We believe that galeterone may reduce the risk of or delay the development of resistance to therapy because galeterone addresses multiple mechanisms of action simultaneously.
- ***Potential for broad utility in prostate cancer.*** We believe that galeterone may be well suited to treat different prostate cancer patient populations, from early-stage prostate cancer patients to end-stage salvage metastatic CRPC patients, because of its efficacy, safety and tolerability.
- ***Potential for efficacy in CRPC patients with C-terminal loss, including AR-V7.*** Because galeterone's distinct mechanism of androgen receptor degradation does not require an intact ligand binding domain for efficacy, we believe galeterone may be effective in prostate cancer tumors that express altered androgen receptors with C-terminal loss, including AR-V7. In contrast, the mechanisms of action of Zytiga and

Xtandi and other similar drugs in development all require the presence of a functional ligand binding domain in order to be effective.

- ***Favorable safety profile.*** We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone demonstrated a favorable safety and tolerability profile.
- ***No requirement for steroids.*** Zytiga must be co-administered with the steroid prednisone to minimize the risk of mineralocorticoid excess, a potentially fatal syndrome characterized by hypertension, hypokalemia, fluid retention and edema. Unlike Zytiga, galeterone has not been shown in clinical trials to cause mineralocorticoid excess and, as a result, does not require co-administration of steroids.
- ***No associated seizure risk.*** Xtandi has shown a risk of grand mal seizures in clinical trials. Unlike Xtandi, galeterone is not in a class of therapeutics that has shown a risk of seizures. We have not had any reports of seizures in clinical trials of galeterone.
- ***Ease of dosing.*** Galeterone is dosed orally once per day, does not require the co-administration of steroids and can be taken with or without food. We believe that this convenient dosing regimen will enhance patient compliance. In contrast, Zytiga must be taken in a fasted state to avoid large increases in absorption, which may cause side effects. Zytiga must also be co-administered with steroids. The steroid co-administered with Zytiga must be taken with food, resulting in a staggered dosing regimen of pills three times per day.
- ***Potential for use as part of combination therapy.*** We believe that galeterone may prove to be well suited for use in combination with other therapies used across all patient populations of prostate cancer because of its favorable safety profile, ease of administration and highly selective, multiple mechanisms of action.

Our Strategy

Our goal is to become a leading biopharmaceutical company that develops and commercializes products for the treatment of prostate cancer and other hormonally-driven diseases. Our strategy includes the following components:

- ***Complete the clinical development of and seek marketing approval for galeterone for the treatment of CRPC patients with prostate cancer tumors that express altered androgen receptors with C-terminal loss.*** Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in CRPC patients with C-terminal loss generally or AR-V7 specifically in the first half of 2015. We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone in these patients and the design of our planned pivotal clinical trial.
- ***Develop galeterone for other prostate cancer indications and patient populations.*** Although our initial development focus is on galeterone for the treatment of prostate cancer in CRPC patients with altered androgen receptors, we are conducting our ARMOR2 trial of galeterone for the treatment of multiple CRPC patient populations. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We also plan to develop galeterone for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents.
- ***Explore the use of galeterone for other hormonally-driven diseases.*** We plan to explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway.
- ***Maximize the commercial potential of galeterone.*** We have worldwide development and commercialization rights to galeterone. If galeterone is approved in the United States, we intend to build a urology- and oncology-focused specialty sales organization in the United States to support the

commercialization of galeterone. We intend to commercialize galeterone outside the United States through collaborations with third parties.

- ***Advance the development of our platform of androgen receptor degradation agents.*** We plan to identify and develop novel compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under an exclusive license from the University of Maryland, Baltimore, or UMB. We believe that such compounds may have utility as monotherapies or in combination with existing therapies in treating patients with androgen receptor signaling diseases, including prostate cancer patients with primary or acquired resistance to existing therapies.

The Treatment of Prostate Cancer

Prostate Cancer Overview

According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States during 2014, approximately 233,000 new cases of prostate cancer will be diagnosed, and approximately 29,000 men will die from the disease. Overall, in the United States, about one in seven men will be diagnosed with prostate cancer during his lifetime, and about one in 36 men will die from the disease.

Prostate cancer is most frequently diagnosed at an early stage, when it is confined to the prostate gland and its immediate surroundings. Advances in screening and diagnosis, including the widespread use of PSA screening, have allowed detection of the disease in its early stages in approximately 85% of all cases diagnosed in the United States. Patients with early-stage disease are typically treated with surgery or radiation therapy, or in limited circumstances, with both. For the majority of men, these procedures are successful in curing the disease. However, for others, these procedures are not curative and their prostate cancer ultimately recurs. Men with recurrent prostate cancer are considered to have advanced prostate cancer. In addition, about 15% of men diagnosed with prostate cancer have metastatic disease at the time of diagnosis. Men with metastatic disease are also considered to have advanced prostate cancer. Men with advanced prostate cancer are most often treated with drug therapy. Decision Resources Group estimates that approximately 310,000 men in the United States currently have advanced prostate cancer and are eligible for treatment with drug therapy.

Treatment of Advanced Prostate Cancer

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. The pathway is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. Testosterone is primarily produced in the testes, adrenal glands and, to a lesser extent, in prostate cancer tumor cells. DHT is a product of enzymatic conversion of testosterone. Once binding has occurred, the bound androgen/androgen receptor complex passes into the nucleus of the tumor cell where it binds to DNA in the cancer cell, triggering abnormal cell growth and tumor progression.

Because testosterone fuels prostate cancer growth, first-line therapy for advanced prostate cancer typically entails androgen deprivation therapy, or ADT, with luteinizing hormone releasing hormone, or LHRH, analogs such as the drug Lupron (leuprolide). ADT reduces testosterone to levels that are commensurate with the levels of a male who has had surgical castration to minimize the testosterone that would otherwise fuel prostate cancer growth. Early-stage patients who receive and respond to this treatment are considered to have hormone-sensitive prostate cancer. ADT has been the principal option for the initial treatment of advanced prostate cancer for more than 50 years.

Most advanced prostate cancer patients initially respond to ADT. However, after initiation of ADT, almost all advanced prostate cancer patients experience a recurrence in tumor growth despite the reduction of testosterone to castrate levels. These patients are considered to be “castration resistant,” and cancer that has

reached this state is considered to be CRPC. The development of CRPC following initiation of ADT is due in part to tumor cells that have adapted to the hormone-deprived environment of the prostate and is generally diagnosed based on either rising levels of PSA or disease progression as evidenced by imaging tests or clinical symptoms. Decision Resources Group estimates that approximately 180,000 men in the United States currently have CRPC and are eligible for treatment with drug therapy. Patients treated with LHRH analogs typically remain on those drugs for the remainder of their lives in order to maintain castrate levels of testosterone.

During the course of ADT or following diagnosis of CRPC, most patients are treated with anti-androgens, which block the binding of androgens to the androgen receptor. An example of an anti-androgen marketed in the United States is the drug Casodex (bicalutamide). Like LHRH analogs, the anti-androgens suppress tumor growth for a period of time in many CRPC patients. However, almost all CRPC patients develop resistance to anti-androgen therapy. Unlike LHRH analogs, however, patients do not typically remain on these drugs because these drugs have been shown to cause tumor growth once the cancer becomes resistant to the treatment. We refer to initial hormonal treatments like LHRH analogs and Casodex as primary hormonal treatments.

Patients with CRPC may have metastatic or non-metastatic disease. Metastatic cancer is cancer that has spread from the organ of origin to one or more locations in the body. Approximately 90% of CRPC patients have radiologic evidence of metastases in the bone, which can cause pain, bone fracture, decreased quality of life and death. Approximately 30% of patients will develop metastases to solid organs, which can cause pain, decreased quality of life and potentially death. Metastases in the organs are referred to as visceral metastases. The liver and the lungs are the most common sites of visceral metastases.

Prior to 2010, the next line of treatment for patients who became resistant to primary hormonal treatment with LHRH analogs and anti-androgens was chemotherapy. At that time, the chemotherapy drug Taxotere (docetaxel) was the primary FDA-approved treatment used for CRPC patients who were resistant to primary hormonal treatments, and there were no effective FDA-approved treatments for CRPC patients following chemotherapy. Since 2010, the FDA has approved five new agents for the treatment of patients with CRPC. These new treatments have provided patients with alternatives to chemotherapy and have resulted in differentiation of disease stages and new patient populations for which treatments can be developed.

Of these new agents, the two with the highest worldwide sales in 2013 were Zytiga and Xtandi. Zytiga was reported to have worldwide 2013 sales of $1.7 billion, and Xtandi was reported to have worldwide 2013 sales of $445 million. Zytiga and Xtandi are members of a class of new drugs that act by disrupting the androgen receptor signaling pathway. We refer to this class of drugs as secondary hormonal treatments.

Zytiga is an oral secondary hormonal treatment approved by the FDA in April 2011 for use in combination with prednisone to treat men with post-chemotherapy metastatic CRPC. In December 2012, the FDA expanded the approval of Zytiga in combination with prednisone to include treatment of pre-chemotherapy metastatic CRPC patients. Zytiga disrupts the androgen receptor signaling pathway by inhibiting CYP17 and reducing production of testosterone in the testes, adrenal glands and prostate cancer tumor cells.

Xtandi is an oral secondary hormonal treatment approved by the FDA in August 2012 to treat men with post-chemotherapy metastatic CRPC. In March 2014, a supplemental new drug application was submitted to the FDA seeking to expand the label for Xtandi to include treatment of pre-chemotherapy metastatic CRPC patients. Xtandi is an androgen receptor antagonist that disrupts the androgen receptor signaling pathway by blocking the binding of testosterone or the androgen DHT with the androgen receptor.

Other new agents include Jevtana (cabazitaxel), a chemotherapeutic agent for use in combination with prednisone to treat men with metastatic CRPC following first-line chemotherapy, Provenge (sipuleucel-T), a prostate cancer immunotherapy to treat men with asymptomatic or minimally symptomatic metastatic CRPC, whether pre-chemotherapy or post-chemotherapy, and Xofigo (radium-223), a bone targeting radiopharmaceutical for the treatment of CRPC patients with symptomatic bone metastases and no visceral metastases that are detectable upon imaging.

Prior to the approval of the new agents, patients had no effective treatment alternatives following chemotherapy. Each of the new agents, however, has been approved for use following first-line chemotherapy. Patients who have undergone chemotherapy treatment and treatment with Zytiga or Xtandi and whose disease has progressed are referred to as salvage patients. There are only limited treatment options for salvage patients.

The treatment of patients with advanced prostate cancer varies depending on the status of the disease, including whether it is metastatic, and depending on the prior treatments that patients have undergone. Figure 1 below identifies the various patient populations within advanced prostate cancer and the treatments that are approved by the FDA for these populations.

Figure 1: Summary of FDA Approved Treatments for Advanced Prostate Cancer Populations

Patient Populations / Treatment Options		Non-Metastatic		Metastatic			
				CRPC			
		Hormone-Sensitive	CRPC	Pre-Chemo	First-Line Chemo	First-Line Post-Chemo	Salvage
Primary Hormonal Treatment	LHRH	✓	✓	✓	✓	✓	✓
	Androgen Receptor Antagonists	✓	✓				
Secondary Hormonal Treatment	Zytiga			✓		✓	
	Xtandi					✓	
Chemotherapy	Taxotere				✓		
	Jevtana					✓	✓
Immunotherapy	Provenge			✓		✓	
Bone Targeting Agent	Xofigo			✓	✓	✓	✓

In addition to Zytiga and Xtandi, we are aware of a number of additional therapies that are in late-stage clinical trials for prostate cancer, including additional secondary hormonal treatment candidates, which are designed to act by the same mechanisms of action of Zytiga and Xtandi.

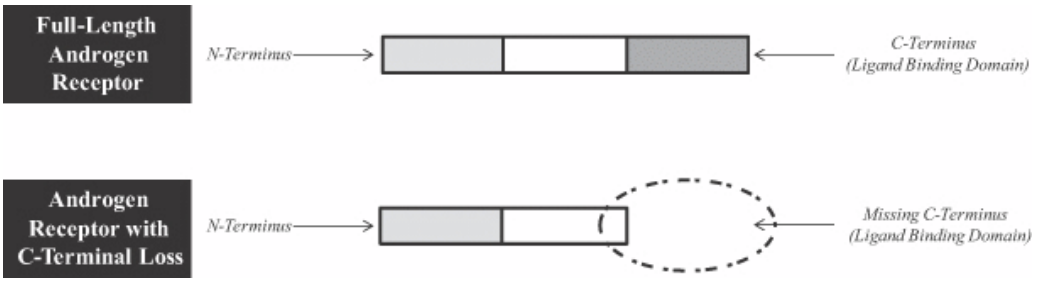
Despite the new therapies, including Zytiga and Xtandi and the additional secondary hormonal treatment candidates, we believe that there continues to be an unmet need as there are patient populations that are not effectively addressed by these therapies, such as CRPC patients with C-terminal loss. Zytiga and Xtandi also have treatment limitations, including efficacy limitations, risk of resistance, risks associated with the co-administration of prednisone with Zytiga, a potential seizure risk observed with Xtandi and a complicated dosing regimen for Zytiga that may limit the ability to use it in combination therapies.

Unmet Need in Prostate Cancer Patients with C-Terminal Loss

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. The pathway and tumor cell growth is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. All proteins, including androgen receptors, are made up of a chain of amino acids that has an N-terminus at one end of the chain and a C-terminus at the other end of the chain as shown in the full-length androgen receptor

depicted in Figure 2 below. In the case of androgen receptors, the C-terminus contains the ligand binding domain. The effectiveness of therapies like Zytiga and Xtandi, which act solely through CYP17 inhibition or androgen receptor antagonism, requires a functional ligand binding domain. As depicted in Figure 2 below, in the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, there is no functional ligand binding domain. This lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. As a result, we believe that patients with truncated androgen receptors with C-terminal loss may not be effectively treated by these therapies.

Figure 2: Full-Length Androgen Receptor and Androgen Receptor with C-Terminal Loss



These limitations of CYP17 inhibitors and androgen receptor antagonists have been supported by recent research from MD Anderson and Johns Hopkins, in which the presence of C-terminal loss and AR-V7 in patients was associated with poor responsiveness of patients' prostate tumors to Zytiga and Xtandi.

MD Anderson. At ASCO, researchers from MD Anderson presented data from a clinical study in which 60 CRPC patients with bone metastases were treated with a sequential combination regimen of Zytiga and Xtandi. In the study, the researchers defined primary resistance as discontinuation of therapy due to symptomatic and/or imaging evidence of disease progression within four months of initiating treatment and benefit as discontinuation of therapy due to symptomatic and/or imaging evidence of disease progression at least four months after initiating treatment. In a subset of 15 patients who were evaluable for C-terminal loss, four patients were identified as having C-terminal loss, including two who were identified as having AR-V7. In this study, the researchers used antibody-based assays to identify the presence of C-terminal loss and AR-V7. All four, or 100%, of these patients showed primary resistance. Of the 11 patients in the subset that did not have C-terminal loss or AR-V7, nine patients, or 82%, showed benefit. These data are set forth in Table 1 below.

Table 1: Summary of MD Anderson C-Terminal Loss and AR-V7 Findings (ASCO)

	N	Primary Resistance	Benefit
AR-V7 positive	2	100% (2/2)	0% (0/2)
C-terminal loss (excluding AR-V7)	2	100% (2/2)	0% (0/2)
Negative for AR-V7 and C-terminal loss	11	18% (2/11)	82% (9/11)

In addition, researchers from MD Anderson presented the results of a second study in an article in *European Urology* accepted for publication in May 2014. In the study, the researchers evaluated bone biopsy specimens from CRPC patients with bone metastases that had been treated with Xtandi to evaluate the effects of Xtandi on cancer and to associate these effects with clinical observations. In the study, the researchers defined resistance and benefit as follows:

- primary resistance, as discontinuation of therapy due to symptomatic and/or imaging evidence of disease progression within four months of initiating Xtandi treatment;

- moderate benefit, as discontinuation of therapy due to symptomatic and/or imaging evidence of disease progression within four to six months of initiating Xtandi treatment; and
- prolonged benefit, as discontinuation of therapy due to symptomatic and/or imaging evidence of disease progression at least six months after initiating Xtandi treatment.

The researchers evaluated a population of 23 patients who had two evaluable biopsies for AR-V7. As shown in Table 2 below, based on identification of AR-V7 at baseline, 86% of the patients with AR-V7 showed primary resistance, and 38% of the patients that did not have AR-V7 showed primary resistance.

Table 2: Summary of MD Anderson AR-V7 Baseline *(European Urology)*

Outcome	N	Primary Resistance	Moderate Benefit	Prolonged Benefit
AR-V7 positive	7	86% (6/7)	14% (1/7)	0% (0/7)
AR-V7 negative	16	38% (6/16)	31% (5/16)	31% (5/16)

Johns Hopkins. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median radiographic progression free survival of the patients with AR-V7 was 2.1 months, compared to 6.1 months in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression free survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median radiographic progression free survival of the patients with AR-V7 was 2.3 months and had not yet been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvement in median radiographic progression free survival were statistically significant.

The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

			Results				
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**
Xtandi	31	38% (12/31)	+ -	0% 52%	0.004	2.1 months 6.1 months	<0.001
Zytiga	31	19% (6/31)	+ -	0% 68%	0.004	2.3 months Not Reached	<0.001

* Results are considered statistically significant if they have a p-value of 0.05 or less, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance.

The Johns Hopkins researchers also reported the prevalence of AR-V7 in different patient groups participating in the trial based on the prior treatment the patient had received. Table 4 below sets out the percentage of patients in each prior treatment group who had AR-V7.

Table 4: Prevalence of AR-V7 in CRPC in the Johns Hopkins Trial

Treatment Status Prior to Entry Into Johns Hopkins Trial	Percentage of Patients in Pre-Treatment Group who had AR-V7
Pre-enzalutamide *and* pre-abiraterone acetate	11.6%
Post-enzalutamide *only*	25.0%
Post-abiraterone acetate *only*	51.2%
Post-enzalutamide *and* post-abiraterone acetate	66.7%

Based on these data, we believe that treatment with Xtandi and Zytiga may be associated with an increase in the prevalence of AR-V7, causing cross-resistance to sequential therapy and leaving patients who are treated with either Xtandi or Zytiga with no currently available secondary hormonal treatment options. By contrast, we believe galeterone has the potential to reduce the prevalence of AR-V7 through its mechanism of androgen receptor degradation.

Galeterone

Overview

Our lead product candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that, like Zytiga and Xtandi, acts by disrupting the androgen receptor signaling pathway. Zytiga and Xtandi each disrupt the pathway at a single point using a single mechanism of action. In contrast, galeterone disrupts the pathway at multiple points by combining the mechanisms of action of Zytiga (CYP17 inhibition) and Xtandi (androgen receptor antagonism) with the additional mechanism of androgen receptor degradation. Unlike CYP17 inhibition and androgen receptor antagonism, the mechanism of action of androgen receptor degradation does not require a functional ligand binding domain. We believe that there are no approved drugs or drugs in clinical trials, other than galeterone, with the mechanism of action of androgen receptor degradation. Subject to discussions with the FDA, we anticipate initiating a pivotal clinical trial of galeterone in the first half of 2015. We plan to meet with the FDA in August 2014 to discuss the possibility of an expedited development pathway for galeterone in CRPC patients with C-terminal loss generally or AR-V7 specifically and the design of our planned pivotal clinical trial.

In addition to our planned pivotal clinical trial, we are conducting our ARMOR2 trial of galeterone for the treatment of multiple CRPC populations. Subject to the results of the ARMOR2 trial and to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We have exclusive worldwide development and commercialization rights to galeterone.

Our initial development strategy for galeterone focusing on patients with C-terminal loss generally, or AR-V7 specifically, is consistent with the increasing focus in drug development of precision medicine therapies for the treatment of cancers caused by genetic and other alterations. We are not aware of any precision medicine therapies in clinical trials for the treatment of prostate cancer that are targeting C-terminal loss splice variants other than galeterone.

Key Differentiating Attributes of Galeterone

Based on preclinical and clinical data, we believe that galeterone has advantages over Zytiga and Xtandi because of the following key differentiating attributes:

- ***Potential for improved efficacy.*** We believe that galeterone, which combines the mechanism of action of androgen receptor degradation with the mechanisms of action of Zytiga (CYP17 inhibition) and Xtandi (androgen receptor antagonism), may further improve progression-free survival and overall survival beyond that of products that depend on only a single mechanism of action. We have reported efficacy data from a total of 115 CRPC patients in our ARMOR1 and our ARMOR2 trials across a number of dose levels that showed meaningful reductions in maximal PSA in patients in the trials.

- ***Potential for lower risk of resistance.*** We believe that galeterone may reduce the risk of or delay the development of resistance to therapy because galeterone addresses multiple mechanisms of action simultaneously. We believe that reducing resistance may delay the development of disease progression.
- ***Potential for broad utility in prostate cancer.*** We believe that galeterone may be well suited to treat different prostate cancer patient populations, from early-stage prostate cancer patients to end-stage salvage metastatic CRPC patients, because of its efficacy, safety and tolerability.
- ***Potential for efficacy in CRPC patients with C-terminal loss, including AR-V7.*** Because galeterone's distinct mechanism of action of androgen receptor degradation does not require an intact ligand binding domain to be effective against prostate cancer tumors, we believe galeterone may be effective in prostate cancer tumors that express altered androgen receptors with C-terminal loss, including AR-V7. In contrast, the mechanisms of action of Zytiga and Xtandi and other similar drugs in development all require the presence of the ligand binding domain in order to be effective.
- ***Favorable safety profile.*** We have administered galeterone to over 200 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone demonstrated a favorable safety and tolerability profile. In our ARMOR2 trial, approximately 90% of all treatment-emergent adverse events reported were grade 1 or 2 in severity and were generally manageable and reversible.
- ***No requirements for steroids.*** Unlike Zytiga, galeterone has not been shown in clinical trials to cause mineralocorticoid excess and does not require co-administration of steroids. Because Zytiga has been shown in clinical trials to cause mineralocorticoid excess, a potentially fatal syndrome characterized by hypertension, hypokalemia, fluid retention and edema, Zytiga is required to be administered with prednisone to reduce the frequency of patients exhibiting mineralocorticoid excess. Despite the co-administration of prednisone, however, approximately 30% of patients treated with Zytiga in a pivotal Phase 3 trial developed symptoms of mineralocorticoid excess. In addition, the chronic use of prednisone poses other safety concerns. Side effects associated with chronic use of prednisone include muscle weakness, osteoporosis, diabetes and increased risk of infection.
- ***No associated seizure risk.*** Unlike Xtandi, we have not had any reports of seizures in clinical trials of galeterone. A 0.9% risk of grand mal seizures was reported in the Xtandi pivotal Phase 3 trial in post-chemotherapy CRPC patients. These seizures have been linked to the inhibition or antagonism by Xtandi of $GABA_A$, a receptor associated with the nervous system. Galeterone is not a $GABA_A$ antagonist.
- ***Ease of dosing.*** Unlike the complicated dosing regimen for Zytiga, galeterone is dosed orally once per day, does not require the co-administration of steroids and can be taken with or without food. We believe that this convenient dosing regimen will enhance patient compliance. In contrast, Zytiga must be taken in a fasted state to avoid large increases in absorption, which may cause side effects. Zytiga also must be co-administered with steroids. Prednisone, the steroid co-administered with Zytiga, must be taken with food in order to avoid potential development of gastric ulcers. As a result, Zytiga and prednisone cannot be taken together and dosing must be carefully coordinated with food intake, resulting in a staggered dosing regimen of pills three times per day.
- ***Potential for use as part of combination therapy.*** Combination therapy using drugs with different mechanisms of action has been an important component of cancer treatment. Combination therapy makes it possible to simultaneously attack different mechanisms responsible for the replication, progression and survival of tumor cells. This is important because of the genetic diversity within a tumor population and because not all cells are equally sensitive to a particular mechanism of action or drug. Because of galeterone's multiple mechanisms of action, galeterone acts as if it were a combination therapy. Moreover, because of galeterone's favorable safety profile, ease of administration and highly selective, multiple mechanisms of action, we believe that it may prove to be well suited for use in combination with other therapies.

Galeterone Clinical Development

In August 2009, we submitted an investigational new drug application, or IND, to the FDA for galeterone for the treatment of CRPC, and in November 2009, we commenced clinical trials of galeterone. As of May 12, 2014, the cut-off date for data presentations at ASCO, we had administered galeterone to a total of 234 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In the Androgen Receptor Modulation Optimized for Response, or ARMOR, program, we had treated 101 CRPC patients in our ongoing ARMOR2 trial and 49 CRPC patients in our ARMOR1 trial. In four additional Phase 1 clinical trials, we also administered galeterone to 84 healthy volunteers.

ARMOR2 Trial

In December 2012, we initiated our ARMOR2 trial, an open label Phase 2 clinical trial of galeterone. The trial is designed as a two-part trial. Part 1 of the trial is a dose escalation phase designed to confirm the dose of galeterone to be evaluated in Part 2 of the trial. Part 2 of the trial is designed to evaluate the efficacy and safety of galeterone at the dose selected in Part 1 in distinct CRPC patient populations. The trial is being conducted at 28 sites in the United States and Canada. In addition, galeterone had been well tolerated and had shown clinically meaningful reductions in levels of PSA.

The primary efficacy endpoints of our ARMOR2 trial are based on a decrease in PSA levels. In setting the primary endpoints of the trial, we considered the standard, accepted use of monitoring PSA levels to determine if a patient's prostate cancer is responding to therapy as well as the use of reductions in PSA levels as a key efficacy endpoint in Phase 2 clinical trials of other prostate cancer agents, as set forth in guidelines developed by the Prostate Cancer Working Group 2, or PCWG2. PCWG2 is an international group of prostate cancer investigators who published guidelines for the design and evaluation of prostate cancer trials.

Part 1 of ARMOR2 Trial

In Part 1 of the trial, we enrolled 25 CRPC treatment-naïve patients with progressive disease and three patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga-refractory patients. The CRPC treatment-naïve patients were enrolled in one of three escalating dose cohorts: 1700 mg/day, 2550 mg/day or 3400 mg/day. The Zytiga-refractory patients all received doses of 2550 mg/day. All patients in Part 1 of the trial received treatment for up to an initial period of 12 weeks followed by optional continued dosing for those patients who tolerated treatment and did not show signs of disease progression. Treatment was continued until disease progression or patient withdrawal due to adverse events or other reasons.

At least 50% of patients at all dose levels achieved a 30% or greater decrease in PSA. Based on the recommendation of the monitoring committee for the trial following review of safety, efficacy and pharmacokinetic results of the three dose groups, we chose the 2550 mg/day dose for further study in Part 2 of the ARMOR2 trial.

Part 2 of ARMOR2 Trial

In Part 2 of the trial, we are currently evaluating a 2550 mg/day dose of galeterone in a total of up to 108 patients in the following advanced prostate cancer populations:

- non-metastatic and metastatic CRPC treatment-naïve patients in a combined cohort of up to 48 patients;
- patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga-refractory patients, in a cohort of up to 30 patients; and
- patients whose disease progressed during treatment with Xtandi, whom we refer to as Xtandi-refractory patients, in a cohort of up to 30 patients.

Table 5 below summarizes the patient populations and primary endpoints for Part 2 of the ARMOR2 trial:

Table 5: Patient Populations and Primary Endpoints for Part 2 of the ARMOR2 Trial

Patient Population	Number of Patients	Primary Endpoint
Non-metastatic CRPC treatment-naïve patients	Up to 48	Percentage of patients with a maximal reduction in PSA levels of at least 30% from baseline to the end of the primary treatment phase
Metastatic CRPC treatment-naïve patients		
Zytiga-refractory patients	Up to 30	Percentage of change in PSA levels from baseline to the end of the primary treatment phase
Xtandi-refractory patients	Up to 30	

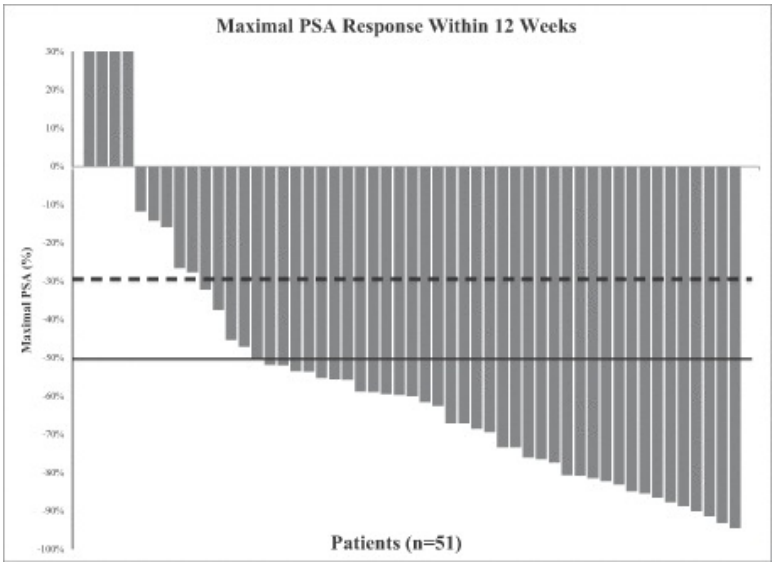
Additional endpoints include incidence of adverse events, change from baseline in safety parameters, response rate and circulating tumor cell, or CTC, enumeration and characterization, including for the evaluation of C-terminal androgen receptor expression in relation to N-terminal androgen receptor expression to identify C-terminal loss and the lack of a functional ligand binding domain.

As of May 12, 2014, we had enrolled 73 patients in Part 2 of the trial. All patients in Part 2 of the trial receive treatment for an initial period of 12 weeks followed by optional continued dosing for those patients who tolerated treatment and did not show signs of disease progression. Treatment will be continued until disease progression or patient withdrawal due to adverse events or other reasons.

Clinical Data Presented at ASCO

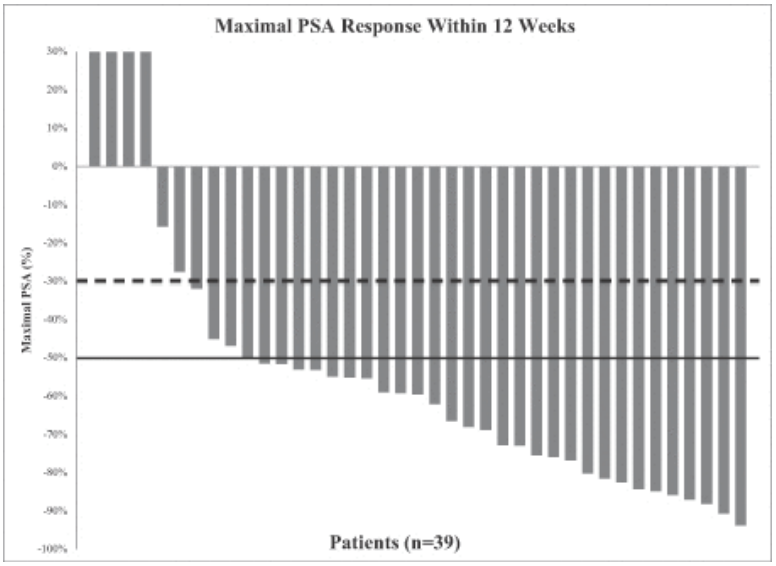
In May 2014 at ASCO, we presented interim efficacy and safety data from our ARMOR2 trial for patients who received the 2550 mg/day dose of galeterone. In 51 evaluable CRPC treatment-naïve patients in Part 1 and Part 2 of the trial, during the first 12 weeks of dosing, 82% had a maximal reduction in PSA levels of at least 30%, and 75% had a maximal reduction in PSA levels of at least 50%, as described in Figure 3 below.

Figure 3: ARMOR2: Maximal PSA Response Waterfall Plot in All Pre-Chemotherapy CRPC Treatment-Naïve Patients (n=51) (2550 mg dose)



In 39 metastatic CRPC treatment-naïve patients who received the 2550 mg/day dose, during the first 12 weeks of dosing, 85% had a maximal reduction in PSA levels of at least 30%, and 77% had a maximal reduction in PSA levels of at least 50%, as described in Figure 4 below.

Figure 4: ARMOR2: Maximal PSA Response Waterfall Plot in Pre-Chemotherapy Metastatic CRPC Treatment-Naïve Patients Treated (n=39) (2550 mg dose)



We also reported 12-week data for 15 Zytiga-refractory patients, two of whom had a maximal reduction in PSA levels of at least 30%. Of the eight Zytiga-refractory patients evaluable by Response Evaluation Criteria in Solid Tumors, or RECIST, five patients had stable disease and three patients had progressive disease as measured by CT/MRI scans by modified RECIST criteria and as measured by bone scans by PCWG2 guidelines. As measured by RECIST criteria, stable disease is achieved when the tumor has not increased in size by 20% and has not decreased by 30%, a partial response occurs when the tumor has decreased in size by at least 30%, and progressive disease occurs when the tumor has increased in size by at least 20% or new tumor lesions are identified.

Our ARMOR2 trial included CTC enumeration and characterization. At ASCO, we presented data from a retrospective subset analysis in which four treatment-naïve CRPC patients in ARMOR2 were identified as having C-terminal loss as determined by the evaluation of C-terminal androgen receptor expression in relation to N-terminal androgen receptor expression. All four of these patients had maximal reductions in PSA levels of at least 50%. We believe that these data support our view that androgen receptor degradation may be active in patients without an intact ligand binding domain and are consistent with our preclinical studies of galeterone.

At ASCO, we also presented interim safety results from all 87 patients treated as of May 12, 2014 in ARMOR2. In these patients, galeterone was well tolerated. Approximately 90% of all treatment-emergent adverse events reported were grade 1 or 2 in severity and were generally manageable and reversible. The majority of these events were assessed as not related or unlikely related to galeterone. In addition, there were no reported cases of seizure or mineralocorticoid excess. The most common adverse events were nausea, decreased appetite, fatigue, diarrhea, pruritus and increased aminotransferase indicating elevated liver enzyme levels. Six of these patients (7%) experienced a grade 3 or grade 4 treatment-emergent increase in aminotransferase indicating elevated liver enzyme levels. These events were asymptomatic, transient and all six of these patients recovered following temporary drug withdrawal. Four of the six patients have been re-challenged at a reduced dose level with none showing a recurrence of a grade 3 or higher adverse event. There were three unexpected serious adverse events in the trial that were assessed by the investigators as possibly related to treatment with galeterone. These treatment-related serious adverse events involved a case of angioedema in a patient who was taking a medication associated with angioedema, an episode of dizziness and fainting in a patient with a history of nausea, diabetes and hypertension who had discontinued treatment with galeterone four days prior to the episode, and acase of hypocalcemia and hyperparathyroidism in a patient with a history of hypocalcemia and hyperparathyroidism. Under the Common Terminology Criteria for Adverse Events established by the National Cancer Institutes, adverse events are reported by grade. Grades 1 or 2 indicate mild to moderate adverse events, grade 3 indicates a severe but not life threatening event with required hospitalization, grade 4 indicates that the event is life threatening and a grade 5 event is death.

Reformulation of Galeterone

The ARMOR2 trial uses a proprietary spray dried dispersion formulation of galeterone in tablet form that we developed after we completed the ARMOR1 trial. Spray dried dispersion is a manufacturing technology used in the pharmaceutical industry to improve dissolution rates and enhance the bioavailability of poorly soluble compounds such as galeterone. During the spray dried dispersion manufacturing process, galeterone and an inert polymer are dissolved in organic solvents and spray dried to produce solid dispersion powder, which is then tableted. The final drug product is an oral tablet.

We developed the tableted spray dried dispersion formulation as a result of findings of exposure variability due to a pronounced food effect with the original drug product used in the ARMOR1 trial. The original formulation was micronized active pharmaceutical ingredient in capsule, which we refer to as the PIC formulation. The spray dried dispersion formulation minimizes the food effect, decreases the exposure variability and increases the exposure levels. We anticipate using our tableted spray dried dispersion formulation in all subsequent clinical trials for galeterone and, if approved for marketing, commercial sales of galeterone.

ARMOR1 Trial

In November 2009, we initiated our ARMOR1 trial, an open label, dose escalation Phase 1 clinical trial of galeterone. We conducted the ARMOR1 trial in 49 CRPC patients at eight sites in the United States using our prior PIC formulation of galeterone. The trial enrolled metastatic and non-metastatic CRPC treatment-naïve patients.

Patients were enrolled in the trial in eight cohorts based on dose level and dosing schedule. Escalating doses of galeterone were administered from 650 mg/day through 2600 mg/day as a single daily dose or a split dose twice daily. The monitoring committee for the trial reviewed all safety data prior to escalation. Galeterone was taken with a patient choice of meal or with a food supplement. Patients received treatment for an initial period of 12 weeks followed by optional continued dosing for those patients who tolerated treatment and did not show signs of disease progression. Treatment was continued until disease progression or patient withdrawal due to adverse events or other reasons.

The trial was designed as a dose finding trial. The primary endpoints for the trial were to assess incidence of adverse events and change from baseline in safety parameters. Secondary endpoints included the percentage of patients with a 50% or greater decrease in PSA during the period from baseline to the earlier of the end of the 12-week treatment period or PSA nadir and changes in disease status from baseline in CT/MRI scans and bone scans over the 12-week treatment period.

A total of 49 patients were enrolled in ARMOR1, of whom 37 patients completed the 12-week treatment period, and 22 patients entered the extension phase of the trial. Of the 12 patients who did not complete the 12-week treatment period, five discontinued treatment due to disease progression, five discontinued treatment due to adverse events and two voluntarily withdrew from the trial.

Safety. Galeterone was well tolerated in the trial. Patients in the trial, as a group, were dosed with galeterone, in the aggregate, for approximately 8,000 days, with individual patients receiving galeterone for up to 20 months. Approximately 90% of treatment-emergent adverse events reported for the first 12 weeks of treatment were grade 1 or grade 2 in severity and were generally manageable and reversible. The majority were assessed as not related or unlikely related to galeterone. The most common treatment-emergent adverse events reported for the first 12 weeks of treatment were fatigue, increased aminotransferase, nausea, diarrhea and pruritus. The incidence of treatment-emergent adverse events was comparable between cohorts and was not dose related. A total of eight patients (or 16%) experienced a grade 3 treatment-emergent increase in aminotransferase indicating elevated liver enzyme levels. These events were asymptomatic and transient. Of the eight patients, two patients voluntarily withdrew from the trial, and six patients restarted at the same dose level or one dose level below with no recurrence of a grade 3 or higher adverse event. A maximum tolerated dose was not reached in the trial. In our ARMOR1 trial, there was only one unexpected serious adverse event assessed by the investigator as possibly related to treatment with galeterone: a case involving a 77-year old patient who developed rhabdomyolysis, an acute disintegration of muscle tissue, and acute renal failure that occurred while receiving simvastatin, a statin known to be associated with rhabdomyolysis. In addition, the patient had underlying chronic renal insufficiency, renal artery stenosis and hydronephrosis requiring stents and presented after a fall, all of which are risk factors for either acute renal failure or rhabdomyolysis.

Efficacy. Patients in each of the doses tested experienced reductions in PSA. In the 12 patients who received the highest dose in the study, 2600 mg/day, maximal PSA decreases of at least 30% were observed in 75% of the patients, and maximal PSA decreases of at least 50% were observed in 42% of the patients. Of the 49 patients in the trial, 22% experienced maximal PSA decreases of at least 50%, and 49% experienced maximal PSA decreases of at least 30%. We believe that these results, while favorable, were adversely impacted by the exposure variability associated with the food effect of the PIC formulation. Radiographic evidence of tumor shrinkage and overall tumor stabilization was seen in multiple patients as assessed by CT/MRI scans and bone scans as measured by RECIST. Thirty-nine patients had measurable disease at baseline, including five patients

receiving the 2600 mg/day dose. Of the five patients, two had partial responses, and a third patient had a near partial response with a reduction in maximal PSA levels of 28%. Of the 39 patients, 22 had stable disease at the end of the 12-week treatment period.

Phase 1 Trials in Healthy Volunteers in Connection with Galeterone Reformulation

During the course of the ARMOR1 trial, we conducted a retrospective analysis of data from the trial which suggested that the PIC formulation of galeterone used in the trial had a food effect, which may have introduced variability into the drug exposure levels. On the basis of this data, we conducted two Phase 1 trials (TOK-200-06 and TOK-200-07) in a total of 36 healthy volunteers to further evaluate the food effect of the PIC formulation of galeterone. In these trials, volunteers received a 975 mg/day dose of galeterone in a fed state with an FDA standardized high calorie/high fat meal or food supplement or in a fasted state in a cross-over design with a seven day washout between treatments. Treatment with galeterone was well tolerated by all volunteers in the trials. The pharmacokinetic results from the trials showed a substantial food effect with increased absorption of 10 to 12 fold in the fed versus the fasted volunteers. As a result, we pursued development of a new formulation to eliminate this food effect. In a Phase 1 clinical trial of galeterone (TOK-200-08), we explored the use of a coated tablet using the active ingredient of the PIC formulation but decided not to take this formulation forward.

We evaluated the proprietary spray dried dispersion formulation, in both capsule and tablet form, in a Phase 1 clinical trial (TOK-200-09) in 24 healthy volunteers. This trial was designed to assess single dose pharmacokinetics and relative bioavailability of the spray dried dispersion formulation under fed and fasted conditions as compared to the PIC formulation of galeterone under fed conditions. Treatment with galeterone was well tolerated by all volunteers in this trial. In addition, the new formulation eliminated the food effect observed with the PIC formulation, reduced drug exposure variability and increased drug exposure levels. We are using our proprietary spray dried dispersion formulation in tablet form in the ongoing ARMOR2 trial and plan to use it in all future trials and, if approved for marketing, commercial sales of galeterone.

Pivotal Clinical Trial

We are currently finalizing our plans for a pivotal clinical trial of galeterone in CRPC patients with C-terminal loss generally or AR-V7 specifically. In May 2014, we held an End-of-Phase 2 meeting with the FDA at which we reviewed the available clinical data and our development plans, including with respect to C-terminal loss and AR-V7. We plan to meet with the FDA in August 2014 to discuss our detailed plans for the pivotal clinical trial. Subject to discussions with the FDA, we anticipate initiating the pivotal clinical trial in the first half of 2015.

Prospective Identification of C-Terminal Loss or AR-V7

We will need to develop assays that sensitively detect C-terminal loss or AR-V7 in order to proceed with our planned pivotal clinical trial and seek approval of, and commercialize, galeterone for patients with these types of truncated androgen receptors. We plan to contract with third parties to develop the assay and to use widely available methodologies and technologies, if possible, in order to minimize development and regulatory risks. We are currently finalizing our strategy for developing this assay and may develop it as an *in vitro* companion diagnostic test or a laboratory may develop it as a conventional laboratory developed test. We expect to discuss with the FDA our development strategy and plans for identifying C-terminal loss or AR-V7 in our pivotal clinical trial, including our plans to use an *in vitro* companion diagnostic test or a conventional laboratory developed test.

Other Development Activities

We plan to explore galeterone's utility in other indications and patient populations in prostate cancer, including early-stage prostate cancer and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies, including with Xofigo, and novel targeted agents, and in other diseases in which the androgen receptor signaling pathway plays a role.

Galeterone Mechanisms of Action

The androgen receptor signaling pathway is the primary pathway that drives prostate cancer growth and has been implicated in other hormonally driven diseases. The pathway is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. Galeterone disrupts the activation of the pathway through multiple mechanisms of action:

- inhibition of the enzyme CYP17, which blocks the synthesis of testosterone;
- androgen receptor antagonism, which blocks the binding of testosterone or DHT with the androgen receptor; and
- androgen receptor degradation, which reduces the amount of androgen receptor protein in the tumor cells.

In order to demonstrate galeterone's multiple mechanisms of action, we conducted preclinical studies with respect to each mechanism.

CYP17 Lyase Inhibition

Like Zytiga, galeterone is an inhibitor of CYP17, a protein with two enzymatic functions: hydroxylase and lyase. Because CYP17 plays a central role in synthesizing the androgens that drive tumor cell growth, CYP17 inhibitors have been developed to treat patients with CRPC. Selectively blocking CYP17 lyase reduces the production of key androgen precursors. However, inhibition of the CYP17 hydroxylase causes an accumulation of certain steroids, such as progesterone, deoxycorticosterone and corticosterone, and a reduction in cortisol, which can result in mineralocorticoid excess. An ideal CYP17 inhibitor will selectively block the lyase function of CYP17 relative to hydroxylase so that these steroids do not accumulate to the extent that they cause mineralocorticoid excess.

We conducted preclinical studies of galeterone and abiraterone to evaluate their relative selectivity with respect to the inhibition of the hydroxylase and lyase functions of CYP17. In these studies, galeterone was shown to selectively block the lyase function of CYP17 relative to the hydroxylase function. In contrast, abiraterone more selectively blocked the hydroxylase function relative to the lyase function, consistent with its published risk for mineralocorticoid excess.

Consistent with these findings, in further preclinical studies in cell cultures, we observed that galeterone inhibited testosterone synthesis comparable to abiraterone, but that abiraterone significantly lowered cortisol levels as compared to galeterone. We believe that this difference is due in part to galeterone's selective inhibition of the lyase function of CYP17.

Androgen Receptor Antagonism

Like Xtandi, galeterone blocks androgens from binding to the androgen receptor. This results in reduced translocation of the androgen receptor into the cell nucleus, which prevents the androgen receptor from acting as a transcription factor and decreases the expression of androgen-responsive genes that drive tumor growth. In *in vitro* studies, galeterone has shown potency of antagonism greater than or comparable to other androgen receptor antagonists, including enzalutamide.

Androgen Receptor Degradation

Galeterone decreases the amount of androgen receptor protein in prostate tumor cells by enhancing degradation of the androgen receptor. This reduces the number of androgen receptors in the tumor cells to which androgen can bind and decreases the sensitivity of androgen responsive cells to androgens. The effect of galeterone to reduce androgen receptor levels has been observed in tumor cell lines and a xenograft model in

mice. We have observed this effect of galeterone in varying degrees in prostate cancer cell lines that express non-mutated full-length androgen receptors and multiple forms of androgen receptor alterations. These alterations include splice variants, such as AR-V7, that are missing large portions of the protein sequence of the androgen receptor in the C-terminus and point mutations, which are single amino acid mutations in the protein sequence of the androgen receptor. In contrast to galeterone, which has been shown to lower androgen receptor levels, in independent preclinical studies and our preclinical studies, reductions in androgen receptor levels have not been observed using *in vitro* or *in vivo* models of prostate cancer treated with abiraterone, bicalutamide or enzalutamide. Abiraterone is the active ingredient in Zytiga, bicalutamide is the active ingredient in Casodex and enzalutamide is the active ingredient in Xtandi. To our knowledge, there are no approved drugs or drugs in clinical development, other than galeterone, with the mechanism of action of androgen receptor degradation.

Preclinical Development

We have conducted *in vitro* and *in vivo* preclinical studies to evaluate galeterone's effect on prostate cancer, including the efficacy of galeterone in hormone-sensitive tumor cell lines, in tumors expressing AR-V7 and other splice variants, in tumors expressing androgen receptor point mutations and in combination with novel targeted agents.

Activity in Hormone Treatment-Resistant Prostate Cancer

We believe that galeterone has the potential to treat tumors that are resistant to hormone treatments because of its differentiated mechanisms of action. In preclinical studies, others have reported key mechanisms of resistance in hormone treatment-resistant prostate cancer, which include:

- increased CYP17 enzyme levels;
- increased production of testosterone and DHT;
- increased wild type or mutant androgen receptor levels;
- alterations in the androgen receptor, such as splice variants and point mutations;
- mutations in the androgen receptor that result in activation by steroids, such as prednisone and progesterone; and
- androgen receptor mutations which convert androgen antagonists into agonists thus leading to activation of the receptor.

Activity in Tumors Expressing Splice Variants, including AR-V7

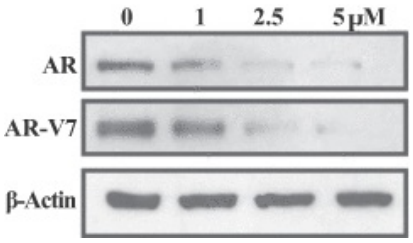
Androgen receptor splice variants are produced in tumor cells due to an aberrant RNA splicing event. As a result, a truncated androgen receptor protein is synthesized that lacks the C-terminal end of the protein, the region of the protein responsible for androgen binding. Tumor cells that express altered androgen receptors that lack the C-terminal end of the protein are not responsive to agents whose activity requires a functional ligand binding domain. In addition, the lack of the ligand binding domain causes the remaining splice variants to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. This indicates the importance of androgen receptor degradation to the prevention of tumor growth.

As a follow-up to preclinical studies in which galeterone had caused degradation of full-length androgen receptors, preclinical studies were conducted in independent laboratories to determine whether galeterone also causes androgen receptor degradation in splice variant proteins.

In preclinical studies, we measured androgen receptor degradation using cell lines that expressed full-length and splice variant androgen receptors. These cells model the expression patterns described in human tumor samples where full-length and splice variant androgen receptor proteins are co-expressed. As shown in Figure 5 below, levels of both full-length androgen receptor and AR-V7 were reduced in a dose dependent fashion

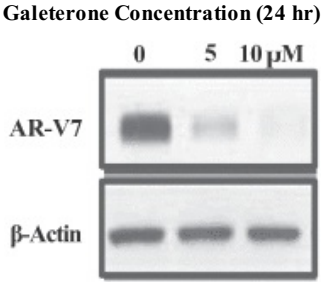
following galeterone treatment. In the figures below, we use as a control beta-actin (ß-Actin), a protein commonly used as a control in these types of experiments.

Figure 5: Galeterone Causes Decreased Levels of Both Full-Length Androgen Receptor (AR) and AR-V7



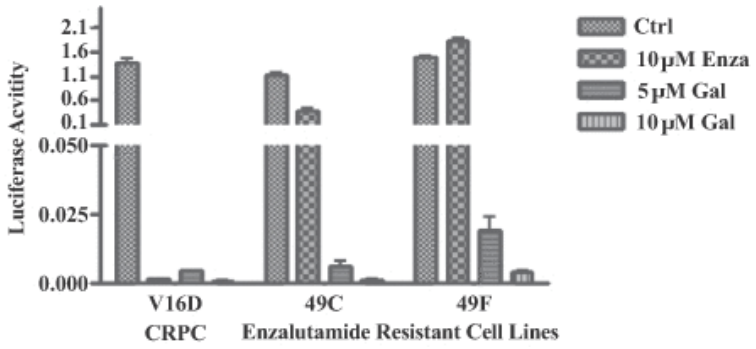
To demonstrate that galeterone would degrade the AR-V7 protein alone, in the absence of the full-length androgen receptor, we studied galeterone in a prostate cancer cell line that only expresses AR-V7, and not the full-length androgen receptor. As shown in Figure 6 below, in this study, AR-V7 protein levels were reduced in a dose dependent fashion in cells that only express AR-V7 and not the full-length androgen receptor, confirming that galeterone can act directly on the AR-V7.

Figure 6: Galeterone Causes Decreased Levels of Androgen Receptor in Cell Line Only Expressing AR-V7



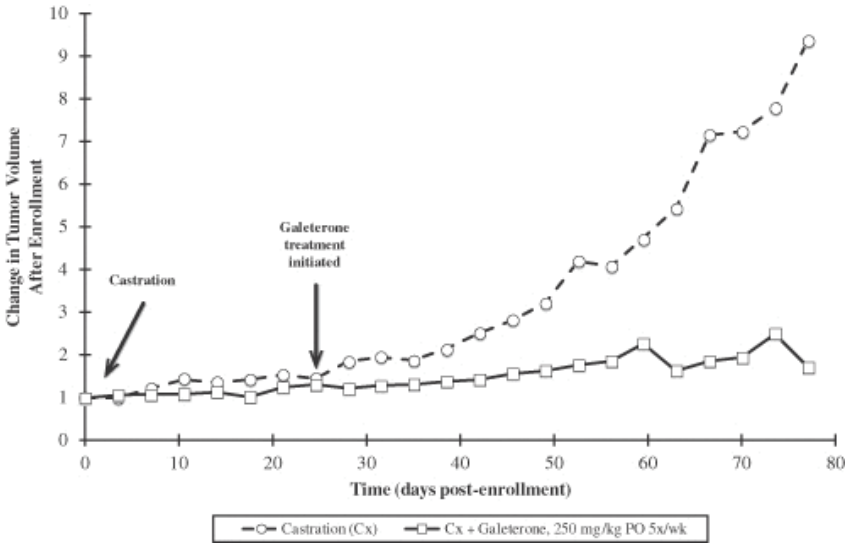
In addition, together with the Vancouver Prostate Centre, we examined whether degradation of androgen receptors translated into reduced androgen receptor signaling and reduced tumor growth in prostate cancer tumor cells which express AR-V7. The Vancouver Prostate Centre conducted a series of studies evaluating the anti-tumor activity of galeterone and enzalutamide in AR-V7 expressing cells. In these studies, galeterone reduced tumor cell proliferation, reduced androgen receptor levels, and decreased nuclear translocation of the androgen receptor, while enzalutamide was only weakly effective in these measures of anti-tumor activity. In these studies, the effect of galeterone or enzalutamide on androgen responsive gene expression was also evaluated by measuring the activity of luciferase, a fluorescent marker, inserted into tumor cells, with lower luciferase activity indicating greater inhibition of androgen signaling. As shown in Figure 7 below, in these studies, the tumor cell line that did not express AR-V7 (V16D) had reduced luciferase activity when treated with enzalutamide or galeterone. However, the enzalutamide-resistant tumor cell lines that did express AR-V7 (49C and 49F) only had reduced luciferase activity when treated with galeterone. When treated with enzalutamide, these tumor cells had increased luciferase activity or only a minimal reduction in luciferase activity, indicating a lower inhibition of androgen signaling relative to galeterone in enzalutamide-resistant tumor cells with AR-V7.

Figure 7: Comparison of Luciferase Activity of Galeterone and Enzalutamide in Enzalutamide-Resistant Tumor Cell Lines



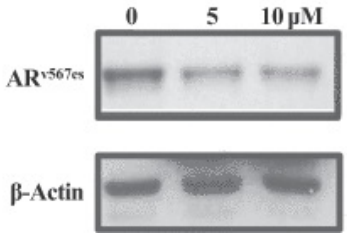
We also evaluated the *in vivo* activity of galeterone in a LuCaP136 xenograft model of human prostate cancer tumor cells grown in castrated mice. LuCaP136 is a prostate cancer cell line that expresses AR-V7. As shown in Figure 8 below, the tumors grew in control animals. However, castrated animals treated with galeterone showed a pronounced tumor growth inhibition.

Figure 8: Galeterone Shows Tumor Growth Inhibition in LuCaP136 (AR-V7 Positive) Castration-Resistant Xenograft Model



We have also evaluated galeterone against a second splice variant, AR^{v567es}. AR^{v567es}, like AR-V7, is a truncated androgen receptor with C-terminal loss. To demonstrate that galeterone would degrade the AR^{v567es} protein alone, in the absence of a full-length androgen receptor, we studied galeterone in a prostate cancer cell line that only expresses AR^{v567es}, and not the full-length androgen receptor. As shown in Figure 9 below, in this study, AR^{v567es} protein levels were reduced in a dose dependent fashion in cells that only express AR^{v567es} and not the full-length androgen receptor, confirming that galeterone can act directly on the AR^{v567es}.

Figure 9: Galeterone Causes Decreased Levels of Androgen Receptor in Cell Line Only Expressing AR^{v567es}



Activity in Androgen Receptor Point Mutations

Patients treated with Xtandi and Zytiga eventually develop resistance such that their tumors continue to grow despite continued treatment. In addition, some patients never respond to initial treatment with Zytiga or Xtandi. Preclinical studies have shown that this resistance may be caused by androgen receptor point mutations such as AR-F876L and AR-T878A. In preclinical studies, galeterone was active against prostate cancer cells that expressed these point mutations.

Galeterone in Combination with Other Therapeutic Drugs

The activation of the Akt/PI3K/mTOR pathway is one of the most frequent alterations observed in human tumor cells. There is growing evidence that the Akt/PI3K/mTOR pathway plays a significant role in prostate cancer tumor progression. Recent scientific publications have shown that there may be a linkage between the androgen receptor signaling pathway and the Akt/PI3K/mTOR pathway such that blocking androgen-dependent signaling may lead to a compensatory upregulation of the Akt/PI3K/mTOR pathway and thus enhanced tumor cell growth. As a result, combination therapies that target both the androgen receptor signaling pathway and the Akt/PI3K/mTOR pathway may have enhanced therapeutic benefit relative to monotherapy.

As part of our exploration of possible therapies to combine with galeterone, we have conducted *in vitro* studies to evaluate whether galeterone acts additively or synergistically with inhibitors of the Akt/PI3K/mTOR pathway, a signaling pathway associated with tumor cell survival, proliferation and invasiveness. In these preclinical studies, we observed that galeterone is synergistic with certain Akt, mTOR and PI3K inhibitors in suppressing prostate cancer cell proliferation. We plan to conduct *in vivo* studies to test drug combinations of galeterone with Akt, mTOR and PI3K inhibitors in xenograft models.

Androgen Receptor Degradation Compounds

We plan to identify and develop novel compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under an exclusive license from UMB. We plan to develop these compounds for use as monotherapies or in combination with existing therapies. We plan to target these compounds for patients with androgen receptor signaling diseases, including prostate cancer patients with primary or acquired resistance to existing therapies.

Manufacturing

Galeterone is a small molecule drug candidate that is manufactured through a reproducible synthetic process from readily available raw materials. Galeterone is manufactured in a proprietary formulation based on spray dried dispersion technology that is designed to produce a product that can provide consistent drug exposure and can be administered with or without food.

We believe that we have sufficient supply of formulated drug to complete the ARMOR2 trial and have begun the manufacture of formulated drug for use in our planned pivotal clinical trial using manufacturers operating under cGMP to manufacture pivotal clinical trial materials. We believe that we will complete the manufacturing of formulated drug for our planned pivotal clinical trial during the third quarter of 2014.

We do not have our own manufacturing facilities. We currently rely, and expect to continue to rely, on a limited number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates after they are approved. If any of our products are approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers and one or more backup manufacturers for the commercial production of those products. We believe that there are a number of qualified manufacturers with which we could enter into commercial supply arrangements. Further, we believe that the process to manufacture galeterone can be scaled up to commercial levels without any unusual equipment.

Commercialization Strategy

We have worldwide development and commercialization rights to galeterone. To maximize the value of these rights, we intend to build a urology- and oncology-focused specialty sales and marketing organization in the United States to support the commercialization of galeterone. We believe that a specialty sales force will be able to target the key prescribing physicians in urology and oncology that treat CRPC. We currently do not have any sales or marketing capabilities or experience. We plan to establish the required capabilities within an appropriate time frame ahead of any product approval and commercialization to support a product launch. To develop the appropriate internal commercial infrastructure in the United States, we will have to invest financial and management resources, some of which will have to be deployed prior to any confirmation that galeterone will be approved. We intend to commercialize galeterone outside the United States through collaborations with third parties.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in obtaining FDA approval for drugs and achieving widespread market acceptance. Our potential competitors' drugs may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of their development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

We are focusing our initial development of galeterone on the treatment of CRPC patients whose prostate tumor cells express an altered androgen receptor that is truncated. Based on their mechanisms of action, preclinical data and the data from the MD Anderson and Johns Hopkins trials, we believe that Zytiga and Xtandi are less responsive in this patient population and do not expect that other drugs in development with similar mechanisms of action will be responsive in this patient population. However, we expect that other drugs with alternative mechanisms of action may be developed for the treatment of this patient population.

We believe that galeterone may be well suited to treat other prostate cancer patient populations. If galeterone is approved for additional indications, it may compete with other secondary hormonal treatments

currently being marketed, such as Zytiga and Xtandi, or with secondary hormonal treatment drug candidates currently in development, such as ARN-509 and ODM-201. Zytiga is marketed in the United States by Johnson & Johnson, and Xtandi is marketed in the United States by Astellas Pharma Inc. and Medivation, Inc. ARN-509 is being developed by Johnson & Johnson and ODM-201 is being developed by Bayer Healthcare and Orion Corporation. In addition, depending on the indication for which galeterone is approved, galeterone may compete with chemotherapy and other compounds that are not secondary hormonal treatments, including Jevtana and Provenge, and compounds that are in clinical development, such as Exelixis, Inc.'s Cometriq and Bavarian Nordic A/S's Prostvac.

We believe the key competitive factors that will affect the development and commercial success of galeterone, if approved, will be efficacy, safety and tolerability profile, probability of drug resistance, convenience of the dosing regimen, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

A third party may hold intellectual property, including patent rights, that is important or necessary to commercialize our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. We may not be able to obtain such licenses on commercially reasonable terms, or at all, in which case our business could be harmed, possibly materially.

We plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment and additional compounds and their derivatives. Specifically, we seek patent protection in the United States and internationally for novel compositions of matter covering the compounds, the chemistries and processes for manufacturing these compounds and the use of these compounds in a variety of therapies.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark

Office, or USPTO, to determine priority of invention or in post-grant challenge proceedings at the USPTO or at a foreign patent office, such as inter partes review and post grant review proceedings at the USPTO and opposition proceedings at the European Patent Office, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

We generally file a provisional patent application with the USPTO first and then subsequently file a corresponding non-provisional patent application, which enables us to establish an earlier effective filing date in the subsequently filed non-provisional patent application. In order to benefit from the earlier effective filing date, we must file a corresponding non-provisional patent application, such as a utility application in the United States or an international application under the Patent Cooperation Treaty, or PCT, within 12 months of the date of the provisional patent application filing. Based on the PCT filing, we may file national and regional patent applications in the United States, the European Union, China, Japan, Australia, Canada, Brazil, India, Indonesia, Israel, Mexico, New Zealand, South Korea, Singapore, South Africa or the Eurasian Patent Organization. To date, we have not filed for patent protection in all national and regional jurisdictions where such protection may be available, and we may decide to abandon national and regional patent applications before a patent is granted. In addition, the patent grant proceeding for each national or regional patent application that we file is an independent proceeding. As a result, it is possible for a patent application to be granted in one jurisdiction and denied in another jurisdiction, and depending on the jurisdiction, the scope of patent protection may vary.

Galeterone Patent Portfolio

As of July 31, 2014, we owned two issued U.S. patents, ten U.S. provisional and non-provisional patent applications, one issued foreign patent and 34 foreign applications in our galeterone patent portfolio. We also had rights under our license agreement with UMB to five issued U.S. patents and 44 issued foreign patents as well as three U.S. patent applications and 13 foreign applications. Our owned and licensed patent and patent applications, if issued, are expected to expire on various dates from 2017 through 2034, without taking into account any possible patent term extensions.

We have an exclusive license from UMB for a U.S. patent covering compositions and methods of use of a class of compounds encompassing galeterone, which expires in 2017. Given its expiration date and the anticipated timing of development and commercialization of galeterone, we do not believe this patent will provide significant protection for galeterone. We have no patent protection specifically covering the chemical structure of galeterone. As a result, a third party that obtains regulatory approval of a product with the same active ingredient as galeterone may be able to market such product so long as the third party does not infringe any other patents owned or licensed by us with respect to galeterone. For this reason, we have filed for or licensed patents and patent applications relating to galeterone covering methods of use, pharmaceutical compositions, combination treatments, prodrugs, metabolites, and analogs of galeterone and their use.

Method of Use. We have licensed from UMB a U.S. patent covering a method of treating prostate cancer in a human subject by administering galeterone, which is expected to expire in 2027. The license also includes granted patents in the European Patent Convention and Japan covering the use of galeterone to treat prostate disease, including prostate cancer and prostatic hyperplasia. Similar patents have been granted or allowed in Australia, Canada, Hong Kong, South Korea, Mexico, New Zealand, Singapore, South Africa, and the Eurasian Patent Organization. These patents are expected to expire in 2026. In addition, we have pending applications in Brazil, China, the European Patent Convention, India, Israel, Indonesia and Japan.

We have also filed three U.S. provisional patent applications covering the use of galeterone in treating Xtandi-resistant prostate cancer mediated by androgen receptor variants, including splice variants such as AR-V7. The term of a patent, if issued, claiming priority to these provisional applications would be expected to expire in 2034.

Pharmaceutical Compositions. We have filed U.S. and international patent applications relating to a galeterone formulation and its use where the galeterone is present in a spray dried dispersion. We have pending applications in the United States, the European Union, Australia, Brazil, Canada, China, India and Japan. The

term of any patent in this family, if issued, would be expected to expire in 2032. In addition, we have licensed from UMB a U.S. patent application covering a pharmaceutical composition of galeterone. The term of any patent, if issued, claiming priority to this application would be expected to expire in 2026.

Combination Treatments. We have filed patent applications or licensed from UMB patent applications covering the use of galeterone in combination with other therapeutic drugs. For example, we have filed U.S. and foreign patent applications covering the use of galeterone in combination with inhibitors of the Akt/PI3K pathway. We have pending applications in the United States, the European Union, Australia, Canada and Japan. The term of any patent in this family, if issued, would be expected to expire in 2032.

Prodrugs, Metabolites and Analogs. We have filed patent applications or licensed from UMB patent applications directed to prodrugs, metabolites or analogs of galeterone. For example, we have licensed a U.S. patent application from UMB directed to certain prodrugs of galeterone. If issued, the term of the resulting patent, if issued, would be expected to expire in 2029. We have also filed patent applications in the United States and certain other countries including Australia, Brazil, Canada, China, the European Union, India and Japan directed to other prodrugs of galeterone. If issued, the term of the resulting patents would be expected to expire in 2030. Further, we have filed patent applications in the United States and certain other countries including Australia, Brazil, Canada, China, the European Union, India and Japan directed to compounds which have been identified as metabolites of galeterone and which may be biologically active. If issued, the term of the resulting patents would be expected to expire in 2030. We have also obtained a license to a UMB PCT patent application directed to analogs of galeterone that disrupt androgen receptor signaling by degrading the androgen receptor. The term of any patent, if issued, claiming priority to this PCT patent application would be expected to extend to 2034.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

License Agreement with University of Maryland, Baltimore

In May 2006, we entered into a master license agreement with UMB. Pursuant to the license agreement, UMB granted us an exclusive worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen steroids including galeterone, which we refer to as licensed products, and to otherwise practice the patent rights in any manner, for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted us a first option to receive an exclusive license to UMB's rights in certain improvements to the licensed products, which improvements we refer to as licensed improvements.

We have exercised our option and acquired exclusive rights to licensed improvements under three amendments to the license agreement. In March 2009, the license agreement was amended to grant us an exclusive license to oral prodrugs of the licensed products. In April 2012, the license agreement was amended to grant us an exclusive license to compositions and methods of inducing endoplasmic reticulum stress. In October 2013, the license agreement was amended to grant us an exclusive license to a patent application directed to analogs of galeterone that disrupt androgen receptor signaling by degrading the androgen receptor.

Under the terms of the license agreement, as amended, we are obligated to use commercially reasonable efforts to develop and commercialize one or more licensed products. We must also achieve specified milestone events by specified dates. Unless our license agreement with UMB is terminated earlier as provided below, our exclusive license from UMB expires on a country-by-country basis as of the later of the expiration date of the last to expire of the claims of the patent rights licensed to us under the agreement in such country or ten years after the first commercial sale of a licensed product in such country. UMB may terminate the agreement if we fail to achieve such milestone events and do not cure such failure within a specified termination notice period. UMB may also terminate the agreement upon our breach of our payment obligations or our other material breaches under the agreement if we do not cure such breach within a specified notice period or upon our bankruptcy or insolvency. We may terminate the agreement at any time, on a country-by-country basis, if we determine that a license under the licensed patent rights in an applicable country is not advantageous to our commercial success, provided that our payment obligations with respect to licensed products in such country would survive termination if we continued to develop and commercialize licensed products in such country following such a termination.

In consideration for the rights granted to us, we made an upfront payment to UMB of $20,000 following the execution of the license agreement and a payment of $10,000 following the execution of each of the March 2009, April 2012 and October 2013 amendments. We are obligated to pay UMB an annual maintenance fee of $10,000 each year until the first commercial sale. In addition, we paid UMB a $50,000 milestone payment upon the submission of our IND for galeterone and a $40,000 milestone payment upon the issuance of the first patent related to UMB's prodrug patent application. We are obligated to make an additional $50,000 milestone payment to UMB for each additional IND we file for a licensed product and a $100,000 milestone payment upon the approval of each NDA for a licensed product by the FDA. We must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by our sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. Our royalty obligations are subject to specified reductions in the event that we are required to obtain additional licenses from third parties or in the event of specified competition from third-party products licensed by UMB. Our minimum annual royalty payment to UMB is $50,000 beginning in the year following the year in which the first commercial sale occurs. We must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, as of April 10, 2012, we assumed responsibility for all patent expenses related to the prosecution and maintenance of the licensed patents.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, clearance, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products and medical devices. The processes for obtaining regulatory clearances and approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale

for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or IND so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- ***Phase 1:*** The drug is initially introduced into a small number of healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- ***Phase 2:*** The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- ***Phase 3:*** Phase 3 clinical trials are commonly referred to as “pivotal” trials, which typically denotes a trial which generates the principal data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. In Phase 3 trials, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical trials that must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies, trials or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of

filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed drug represents a significant improvement when compared with other

available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA

will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical

trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug…"

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes

reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant

pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Patent Term Restoration and Extension

A patent claiming a new drug product or medical device may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a new drug product or medical device is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for approval of the product, plus the time between the

submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product or medical device is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs or medical devices for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Companion Diagnostics and Regulation of Laboratory Developed Tests in the United States

We expect that galeterone may rely upon *in vitro* companion diagnostics for use in selecting patients with C-terminal loss. In July 2014, the FDA issued final guidance stating that if an *in vitro* diagnostic is essential to the safe and effective use of a therapeutic product, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product. *In vitro* diagnostics marketed in the United States are regulated as medical devices. As a result, unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to the Premarket Approval or PMA process.

510(k) Premarket Notification

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device, which is a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976, that is a class I or II device, or a class III device for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted and filed with the FDA, but it can take significantly longer and clearance is never assured. The FDA has issued guidance documents meant to expedite review of a 510(k) and facilitate interactions between manufacturers and the agency. To demonstrate substantial equivalence, a manufacturer must show that the device has the same intended use as a predicate device and the same technological characteristics, or the same intended use and different technological characteristics and does not raise new questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. If the FDA concludes that the device is not substantially equivalent to a predicate device, the manufacturer will need to submit a PMA to market the device. Alternatively, a manufacturer may request a *de novo* classification if the device is of low to moderate risk and there is no predicate device upon which to base a substantial equivalence determination.

Premarket Approval

The PMA process for approval to market a medical device is more complex, costly, and time consuming than the 510(k) clearance procedure. A PMA must be supported by extensive data, including technical information regarding device design and development, preclinical studies, clinical studies, manufacturing and controls information and labeling information, that demonstrates the safety and effectiveness of the device for its intended use. The FDA may refer a PMA to an advisory committee for its recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. If the FDA's evaluations of both the PMA and the manufacturing facility for the device are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years, and the process can be expensive and uncertain. Moreover, even if the FDA approves a PMA, the FDA may approve the

device with an indication that is narrower or more limited than originally sought, and the agency may impose post-approval conditions that it believes necessary to ensure the safety and effectiveness of the device.

Regulation of Laboratory Development Tests

Laboratory Developed Tests, or LDTs, are tests that are designed, manufactured, validated and used within a single laboratory. The FDA has historically not required clearance or approval of such tests as medical devices. In 1992, the FDA expressed its view that although LDTs are subject to FDA regulation as devices but that the FDA would generally exercise enforcement discretion and not apply the regulatory requirements for medical devices to LDTs. More recently, however, in July 2014, the FDA notified Congress of its intent to issue two draft guidance documents regarding the FDA's oversight of LDTs, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," which we refer to as the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," which we refer to as the Notification Guidance. Under the Framework Guidance, the FDA plans to take a risk-based approach to determining the level of regulation to which the LDTs will be subject with certain LDTs being subject to full FDA enforcement discretion; certain LDTs being subject to partial FDA enforcement discretion; and the remaining LDTs being subject to full FDA regulation. The intent of the Notification Guidance is to explain to laboratories the process for notifying the FDA that they "manufacture, prepare, propagate, compound, or process" LDTs and how to comply with the medical device reporting requirements. The FDA has indicated that the enforcement of these regulatory requirements in the Framework Guidance and the Notification Guidance will be phased in over several years.

LDTs are subject to the requirements of the Clinical Laboratory Improvement Amendments of 1988 or CLIA. That statute establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Specifically, under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that laboratories hold a certificate applicable to the type of work it performs and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring that laboratories be certified by the federal government and comply with various operational, personnel, facilities administration, quality and proficiency requirements intended to ensure that clinical laboratory testing services are accurate, reliable and timely. On February 6, 2014, the Department of Health and Human Services issued a final rule amending CLIA regulations to give patients direct access to laboratory test results upon request. CLIA compliance and certification is a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. Under CLIA, laboratories are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections.

CLIA further provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. Several states require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of testing methodology, and has various requirements over and above CLIA, including those for personnel qualifications, proficiency testing, and physical facility, equipment and quality control standards.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or

marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Review and Approval of In Vitro Diagnostics in the European Union

In the European Economic Area, or EEA, *in vitro* diagnostic medical devices are regulated as medical devices and are required to conform with the essential requirements of the E.U. Directive on *in vitro* diagnostic medical devices (Directive No 98/79/EC, as amended). As medical devices, *in vitro* diagnostic medical devices must comply with the Essential Requirements in Annex I to the EU Medical Devices Directive (Council Directive 93/42/EEC), or the Essential Requirements. Specifically, a manufacturer must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices, where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a third-party organization designated by competent authorities of a European Union country to conduct conformity assessments, or a Notified Body. Notified Bodies are independent testing houses, laboratories, or product certifiers typically based within the European Union and authorized by the European member states to perform the required conformity assessment tasks, such as quality system audits and device compliance testing. The Notified Body would typically audit and examine the product's Technical File and the quality system for the manufacture, design and final inspection of the product before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products and devices for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result,

increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, require manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Facilities

Our headquarters are located in Cambridge, Massachusetts, where we occupy approximately 2,860 square feet of office space. The term of the lease expires on a month-to-month basis.

Employees

As of July 31, 2014, we had 15 full-time employees, eight of whom were primarily engaged in research and development activities.

Management

The following table sets forth the name, age and position of each of our executive officers and directors as of July 31, 2014.

Name	Age	Position(s)
Executive Officers		
Jodie P. Morrison	39	President and Chief Executive Officer, Director
John S. McBride	62	Chief Operating Officer and Chief Financial Officer
Karen J. Ferrante, M.D.	56	Head of Research and Development and Chief Medical Officer
Non-Employee Directors		
Seth L. Harrison, M.D.(1)(2)(3)	53	Chairman of the Board of Directors
Reinhard J. Ambros, Ph.D.*	58	Director
Timothy J. Barberich(1)(2)(3)	66	Director
David A. Kessler, M.D.(2)(3)	63	Director
Campbell Murray, M.D.*	38	Director
Joseph A. Yanchik, III(1)	50	Director

(1) Member of audit committee.

(2) Member of compensation committee.

(3) Member of nominating and corporate governance committee.

* Drs. Ambros and Murray have notified us that they will resign from our board of directors contingent upon and effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

** Committee memberships will be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers

Jodie P. Morrison has served as our President and Chief Executive Officer and as a member of our board of directors since March 2013. From December 2006 until March 2013, Ms. Morrison held other senior positions with us, including Chief Operating Officer, Head of Clinical Affairs and Program Operations and Vice President of Clinical Affairs and Program Operations. Prior to joining our company, Ms. Morrison served as Director of Clinical Operations and Medical Affairs at Dyax Corporation, or Dyax. Prior to joining Dyax, Ms. Morrison held clinical management positions at both Curis, Inc. and at Diacrin, Inc. Ms. Morrison received a B.A. in neuroscience from Mount Holyoke College, her clinical research certification from the Boston University School of Medicine and her business training through the Greater Boston Executive Program at the MIT Sloan School of Management. We believe Ms. Morrison is qualified to serve on our board of directors due to her service as our President and Chief Executive Officer, her years of service as our Chief Operating Officer and her extensive knowledge of our company and industry.

John S. McBride has served as our Chief Operating Officer since February 2014 and as our Chief Financial Officer since April 2014. Prior to joining our company, Mr. McBride founded and served as President of Alliance Life Science Advisors, Inc., a consulting firm focused on assisting life science companies with strategic planning, business development and financing projects from March 2012 until February 2014. Prior to founding Alliance Life Science Advisors, Inc., Mr. McBride was an independent consultant from January 2009 until March 2012. In addition, Mr. McBride previously served as Executive Vice President and Chief Operating Officer of Gloucester Pharmaceuticals, Inc., Global Head of Oncology Licensing at Pharmacia Corporation, Executive Vice President, Business Operations and Chief Financial Officer at CytoTherapeutics, Inc., Vice President, Business Development and Treasurer at Phytera, Inc., Vice President, Commercial Development at Sparta Pharmaceuticals, Inc. and Vice President, Business Development at U.S. Bioscience, Inc. Currently,

Mr. McBride serves as a member of the board of directors of Intezyne, Inc. From August 2008 until June 2013, Mr. McBride served as a member of the board of directors of Niiki Pharma Inc. Mr. McBride received a B.S. in biochemistry and an M.S. in chemical engineering from the University of Wisconsin and an M.B.A. from the Wharton School, University of Pennsylvania.

Karen J. Ferrante, M.D. has served as our Head of Research and Development and Chief Medical Officer since April 2014. Prior to joining our company, Dr. Ferrante served as oncology therapeutic area head and Takeda Cambridge, USA site head for Takeda Pharmaceuticals from May 2013 until July 2013 and held senior positions at Millennium Pharmaceuticals, which was acquired by Takeda Pharmaceuticals in May 2008, including Chief Medical Officer, a Head of Research and Development and Senior Vice President, Clinical Development from September 2007 until May 2013. In addition, Dr. Ferrante previously held positions of increasing responsibility at Pfizer Global Research & Development, including Vice President and Therapeutic Area Clinical Leader in Oncology Development, and served as Associate Director of Clinical Oncology at Bristol-Myers Squibb Company, or BMS. Prior to joining BMS, Dr. Ferrante served as a staff physician at the Beth Israel Deaconess Hospital. She also served as instructor, clinical instructor and clinical fellow in medicine at the Harvard Medical School while completing her internship and residency in internal medicine followed by her fellowship in hematology and oncology at Beth Israel Deaconess Hospital. Currently, Dr. Ferrante serves as a member of the board of directors of Progenics Pharmaceuticals, Inc. Dr. Ferrante received a B.S. in chemistry and biology from Providence College and an M.D. from Georgetown University.

Non-Employee Directors

Seth L. Harrison, M.D. is one of our founders and has served as a member of our board of directors since April 2005 and as Chairman of our board of directors since August 2005. In September 1999, Dr. Harrison founded Apple Tree Partners, or Apple Tree, a life sciences investment firm, and since that time has served as Apple Tree's Managing Partner. In addition, Dr. Harrison previously served as our Chief Executive Officer from August 2008 until September 2011. Currently, Dr. Harrison serves as a member of the boards of directors of Heartware International, Inc., or Heartware, and Aileron Therapeutics, Inc., or Aileron, and as Chairman of the board of directors of Braeburn Pharmaceuticals. From 2002 until 2010, Dr. Harrison served as a member of the board of directors of the International Partnership for Microbicides, a Rockefeller Foundation/Gates Foundation sponsored public-private partnership engaged in the development of anti-HIV microbicides. Dr. Harrison received an A.B. from Princeton University, an M.D. and M.B.A., both from Columbia University, and completed a surgery internship at the Presbyterian Hospital in the City of New York. We believe Dr. Harrison is qualified to serve on our board of directors due to his strong medical and venture capital background, his extensive experience with development-stage companies such as ours and his service on the boards of directors of a range of public and private companies.

Reinhard J. Ambros, Ph.D. has served as a member of our board of directors since May 2009. Dr. Ambros has served as Global Head of Novartis Venture Funds since August 2005. Previously, he served as Head of Group Strategic Planning for Novartis Corporation from 2001 until 2005. Prior to that, he served as global head of business development and licensing for cardiovascular and metabolic diseases at Novartis Pharma AG. Currently, Dr. Ambros serves as a member of the boards of directors of Aileron, FORMA Therapeutics, Inc., Genedata AG and Symetis SA. Dr. Ambros received an M.S. from the University of Regensburg, Germany, and a Ph.D. in medicinal chemistry and pharmacology from the University of Regensburg, Germany. We believe Dr. Ambros is qualified to serve on our board of directors due to his management experience in the biotechnology sector and his service on other boards of directors.

Timothy J. Barberich has served as a member of our board of directors since February 2010. Mr. Barberich founded Sepracor, Inc., or Sepracor, in 1984 and served as Chief Executive Officer and Chairman of the board of directors of Sepracor until November 2009 when Sepracor was acquired by Dainippon Sumitomo. Prior to founding Sepracor, Mr. Barberich served as a senior executive at Millipore Corporation. Mr. Barberich currently serves on the boards of directors of Heartware, GI Dynamics, Inc., Verastem Pharmaceuticals, Inc.,

Neurovance and BioNevia, Inc. He previously served on the Board of Trustees of the Boston Medical Center and the board of the Pharmaceutical Research and Manufacturers' Association. Mr. Barberich received a B.S. in chemistry from Kings College. We believe Mr. Barberich is qualified to serve on our board of directors due to his significant experience in the development and commercialization of pharmaceutical products, his leadership experience at other pharmaceutical companies and his service on other boards of directors.

David A. Kessler, M.D. has served as a member of our board of directors since March 2009. Dr. Kessler has served as Professor of Pediatrics and Epidemiology and Biostatistics at the University of California, San Francisco, or UCSF, School of Medicine since 2003. Dr. Kessler served as the Dean of the School of Medicine and the Vice Chancellor for Medical Affairs at UCSF from 2003 until 2007 and Dean of the Yale University School of Medicine from 1997 until 2003. Dr. Kessler served as Commissioner of the FDA from November 1990 until March 1997. He also currently serves as a senior advisor to TPG Capital. Dr. Kessler was elected a member of the Institute of Medicine in 1993. Currently, Dr. Kessler serves on the board of directors of Immucor, Inc. He previously served on the board of directors of Aptalis. Dr. Kessler received a B.A. from Amherst College, a J.D. from The University of Chicago Law School and an M.D. from Harvard Medical School. In addition, Dr. Kessler received an Advanced Professional Certificate from the New York University Graduate School of Business Administration. We believe Dr. Kessler is qualified to serve on our board of directors due to his extensive healthcare and regulatory experience.

Campbell Murray, M.D. has served as a member of our board of directors since May 2009. Dr. Murray has served as a Managing Director of Novartis Venture Funds since August 2005. Previously, Dr. Murray served as the Director of Special Projects at the Novartis Institutes for BioMedical Research from July 2004 until July 2005. Currently, Dr. Murray serves as a member of the boards of directors of Aerpio Therapeutics, Alios BioPharm, Euthymics Bioscience, Inc., Galera Therapeutics, ImaginAb and Neurovance. He previously served on the boards of directors of Akebia Therapeutics, Aileron and ProCertus BioPharm. Dr. Murray received a bachelor of human biology from the University of Auckland Medical School, an M.B.A. from Harvard Business School, an M.P.P. from the John F. Kennedy School of Government, and an MBChB (M.D.) from the University of Auckland Medical School. We believe that Dr. Murray is qualified to serve on our board of directors due to his extensive investment experience in the biotechnology sector.

Joseph A. Yanchik, III is one of our founders and has served as a member of our board of directors since August 2005. Mr. Yanchik served as our Chief Executive Officer from August 2005 until August 2008. Mr. Yanchik has served as the President and Chief Executive Officer of Aileron since July 2005. Mr. Yanchik previously served as Venture Partner at Apple Tree from June 2005 until September 2009, Vice President of Corporate Development at Mendel Biotechnology and founder and Chief Business Officer of Poetic Genetics, Inc. Prior to that, Mr. Yanchik specialized in corporate and securities law at Cahill Gordon & Reindel and Venture Law Group. Mr. Yanchik received a B.B.A. from Loyola College and a J.D. from the Villanova University School of Law. We believe Mr. Yanchik is qualified to serve on our board of directors due to his extensive business, legal and investment experience and experience as an executive.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition

Our board of directors currently consists of seven members, all of whom were elected as directors pursuant to a voting agreement that we have entered into with the holders of our redeemable convertible preferred stock and certain of our founders. The voting agreement will terminate upon the closing of this offering, and there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by

resolution of the board of directors. Our restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be Jodie P. Morrison and Joseph A. Yanchik, III, and their term will expire at the annual meeting of stockholders to be held in 2015;
- the class II directors will be Timothy J. Barberich and David A. Kessler, and their term will expire at the annual meeting of stockholders to be held in 2016; and
- the class III directors will be Seth L. Harrison, and his term will expire at the annual meeting of stockholders to be held in 2017.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of a board member is identification of a member who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Director Independence

Rule 5605 of the NASDAQ Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Rule 5605(a)(2) of the NASDAQ Listing Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In August 2014, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Jodie P. Morrison and Seth L. Harrison, is an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules. Ms. Morrison is not an independent director under Rule 5605(a)(2) because she is our President and Chief Executive Officer. Dr. Harrison is not an independent director under Rule 5605(a)(2) because he served as our Chief Executive Officer from August 2008 until September 2011. We expect Dr. Harrison will become an independent director as of September 23, 2014. Our board of directors also determined that Messrs. Yanchik and Barberich, who will be members of our audit committee upon the effectiveness of the registration statement of which this prospectus forms a part, and Messrs. Kessler and Barberich, and Dr. Harrison as of September 23, 2014, who will comprise our compensation committee upon the effectiveness of the registration statement of which this prospectus forms a part, satisfy the independence standards for such committees established by the SEC and the NASDAQ Listing Rules, as applicable. Dr. Harrison is not an independent director for the purpose of membership on our audit committee under Rule 10A-3 because of his affiliation with entities affiliated with Apple Tree Partners II, L.P., which beneficially own approximately 49% of our outstanding common stock prior to this offering.

Under applicable NASDAQ rules, we are permitted to phase-in our compliance with the independence requirements for our audit, compensation and nominating and corporate governance committees. The phase-in periods with respect to director independence allow us to have only one independent member on each of the audit committee, compensation committee and nominating and corporate governance committee upon the listing date of our common stock, a majority of independent members on each of these committees and our audit committee within 90 days of the listing date and fully independent committees within one year of the listing date. We expect that by the first anniversary of our listing on The NASDAQ Global Market, each of these committees will comply with the applicable independence requirements.

Board Committees

Our board of directors has established an audit committee and a compensation committee and, effective upon the effectiveness of the registration statement of which this prospectus forms a part, will establish a nominating and corporate governance committee. Each of these committees will operate under a charter that will be approved by our board of directors.

Audit Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our audit committee will be Joseph A. Yanchik, III, Timothy J. Barberich and Seth L. Harrison. Mr. Yanchik will be the chair of the audit committee. None of the members of our audit committee qualifies as an audit committee financial expert within the meaning of SEC regulations and the NASDAQ Listing Rules. Following this offering, we plan to seek to identify a director to serve on the audit committee who would qualify as an audit committee financial expert. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. Our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;

- overseeing our internal audit function, if any;
- discussing our risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules. All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our registered public accounting firm must be approved in advance by our audit committee.

Compensation Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our compensation committee will be Timothy J. Barberich, Seth L. Harrison and David A. Kessler. Mr. Barberich will be the chair of the compensation committee. Our compensation committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. Our compensation committee's responsibilities will include:

- reviewing and approving, or making recommendations to our board with respect to, the compensation of our Chief Executive Officer and other executive officers;
- overseeing the evaluation of our senior executives;
- reviewing and making recommendations to our board of directors with respect to our incentive-compensation and equity-based compensation plans;
- overseeing and administering our equity-based plans;
- reviewing and making recommendations to our board with respect to director compensation;
- reviewing and discussing with management our "Compensation Discussion and Analysis" disclosure to the extent such disclosure is required by SEC rules; and
- preparing the compensation committee report required by SEC rules.

Nominating and Corporate Governance Committee

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our nominating and corporate governance committee will be Seth L. Harrison, Timothy J. Barberich and David A. Kessler. Dr. Harrison will be the chair of the nominating and corporate governance committee. Upon the closing of this offering, the nominating and corporate governance committee's responsibilities will include:

- identifying individuals qualified to become members of our board;
- recommending to our board the persons to be nominated for election as directors and to each of our board's committees;
- developing and recommending to our board corporate governance principles; and
- overseeing an annual evaluation of our board.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more

executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is an officer or employee of our company, and other than Dr. Harrison, who served as our Chief Executive Officer from August 2008 until September 2011, none of the members of our compensation committee has ever been an officer or employee of our company.

Code of Business Conduct and Ethics

We plan to adopt a written code of business conduct and ethics that will be effective upon the closing of this offering and apply to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following this offering, a copy of the code will be posted on the Corporate Governance section of our website, which is located at www.tokaipharma.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Director Compensation

We currently do not have a formal non-employee director compensation policy. In 2013, we paid $2,000 and $6,000 in cash to Dr. Kessler and Mr. Barberich, respectively, as compensation for board of directors meetings attended in person. In addition, on June 26, 2013, we granted options to purchase 108,625 shares and 81,614 shares of common stock to Dr. Kessler and Mr. Barberich, respectively, with an exercise price of $0.15 per share. With respect to 61,197 of the shares of common stock underlying the option granted to Dr. Kessler, those shares vested as to 2.083% of the shares on July 1, 2013 and as to an additional 2.083% of the shares at the beginning of each successive month thereafter until June 1, 2017, and with respect to 47,428 of the shares of common stock underlying the option granted to Dr. Kessler, those shares vested as to 8.333% of the shares on October 24, 2013 and as to an additional 2.083% of the shares at the beginning of each successive month thereafter until June 1, 2017. With respect to 45,979 of the shares of common stock underlying the option granted to Mr. Barberich, those shares vested as to 2.083% of the shares on July 1, 2013 and as to an additional 2.083% of the shares at the beginning of each successive month thereafter until June 1, 2017, and with respect to 35,635 of the shares of common stock underlying the option granted to Mr. Barberich, those shares vested as to 8.333% of the shares on October 24, 2013 and as to an additional 2.083% of the shares at the beginning of each successive month thereafter until June 1, 2017.

None of our other non-employee directors receives any compensation. We reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings. We do not pay any compensation to our President and Chief Executive Officer in connection with her service on our board of directors. The compensation that we pay to our President and Chief Executive Officer is discussed in the “Executive Compensation” section of this prospectus.

Our board of directors intends to approve a compensation policy for our non-employee directors that will become effective upon the closing of this offering. This policy will be intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors’ interests with those of our stockholders.

Executive Compensation

This section discusses the material elements of our executive compensation policies for our "named executive officers" and the most important factors relevant to an analysis of these policies. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers named in the "Summary Compensation Table" below, or our "named executive officers," and is intended to place in perspective the data presented in the following tables and the corresponding narrative.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have begun, and we expect to continue in the coming months, to evaluate the need for revisions to our executive compensation program to ensure our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

Summary Compensation Table

The following table sets forth information regarding compensation earned by our President and Chief Executive Officer and our next two highest paid executive officers during the year ended December 31, 2013. We refer to these individuals as our named executive officers.

Name	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Jodie P. Morrison(2) *President and Chief Executive Officer*	2013	330,103	91,875	547,134	565(3)	969,677
Martin D. Williams *Former President and Chief Executive Officer*	2013	87,500	—	—	268,215(4)	355,715
Adrian Senderowicz, M.D. *Former Chief Medical Officer*	2013	68,750	—	—	118,227(5)	186,977

(1) Amounts listed represent the aggregate fair value amount computed as of the grant date of the option awards granted during 2013 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 9, Stock-Based Awards, to our consolidated financial statements included elsewhere in this prospectus.
(2) Ms. Morrison also serves as a member of our board of directors but does not receive any additional compensation for her service as a director.
(3) Represents the dollar value of a group life insurance premium paid during the fiscal year with respect to life insurance for Ms. Morrison.
(4) Consists of (i) $262,500 paid as severance to Mr. Williams following his departure from our company effective March 27, 2013, (ii) $5,385 in accrued vacation and (iii) $330, which represents the dollar value of a group life insurance premium paid during the fiscal year with respect to life insurance for Mr. Williams.
(5) Consists of (i) $114,594 paid as severance to Dr. Senderowicz following his departure from our company effective March 27, 2013, (ii) $3,173 in accrued vacation and (iii) $460, which represents the dollar value of a group life insurance premium paid during the fiscal year with respect to life insurance for Dr. Senderowicz.

Narrative Disclosure to Summary Compensation Table

Base salary. In 2013, we paid $330,103 in base salary to Ms. Morrison and, before their departure from our company effective March 27, 2013, $87,500 in base salary to Mr. Williams and $68,750 in base salary to Dr. Senderowicz. We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. In connection with the departures from our company of Mr. Williams and

Dr. Senderowicz effective March 27, 2013, we agreed to make severance payments to Mr. Williams and Dr. Senderowicz pursuant to a separation agreement entered into with each of them. See "—Employment Agreements, Severance and Change in Control Agreements" for additional information.

Annual bonus. Our board of directors may, in its discretion, award bonuses to our named executive officers from time to time. We typically establish annual bonus targets based around a set of specified corporate goals for our named executive officers and conduct an annual performance review to determine the attainment of such goals. Our management may propose bonus awards to the compensation committee of the board or the board primarily based on such review process. Our board of directors makes the final determination of the eligibility requirements for and the amount of such bonus awards. With respect to 2013, we awarded a bonus of $91,875 to Ms. Morrison based on her individual performance and our performance as a company that year. We did not award a bonus to any other named executive officer in 2013.

Equity incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly our compensation committee and board of directors periodically review the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options. In 2013, we granted options to purchase 5,303,609 shares of our common stock to Ms. Morrison in connection with her elevation to President and Chief Executive Officer, of which options to purchase 3,573,425 shares are subject to time-based vesting and options to purchase 1,730,184 shares are subject to performance-based vesting. See "—Outstanding Equity Awards at Year End." We did not grant equity awards to any of our other named executive officers in 2013.

Outstanding Equity Awards at Year End

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2013.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date
Jodie P. Morrison	26,950	—	0.22	5/27/2018
President and Chief Executive Officer	234,958	—	0.06	5/6/2019
	398,373	239,023(1)	0.13	6/28/2021
	30,220	23,505(2)	0.13	9/7/2021
	37,775	29,381(3)	0.13	9/7/2021
	123,898	96,366(4)	0.13	9/7/2021
	155,629	121,045(5)	0.13	9/7/2021
	338,739	2,371,170(6)	0.15	6/26/2023
	107,940	755,577(7)	0.15	6/26/2023
	—	1,730,184(8)	0.15	6/26/2023
Martin D. Williams	—	—	—	—
Former President and Chief Executive Officer				
Adrian Senderowicz, M.D.	—	—	—	—
Former Chief Medical Officer				

(1) This option vested as to 2.083% of the shares underlying the option on July 1, 2011 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through June 1, 2015.

(2) This option vested as to 2.083% of the shares underlying the option on October 1, 2011 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through September 1, 2015.
(3) This option vested as to 2.083% of the shares underlying the option on October 7, 2011 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through September 1, 2015.
(4) This option vested as to 8.333% of the shares underlying the option on January 27, 2012 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through September 1, 2015.
(5) This option vested as to 20.833% of the shares underlying the option on July 12, 2012 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through September 1, 2015.
(6) This option vested as to 2.083% of the shares underlying the option on July 1, 2013 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through June 1, 2017.
(7) This option vested as to 8.333% of the shares underlying the option on October 24, 2013 and vests as to an additional 2.083% of the shares underlying the option monthly thereafter through June 1, 2017. This option is also subject to acceleration by 12 months upon the consummation of this offering.
(8) This option is a performance-based option that vests as to 100% of the shares underlying the option upon the consummation of this offering.

Employment Agreements, Severance and Change in Control Agreements

Jodie P. Morrison

In June 2013, in connection with our appointment of Ms. Morrison as our President and Chief Executive Officer, we entered into an employment agreement with Ms. Morrison. The employment agreement establishes Ms. Morrison's title, her base salary, her eligibility for an annual bonus of up to 25% of her base salary, and her eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of her employment under specified conditions. Ms. Morrison's employment is at will. We granted Ms. Morrison two stock options pursuant to the employment agreement: an option for the purchase of 3,573,425 shares that is subject to time-based vesting and an option for the purchase of 1,730,184 shares that is subject to performance-based vesting.

Under the terms of the employment agreement, if Ms. Morrison's employment is terminated by us without cause or by Ms. Morrison for good reason, each as defined in her employment agreement, and subject to Ms. Morrison's execution of a general release of potential claims against us, we have agreed to continue to pay her then-current base salary for a period of 12 months. In addition, if Ms. Morrison's employment is terminated by us without cause or by Ms. Morrison for good reason within one year following a change of control, as defined in her stock option agreement, and subject to Ms. Morrison's execution of a general release of potential claims against us, the time-vested option granted to Ms. Morrison upon her appointment as Chief Executive Officer will accelerate in full.

The time-based option is also subject to acceleration by 12 months upon the consummation of this offering. The performance-based option granted to Ms. Morrison upon her appointment as Chief Executive Officer will vest as to 100% of the number of shares of common stock underlying the option upon the consummation of this offering.

In addition, under each stock option agreement that we have entered into with Ms. Morrison, other than the stock option agreement for the performance-based option described above, we have agreed that if Ms. Morrison is terminated without cause or resigns for good reason in connection with or within one year after a change in control of our company (as defined in the applicable stock option agreement), then that stock option will vest in full.

Martin D. Williams

In connection with Mr. Williams' departure from our company effective March 27, 2013, we entered into a separation agreement with Mr. Williams under which we agreed to make severance payments to Mr. Williams in the amount of his then-current base salary for 12 months following his departure.

Adrian Senderowicz, M.D.

In connection with Dr. Senderowicz's departure from our company effective March 27, 2013, we entered into a separation agreement with Dr. Senderowicz under which we agreed to make severance payments to Dr. Senderowicz in the amount of his then-current base salary for six months following his departure.

In 2014, we entered into employment agreements with Mr. McBride and Dr. Ferrante in connection with their commencing employment with us.

John S. McBride

Mr. McBride's employment agreement establishes his title, his base salary, his eligibility for an annual bonus of up to 20% of his base salary, and his eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of his employment under specified conditions. Mr. McBride's employment is at will. Pursuant to Mr. McBride's employment agreement, we granted Mr. McBride a stock option for the purchase of 2,190,107 shares that is subject to time-based vesting.

Under the terms of the employment agreement, if Mr. McBride's employment is terminated by us without cause, as defined in his employment agreement, and subject to Mr. McBride's execution of a general release of potential claims against us, we have agreed to continue to pay his then-current base salary for a period of six months.

In addition, under the terms of Mr. McBride's stock option agreement, if Mr. McBride's employment is terminated by us without cause or by Mr. McBride for good reason, each as defined in his stock option agreement, within one year following a change of control event, the option will become exercisable in full with respect to the shares then underlying the option.

Karen J. Ferrante, M.D.

The employment agreement establishes Dr. Ferrante's title, her base salary, her eligibility for an annual bonus of up to 20% of her base salary, and her eligibility for benefits made available to employees generally and also provides for certain benefits upon termination of her employment under specified conditions. Dr. Ferrante's employment is at will. Pursuant to Dr. Ferrante's employment agreement, we granted Dr. Ferrante a stock option for the purchase of 2,701,653 shares that is subject to time-based vesting.

Under the terms of the employment agreement, if Dr. Ferrante's employment is terminated by us without cause, as defined in her employment agreement, and subject to Dr. Ferrante's execution of a general release of potential claims against us, we have agreed to continue to pay her then-current base salary:

- for a period of six months if Dr. Ferrante's termination occurs within six months of Dr. Ferrante's commencement of employment with us;
- for a period equal to the number of full months worked if Dr. Ferrante's termination occurs more than six months but less than 12 months after Dr. Ferrante's commencement of employment with us; and
- for a period of 12 months if Dr. Ferrante's termination occurs on or after the one year anniversary of Dr. Ferrante's commencement of employment with us.

In addition, under the terms of Dr. Ferrante's stock option agreement, if Dr. Ferrante's employment is terminated by us without cause or by Dr. Ferrante for good reason, each as defined in her stock option agreement, within one year following a change of control event, the option will become exercisable in full with respect to the shares then underlying the option.

Other Agreements

We have also entered into employee confidentiality, inventions, non-solicitation and non-competition agreements with each of our named executive officers. Under the employee confidentiality, inventions, non-solicitation and non-competition agreements, each named executive officer has agreed (1) not to compete with us during his or her employment and for a period of one year after the termination of his or her employment, (2) not to solicit our employees during his or her employment and for a period of one year after the termination of his or her employment, (3) to protect our confidential and proprietary information and (4) to assign to us related intellectual property developed during the course of his or her employment.

Stock Option and Other Compensation Plans

2007 Stock Incentive Plan

Our 2007 Stock Incentive Plan, as amended, which we refer to as the 2007 Plan, was first adopted by our board of directors and first approved by our stockholders in May 2007. Our 2007 Plan was amended in June 2008, March 2009, May 2009, September 2011, May 2013, February 2014 and April 2014. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2007 Plan; however, incentive stock options may only be granted to employees. In accordance with the terms of the 2007 Plan, our board of directors, or a committee or executive officer appointed by our board, administers the 2007 Plan and, subject to any limitations in the 2007 Plan, selects the recipients of awards and determines:

- the number of shares of common stock covered by options and the dates upon which those options become exercisable;
- the type of options to be granted;
- the exercise prices of options;
- the duration of options; and
- the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of those awards, including the issue price, conditions for repurchase or forfeiture and repurchase price.

If our board of directors delegates authority to an executive officer to grant awards under the 2007 Plan, the executive officer has the power to make awards to employees, directors, consultants and advisors, except officers or executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards, and the maximum number of shares subject to awards that such executive officer may make.

In the event of a reorganization event, as defined in the 2007 Plan, our board shall take any one or more of the following actions as to all or any outstanding awards on such terms as the board determines:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unexercised awards shall become exercisable in full and will terminate immediately prior to the consummation of such reorganization event, unless exercised by the participant within a specified period following the date of such notice;
- provide that all outstanding awards shall become realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, which we refer to as the acquisition price, make or provide for a cash payment to the participants with respect to each award held

by a participant equal to (a) the acquisition price times the number of shares of our common stock subject to the participant's awards (to the extent the exercise price of such awards does not exceed the acquisition price) minus (b) the aggregate exercise price of all such outstanding awards, in exchange for the termination of such options or other awards;

- in connection with a liquidation or dissolution, provide that awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof); and
- provide for any combination of the foregoing.

As of July 31, 2014, there were options to purchase an aggregate of 17,111,343 shares of common stock outstanding under the 2007 Plan at a weighted average exercise price of $0.27 per share, and an aggregate of 1,800,811 shares of common stock had been issued upon the exercise of options granted under the 2007 Plan. As of July 31, 2014, there were 459,555 shares of common stock reserved for future issuance under the 2007 Plan. On and after the effective date of the 2014 Stock Incentive Plan described below, which we refer to as the 2014 Plan, we will grant no further stock options or other awards under the 2007 Plan.

2014 Stock Incentive Plan

We expect our board of directors to adopt and our stockholders to approve the 2014 Plan, which will become effective immediately prior to the closing of this offering. The 2014 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and other stock-based awards. Upon effectiveness of the 2014 Plan, the number of shares of our common stock that will be reserved for issuance under the 2014 Plan will be shares.

Our employees, officers, directors, consultants and advisors will be eligible to receive awards under the 2014 Plan; however, incentive stock options may only be granted to our employees. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the 2014 Plan is per calendar year.

Pursuant to the terms of the 2014 Plan, our board of directors will select the recipients of awards and determine:

- the number of shares of common stock covered by options and the dates upon which those options become exercisable;
- the exercise price of options;
- the duration of options;
- the methods of payment of the exercise price of options; and
- the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of such awards, including the issue price, conditions for repurchase, repurchase price and performance conditions, if any.

Upon a merger or other reorganization event, our board of directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2014 Plan, as to some or all outstanding awards, other than restricted stock awards:

- provide that all outstanding awards will be assumed or substituted by the successor corporation;
- upon written notice to a participant, provide that the participant's unexercised options or awards will terminate immediately prior to the consummation of such transaction unless exercised by the participant;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;

- in the event of a reorganization event pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants equal to the excess, if any, of the acquisition price times the number of shares of our common stock subject to such outstanding awards (to the extent then exercisable at prices not in excess of the acquisition price), over the aggregate exercise price of all such outstanding awards and any applicable tax withholdings, in exchange for the termination of such awards; and
- provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights under each outstanding restricted stock award will continue for the benefit of the successor company and will, unless our board of directors may otherwise determine, apply to the cash, securities or other property into which our common stock is converted pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

No award may be granted under the 2014 Plan after . Our board of directors may amend, suspend or terminate the 2014 Plan at any time, except that stockholder approval will be required to comply with applicable law or stock market requirements.

2014 Employee Stock Purchase Plan

We expect our board of directors to adopt and our stockholders to approve the 2014 Employee Stock Purchase Plan, which we refer to as our 2014 ESPP. Our 2014 ESPP will become effective immediately prior to the closing of this offering. The 2014 ESPP provides eligible employees with the opportunity to purchase up to an aggregate of shares of our common stock.

All employees and all employees of a designated subsidiary, as defined in the 2014 ESPP, are eligible to participate in the 2014 ESPP, subject to limited exceptions set forth in the 2014 ESPP.

However, no employee is eligible to receive an option to purchase shares of our common stock under the 2014 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our common stock immediately after the grant of an option under the 2014 ESPP. Additionally, no employee may purchase shares of our common stock with an aggregate value of more than $25,000 per calendar year in which the option is outstanding under the 2014 ESPP, as determined by the value of such shares as of the date the option is granted.

We may make one or more offerings to our employees to purchase stock under the 2014 ESPP at such time or times as determined by our board of directors with each offering continuing for a six-month period, which we refer to as a plan period. However, our board of directors or a committee appointed by our board of directors may, in its discretion, choose a different plan period of twelve months or less for any offerings made under the 2014 ESPP. Our board of directors has not yet determined when the first plan period under the 2014 ESPP will commence. Payroll deductions made during each plan period will be held in payroll deductions accounts for all participating employees for the purchase of our common stock at the end of each plan period

On the commencement date of each plan period, we will grant to each eligible employee who is then a participant in the 2014 ESPP an option to purchase shares of our common stock. The employee may authorize up to a maximum of 15% of his or her base pay to be deducted by us during the plan period. Each employee who continues to be a participant in the 2014 ESPP on the last business day of the plan period will be deemed to have exercised the option to the extent of the employee's accumulated payroll deductions, subject to the maximum

share ownership limits for the 2014 ESPP. Under the terms of the 2014 ESPP, the option exercise price will be determined by our board of directors or a committee appointed by our board of directors for each plan period. Our board of directors or a committee appointed by our board of directors may set whether the option exercise price will be based on the closing price of our common stock on (1) the first business day of the plan period or (2) the last business day of the plan period, or the lower of such closing prices, provided that the option exercise price will be at least 85% of the applicable closing price. In no event may an employee purchase in any one plan period a number of shares that exceeds the number of shares determined by dividing (1) the product of $2,083 and the number of full months in the plan period by (2) the closing price of a share of our common stock on the commencement date of the plan period.

An employee who is not a participant in the 2014 ESPP on the last day of the plan period is not entitled to exercise any option, and any balance held in the employee's accumulated payroll deduction account will be refunded. An employee's rights under the 2014 ESPP terminate upon voluntary withdrawal from the purchase plan at any time prior to the last business day of the applicable plan period or when the employee ceases employment for any reason, as defined in the 2014 ESPP, before the last business day of the applicable plan period.

In the event of any stock splits, reverse stock splits, stock dividends, recapitalizations, combination of shares, reclassification of shares, spin-offs or other similar events or changes in capitalization or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, we will be required to make equitable adjustments in connection with the 2014 ESPP to the extent determined by our board of directors or a committee appointed by our board of directors.

Upon a merger or other reorganization event, our board of directors or a committee appointed by our board of directors may take any one or more of the following actions pursuant to the 2014 ESPP as to some or all outstanding options:

- provide that options will be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will terminate immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or by a committee appointed by our board of directors;
- upon written notice to employees, provide that all outstanding options shall be cancelled as of a date prior to the effective date of such reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, change the last day of the plan period to be the date of the consummation of the reorganization event and make or provide for a cash payment equal to (1) the acquisition price multiplied by the number of shares of our common stock subject to the participant's option that could be purchased based on the employee's accumulated payroll deductions at such time, minus (2) the aggregate option price of such option; or
- provide that, in connection with a liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the option price).

Our board of directors may at any time amend or terminate the 2014 ESPP, except that we must obtain stockholder approval for any amendment that requires stockholder approval under Section 423 of the Internal Revenue Code, and our board of directors may not make any amendment that would cause the 2014 ESPP to fail to comply with Section 423 of the Internal Revenue Code. Upon termination of the 2014 ESPP, we will refund any balance held in the payroll deduction accounts of participating employees.

401(k) Retirement Plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate, beginning on the first day of the month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to $17,500 in 2014, and have the amount of the reduction contributed to the 401(k) plan. Currently, we do not match employee contributions.

Limitation of Liability and Indemnification

As permitted by Delaware law, we expect our board of directors and stockholders to adopt provisions in our restated certificate of incorporation, which will be effective as of the closing date of this offering, that limit or eliminate the personal liability of our directors. Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breaches of their fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, including injunctive relief or rescission. If Delaware law is amended to authorize the further elimination or limiting of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law as so amended.

As permitted by Delaware law, our certificate of incorporation that will be effective as of the closing date of this offering will also provide that:

- we will indemnify our directors and officers to the fullest extent permitted by law;
- we may indemnify our other employees and other agents to the same extent that we indemnify our officers and directors, unless otherwise determined by our board of directors; and
- we will advance expenses to our directors and officers in connection with legal proceedings in connection with a legal proceeding to the fullest extent permitted by law.

The indemnification provisions contained in our certificate of incorporation that will be effective as of the closing date of this offering are not exclusive. In addition, we plan to enter into indemnification agreements with each of our directors and executive officers. We expect that each of these indemnification agreements will provide, among other things, that we will indemnify such director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer, as applicable, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe that his or her conduct was unlawful. We expect that each of these indemnification agreements will provide that in the event that we do not assume the defense of a claim against a director or officer, as applicable, we will be required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us.

We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. Insofar as indemnification for liabilities arising under the Securities Act of 1933, which we

refer to as the Securities Act, may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we understand that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

In addition, we maintain standard policies of insurance under which coverage is provided to our directors and officers against losses arising from claims made by reason of breach of duty or other wrongful act, and to us with respect to payments which may be made by us to such directors and officers pursuant to the above indemnification provisions or otherwise as a matter of law.

Related Person Transactions

The following is a description of transactions since January 1, 2011 to which we have been a party, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or affiliates or immediate family members of any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties.

Series D-3 Redeemable Convertible Preferred Stock Financing

During September 2011, January 2012 and July 2012, we issued and sold an aggregate of 42,935,192 shares of our Series D-3 redeemable convertible preferred stock at a purchase price per share of $0.54617142 for an aggregate purchase price of $23.4 million.

The following table sets forth the number of shares of Series D-3 redeemable convertible preferred stock that were issued to our directors, executive officers and holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers and holders of more than 5% of our voting securities in connection with the Series D-3 redeemable convertible preferred stock financing and the aggregate cash purchase price paid by such persons and entities.

Purchaser	Shares of Series D-3 Redeemable Convertible Preferred Stock	Purchase Price
Entities affiliated with Apple Tree Partners II, L.P.(1)	24,046,035	$13,133,257
Novartis BioVentures Ltd.(2)	13,222,826	$ 7,221,930
Trusts and other entities affiliated with Muneer A. Satter(3)	3,931,085	$ 2,147,046

(1) Consists of 13,370,422 shares of Series D-3 redeemable convertible preferred stock and 10,675,613 shares of Series D-3 redeemable convertible preferred stock purchased by Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P., respectively. Dr. Seth L. Harrison, a member of our board of directors, is a principal of the general partner of each of Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P. and is affiliated with these entities. See "Principal Stockholders."

(2) Dr. Reinhard J. Ambros and Dr. Campbell Murray, two members of our board of directors, are employees of a corporation that is affiliated with Novartis BioVentures Ltd. See "Principal Stockholders."

(3) Consists of shares of Series D-3 redeemable convertible preferred stock purchased by the Muneer A. Satter Revocable Trust and various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive control over all such shares.

Series E Redeemable Convertible Preferred Stock Financing

During May 2013 and October 2013, we issued and sold an aggregate of 56,892,391 shares of our Series E redeemable convertible preferred stock at a purchase price per share of $0.62398475 for an aggregate purchase price of $35.5 million.

The following table sets forth the number of shares of Series E redeemable convertible preferred stock that were issued to our directors, executive officers and holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers and holders of more than 5% of our voting securities in connection with the Series E redeemable convertible preferred stock financing and the aggregate cash purchase price paid by such persons and entities.

Purchaser	Shares of Series E Redeemable Convertible Preferred Stock	Purchase Price
Apple Tree Partners II – Annex, L.P.(1)	24,199,308	$ 15,099,997
Novartis BioVentures Ltd.(2)	15,064,469	$ 9,399,999
Trusts and other entities affiliated with Muneer A. Satter(3)	8,013,003	$ 4,999,992

(1) Dr. Seth L. Harrison, a member of our board of directors, is a principal of the general partner of Apple Tree Partners II – Annex, L.P. and is affiliated with this entity. See "Principal Stockholders."

(2) Dr. Reinhard J. Ambros and Dr. Campbell Murray, two members of our board of directors, are employees of a corporation that is affiliated with Novartis BioVentures Ltd. See "Principal Stockholders."

(3) Consists of shares of Series E redeemable convertible preferred stock purchased by the Muneer A. Satter Revocable Trust and various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive control over all such shares.

Agreements with Our Stockholders

We have entered into a fifth amended and restated investor rights agreement with the purchasers of our redeemable convertible preferred stock, including some of our 5% stockholders and their affiliates and entities affiliated with our directors. The investor rights agreement provides those holders with the right to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration Rights" for additional information.

We have also entered into a stockholders' agreement with certain purchasers of our common stock and redeemable convertible preferred stock. The stockholders' agreement provides for rights of first refusal and co-sale rights in respect of sales of securities by certain holders of our capital stock. The stockholders' agreement also provides holders of our redeemable convertible preferred stock with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to specified exceptions. The stockholders' agreement also contains provisions with respect to the election of our board of directors and its composition. The rights of first refusal, co-sale rights and participation rights under this agreement do not apply to this offering, and the stockholders' agreement will terminate upon the closing of this offering.

Severance and Change in Control Agreements

See the "Management—Employment Agreements, Severance and Change in Control Agreements" section of this prospectus for a further discussion of these arrangements.

Indemnification of Officers and Directors

Our certificate of incorporation that will be effective as of the closing date of this offering provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we expect to enter into indemnification agreements with each of our officers and directors that may be broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law. See the "Executive Compensation—Limitation of Liability and Indemnification" section of this prospectus for a further discussion of these arrangements.

Policies and Procedures for Related Person Transactions

Our board of directors plans to adopt a written related person transaction policy, which will become effective at the time of this offering, to set forth policies and procedures for the review and approval or ratification of related person transactions. Effective upon the closing of this offering, we expect this policy will cover any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds $120,000, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person.

We expect that our related person transaction policy will contain exceptions for any transaction or interest that is not considered a related person transaction under SEC rules as in effect from time to time. In addition, we expect that the policy will provide that an interest arising solely from a related person's position as an executive officer of another entity that is a participant in a transaction with us will not be subject to the policy if each of the following conditions is met:

- the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity;
- the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction with us and do not receive any special benefits as a result of the transaction; and
- the amount involved in the transaction is less than the greater of $200,000 and 5% of the annual gross revenue of the company receiving payment under the transaction.

We expect that the policy will provide that any related person transaction proposed to be entered into by us must be reported to our and will be reviewed and approved by our audit committee in accordance with the terms of the policy, prior to effectiveness or consummation of the transaction whenever practicable. We expect that the policy will provide that if our determines that advance approval of a related person transaction is not practicable under the circumstances, our audit committee will review and, in its discretion, may ratify the related person transaction at the next meeting of the audit committee. We expect that the policy will also provide that alternatively, our may present a related person transaction arising in the time period between meetings of the audit committee to the chair of the audit committee, who will review and may approve the related person transaction, subject to ratification by the audit committee at the next meeting of the audit committee.

In addition, we expect that the policy will provide that any related person transaction previously approved by the audit committee or otherwise already existing that is ongoing in nature will be reviewed by the audit committee annually to ensure that such related person transaction has been conducted in accordance with the previous approval granted by the audit committee, if any, and that all required disclosures regarding the related person transaction are made.

We expect that the policy will provide that transactions involving compensation of executive officers will be reviewed and approved by our compensation committee in the manner to be specified in the charter of the compensation committee.

We expect that a related person transaction reviewed under this policy will be considered approved or ratified if it is authorized by the audit committee in accordance with the standards set forth in the policy after full disclosure of the related person's interests in the transaction. As appropriate for the circumstances, the policy provides that the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;

- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of business of our company;
- whether the transaction with the related person is proposed to be, or was, entered into on terms no less favorable to us than the terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

We expect that the policy will provide that the audit committee will review all relevant information available to it about the related person transaction. We expect that the policy will provide that the audit committee may approve or ratify the related person transaction only if the audit committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. We expect that the policy will provide that the audit committee may, in its sole discretion, impose such conditions as it deems appropriate on us or the related person in connection with approval of the related person transaction.

Principal Stockholders

The following table sets forth information regarding the beneficial ownership of our common stock as of July 31, 2014 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days after July 31, 2014. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to community property laws, where applicable. The information is not necessarily indicative of beneficial ownership for any other purpose.

The number of shares beneficially owned in the following table assumes the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock upon the closing of this offering. The percentage ownership calculations for beneficial ownership prior to this offering are based on 160,837,642 shares outstanding as of July 31, 2014, assuming the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of common stock upon the closing of this offering. Percentage ownership calculations for beneficial ownership after this offering also include the shares we are offering hereby. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Tokai Pharmaceuticals, Inc., One Broadway, 14th Floor, Cambridge, Massachusetts 02142.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days after July 31, 2014. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders:			
Entities affiliated with Apple Tree Partners[1] 47 Hulfish Street, Suite 441 Princeton, NJ 08542	79,044,107	49.15%	
Novartis BioVentures Ltd.[2] PO Box HM 2899 Hamilton HM LX Bermuda	45,223,369	28.12%	
Trusts and other entities affiliated with Muneer A. Satter[3] Satter Investment Management, LLC 676 North Michigan Ave., Suite 4000 Chicago, IL 60611	16,979,131	10.56%	

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Executive Officers and Directors:			
Jodie P. Morrison[4]	2,459,853	1.51%	
Martin D. Williams	1,767,867	1.10%	
Adrian Senderowicz, M.D.	154,776	*	
Seth L. Harrison, M.D.[5]	81,271,016	50.53%	
Reinhard J. Ambros, Ph.D.[2]	45,223,369	28.12%	
Timothy J. Barberich[6]	1,429,313	*	
David A. Kessler, M.D.[7]	215,102	*	
Campbell Murray, M.D.[2]	45,223,369	28.12%	
Joseph A. Yanchik, III[8]	494,238	*	
All executive officers and directors as a group (11 persons)[9]	133,967,706	81.31%	

* Represents beneficial ownership of less than one percent of our outstanding stock.

(1) Consists of (i) 100 shares of common stock and 44,169,086 shares of common stock underlying shares of redeemable convertible preferred stock held by Apple Tree Partners II, L.P. and (ii) 34,874,921 shares of common stock underlying shares of redeemable convertible preferred stock held by Apple Tree Partners II – Annex, L.P. Dr. Seth L. Harrison, a member of our board of directors, is a principal of the general partner of each of Apple Tree Partners II, L.P. and Apple Tree Partners II –Annex, L.P., and Dr. Harrison disclaims beneficial ownership of the shares held by each of Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P., except to the extent of his pecuniary interest therein. Dr. Harrison has sole voting and investment control and power over the shares held by Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P.

(2) Consists of 45,223,369 shares of common stock underlying shares of redeemable convertible preferred stock held by Novartis BioVentures Ltd., a Bermuda corporation. The board of directors of Novartis BioVentures Ltd. has sole voting and investment control and power over such shares. None of the members of its board of directors has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares. Dr. Reinhard J. Ambros and Dr. Campbell Murray, two members of our board of directors, are also employees of a corporation that is affiliated with Novartis BioVentures Ltd. Each of Drs. Murray and Ambros disclaims beneficial ownership of the shares held by Novartis BioVentures Ltd., except to the extent of their pecuniary interest arising as a result of their employment by such affiliate of Novartis BioVentures Ltd. Novartis BioVentures Ltd. is an indirectly owned subsidiary of Novartis AG.

(3) Consists of 16,979,131 shares of common stock underlying shares of redeemable convertible preferred stock held by the Muneer A. Satter Revocable Trust and various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive control over all such shares.

(4) Consists of (i) 100,000 shares of common stock and (ii) 2,359,853 shares of common stock underlying options that are exercisable as of July 31, 2014 or will become exercisable within 60 days after such date.

(5) Consists of (i) 2,226,909 shares of common stock held by Dr. Harrison, (ii) 100 shares of common stock and 44,169,086 shares of common stock underlying shares of redeemable convertible preferred stock held by Apple Tree Partners II, L.P. and (iii) 34,874,921 shares of common stock underlying shares of redeemable convertible preferred stock held by Apple Tree Partners II – Annex, L.P. Dr. Harrison is a principal of the general partner of each of Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P., and Dr. Harrison disclaims beneficial ownership of the shares held by each of Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P., except to the extent of his pecuniary interest therein. Dr. Harrison has sole voting and investment control and power over the shares held by Apple Tree Partners II, L.P. and Apple Tree Partners II – Annex, L.P.

(6) Consists of (i) 1,267,686 shares of common stock underlying shares of redeemable convertible preferred stock and (ii) 161,627 shares of common stock underlying options that are exercisable as of July 31, 2014 or will become exercisable within 60 days after such date.

(7) Consists of 215,102 shares of common stock underlying options that are exercisable as of July 31, 2014 or will become exercisable within 60 days after such date.
(8) Consists of (i) 267,470 shares of common stock and (ii) 226,768 shares of common stock underlying options that are exercisable as of July 31, 2014 or will become exercisable within 60 days after such date.
(9) Includes 3,915,522 shares of common stock underlying options that are exercisable as of July 31, 2014 or will become exercisable within 60 days after such date. See footnote 2 with respect to Drs. Ambros and Murray and footnotes 1 and 5 with respect to Dr. Harrison.

Description of Capital Stock

General

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of preferred stock, par value $0.001 per share, all of which preferred stock will be undesignated. The following description of our capital stock and provisions of our restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We have filed copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

Common Stock

As of July 31, 2014, we had outstanding 160,837,642 shares of common stock, held of record by 41 stockholders, assuming the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter, except as otherwise disclosed below. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Stock Options

As of July 31, 2014, options to purchase 17,111,343 shares of our common stock at a weighted average exercise price of $0.27 per share were outstanding, of which options to purchase 5,497,468 shares of our common stock were exercisable, at a weighted average exercise price of $0.18 per share.

Registration Rights

We have entered into a fifth amended and restated investor rights agreement, dated as of May 13, 2013, which we refer to as the Investor Rights Agreement, with certain of our stockholders. Upon the closing of this offering, holders of a total of shares of our common stock as of , 2014, including for this purpose shares of our common stock issuable upon conversion of our preferred stock upon the closing of this offering, will have the right to require us to register these shares under the Securities Act under specified circumstances as described below and will have incidental registration rights as described below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act.

Demand registration rights

Beginning on the 180th day after the effective date of the registration statement of which this prospectus forms a part, subject to specified limitations set forth in the Investor Rights Agreement, at any time the holders of a majority of the then outstanding shares of our common stock issuable upon conversion of our Series C, Series D and Series E preferred stock upon the closing of this offering, acting together, may demand in writing that we register registrable securities, as defined under the Investor Rights Agreement, under the Securities Act so long as the total amount of registrable shares requested to be registered represents at least 20% of the then-outstanding registrable shares or has an aggregate expected price to the public of at least $10.0 million. We are not obligated to file a registration statement pursuant to this demand provision on more than two occasions during the term of the Investor Rights Agreement, subject to specified exceptions.

In addition, at any time after we become eligible to file a registration statement on Form S-3 under the Securities Act, subject to specified limitations, a holder or holders of a majority of the then outstanding shares of our common stock issuable upon conversion of our Series C, Series D and Series E preferred stock upon the closing of this offering may demand in writing that we register on Form S-3 registrable shares held by them so long as the total amount of registrable shares requested to be registered has an aggregate expected price to the public of at least $7.5 million unless such request is for all remaining registrable securities. We are not obligated to file a registration statement pursuant to this demand provision on more than two occasions during any 12-month period, subject to specified exceptions.

Incidental registration rights

If, at any time after the closing of this offering, we propose to file a registration statement to register any of our securities under the Securities Act, either for our own account or for the account of any of our stockholders, other than pursuant to the demand registration rights described above and other than pursuant to a Form S-4 or Form S-8, the holders of our registrable securities are entitled to notice of registration and, subject to specified exceptions, we will be required to use commercially reasonable efforts to register the registrable securities then held by them that they request that we register.

Expenses

Pursuant to the Investor Rights Agreement, we are required to pay all registration expenses, including registration fees, printing expenses, fees and disbursements of our counsel and accountants and reasonable fees and disbursements of one counsel representing any selling stockholders, other than any underwriting discounts and commissions, related to any demand or incidental registration. The Investor Rights Agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify any selling

stockholders in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Anti-Takeover Effects of Delaware Law and our Charter and Bylaws

Delaware law contains, and upon the closing of this offering our certificate of incorporation and our bylaws will contain, provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Staggered Board; Removal of Directors

Upon the closing of this offering, our certificate of incorporation and bylaws will divide our board of directors into three classes with staggered three-year terms. In addition, a director will only be able to be removed for cause and only by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, will only be able to be filled by vote of a majority of our directors then in office. The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action by Written Consent; Special Meetings

Upon the closing of this offering, our certificate of incorporation will provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Upon the closing of this offering, our certificate of incorporation and bylaws will also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors.

Advance Notice Requirements for Stockholder Proposals

Upon the closing of this offering, our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Delaware Business Combination Statute

Upon the closing of this offering, we will be subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly-held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Amendment of Certificate of Incorporation and Bylaws

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Effective upon the closing of this offering, our bylaws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above under "—Staggered Board; Removal of Directors" and "—Stockholder Action by Written Consent; Special Meetings."

Listing on The NASDAQ Global Market

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "TKAI."

Authorized but Unissued Shares

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the NASDAQ Listing Rules. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be .

Shares Eligible for Future Sale

Prior to this offering, there has been no public market for our common stock, and a liquid public trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "TKAI."

Upon the closing of this offering, we will have outstanding shares of common stock, after giving effect to the issuance of the shares of common stock in this offering and the conversion of all outstanding shares of our preferred stock into 155,586,141 shares of common stock upon the closing of this offering, and assuming no exercise of outstanding options after July 31, 2014. Of the shares to be outstanding immediately after the closing of this offering, the shares sold by us in this offering (assuming that the underwriters do not exercise their over-allotment option), will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act and will further be subject to either restrictions on transfer under the lock-up agreements described below or restrictions on transfer for a period of 180 days from the effectiveness of the registration statement of which this prospectus forms a part under stock option agreements entered into between us and the holders of those shares. Following the expiration of these restrictions, these shares will become eligible for public sale if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and any additional contractual lock-up period and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date Available for Sale	Number of Shares Eligible for Sale	Comment
On the date of this prospectus		Shares sold in this offering and shares saleable under Rule 144 that are not subject to a lock-up
90 days after the date of this prospectus		Shares saleable under Rules 144 and 701 that are not subject to a lock-up
180 days after the date of this prospectus		Lock-up released; shares saleable under Rules 144 and 701

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or

- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and The NASDAQ Stock Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of our outstanding common stock, who collectively own % of our common stock, based on shares outstanding as of July 31, 2014, have agreed that, without the prior written consent of BMO Capital Markets Corp. and Stifel, Nicolaus & Company, Incorporated on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, either directly or indirectly:

- offer, sell, pledge, contract to sell, purchase any option to sell, grant any option for the purchase of, lend, or otherwise dispose of, or require us to file with the SEC a registration statement under the Securities Act to register, any shares of our common stock or any securities convertible into, exercisable for or exchangeable for our common stock, whether any such transaction is to be settled by delivery of shares of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to enter into any such transaction; or
- enter into any swap or other derivative transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of such shares of our common stock, whether any such transaction is to be settled by delivery of shares of our common stock or other securities, in cash or otherwise, or publicly disclose the intention to enter into any such transaction.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled “Underwriting.” Upon the expiration of the applicable lock-up periods and any additional contractual lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Registration Rights

Subject to the lock-up agreements described above, upon the closing of this offering, the holders of an aggregate of shares of our common stock as of , 2014, including for this purpose shares of our common stock issuable upon conversion of our preferred stock upon the closing of this offering, will have the right to require us to register these shares under the Securities Act under specified circumstances.

After registration pursuant to these rights and expiration of the lock-up agreement, these shares will become freely tradable without restriction under the Securities Act. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Stock Options

As of July 31, 2014, options to purchase 17,111,343 shares of our common stock at a weighted average exercise price of $0.27 per share were outstanding, of which options to purchase 5,497,468 shares of our common stock were exercisable, at a weighted average exercise price of $0.18 per share. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock subject to outstanding options and options and other awards issuable pursuant to our equity compensation plans.

Material U.S. Federal Tax Considerations for Non-U.S. Holders of Common Stock

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is not for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- owners deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that have a functional currency other than the U.S. dollar;

- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale, exchange or other disposition of our common stock." Any such distributions will also be subject to the discussion below under the section titled "Withholding and information reporting requirements—FATCA."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

In general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on our common stock" also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may withhold 10% of the proceeds payable to a non-U.S. holder from a sale of our common stock and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

U.S. Federal Estate Tax

Shares of our common stock that are owned or treated as owned at the time of death by an individual who is not a citizen or resident of the United States, as specifically defined for U.S. federal estate tax purposes, are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on our common stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Withholding and Information Reporting Requirements—FATCA

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA will only apply (1) to payments of dividends on our common stock made after June 30, 2014, and (2) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Underwriting

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. BMO Capital Markets Corp., Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C. are the representatives of the underwriters.

Underwriters	Number of Shares
BMO Capital Markets Corp.	
Stifel, Nicolaus & Company, Incorporated	
William Blair & Company, L.L.C.	
Janney Montgomery Scott LLC	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until that option is exercised. If an underwriter fails or refuses to purchase any of its committed shares, the purchase commitments of the non-defaulting underwriters may be increased or the offering may be terminated.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise this option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above, and the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriters propose to offer the shares of our common stock directly to the public at the initial public offering price set forth on the cover of this prospectus and to certain dealers at such offering price less a concession not in excess of $ per share. After the initial public offering of the shares, the offering price and the selling concession may be changed by the underwriters.

The following table shows the per share and total underwriting discounts and commissions to be paid by us to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately $, all of which will be paid by us. We have agreed to reimburse the underwriters for certain of their expenses, in an amount up to $, incurred in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

In addition, we have previously agreed to pay a fee upon the closing of this offering to a financial advisor equal to the greater of $0.5 million and 1% of the gross proceeds of this offering in connection with strategic and financial advisory services unrelated to this offering.

We and our officers and directors and the holders of substantially all of our capital stock and options have agreed with the underwriters that, for a period of 180 days after the date of this prospectus, subject to certain exceptions, we

and they will not (1) offer, sell, pledge, contract to sell, purchase any option to sell, grant any option for the purchase of, lend, or otherwise dispose of, or require us to file with the SEC a registration statement under the Securities Act to register, any shares of common stock or any securities convertible into, exercisable for or exchangeable for common stock of which the undersigned is now, or may in the future become, the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act), or (2) enter into any swap or other derivative transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or other securities, in cash or otherwise, or publicly disclose the intention to enter into any transaction described in clause (1) or (2) above, except with the prior written consent of BMO Capital Markets Corp. and Stifel, Nicolaus & Company, Incorporated; provided that BMO Capital Markets Corp. and Stifel, Nicolaus & Company, Incorporated, on behalf of the underwriters, have agreed to notify us at least three business days before the effective date of any release or waiver granted to one of our officers or directors, and we have agreed to announce the impending release or waiver by issuing a press release through a major news service at least two business days before the effective date of the release or waiver.

The restrictions described in this paragraph do not apply to the following, subject to certain limitations set forth in the lock-up agreements:

- transfers of securities as a bona fide gift;
- the surrender or forfeiture of securities to us to satisfy tax withholding obligations upon exercise or vesting of stock options or equity awards;
- transfers of securities to any immediate family member or any trust for the direct or indirect benefit of the lock-up signatory or an immediate family member of the lock-up signatory or to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the lock-up signatory and/or one or more immediate family members of the lock-up signatory in a transaction not involving a disposition for value;
- transfers of securities upon death of the lock-up signatory by will or intestate succession;
- if the lock-up signatory is a corporation, partnership, limited liability company, trust or other business entity, transfers of securities to one or more affiliates of the lock-up signatory or transfers or distributions of securities to the partners, members or stockholders or other equityholders of the lock-up signatory or, in the case of a corporation, transfers of securities to a wholly-owned subsidiary of the lock-up signatory; and
- the entry into any trading plan established pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of securities, provided that such plan does not provide for any sales or other dispositions of securities during the lock-up period and no public announcement or filing under the Exchange Act is made by us or on our behalf regarding the establishment of such plan.

See “Shares Eligible for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for our common stock. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol “TKAI.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been

covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on The NASDAQ Global Market, in the over-the-counter market or otherwise.

In connection with this offering, the underwriters may engage in passive market making transactions in the common stock on The NASDAQ Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and may end passive market making activities at any time.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act and to contribute to payments that the underwriters may be required to make for these liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of our common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided,

and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000, or the FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Legal Matters

The validity of the shares of common stock being offered will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. The underwriters are represented by Goodwin Procter LLP, Boston, Massachusetts, in connection with certain legal matters related to this offering.

Experts

The financial statements as of December 31, 2012 and 2013 and for each of the two years in the period ended December 31, 2013 and, cumulatively, for the period from March 26, 2004 (date of inception) to December 31, 2013 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

Where You Can Find More Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock to be sold in this offering. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document filed as an exhibit are not necessarily complete, and in each instance, we refer you to the copy of the contract or other documents filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website.

Upon the closing of this offering, we will be subject to the informational and periodic reporting requirements of the Exchange Act. We will fulfill our obligations with respect to such requirements by filing periodic reports and other information with the SEC. We intend to furnish our stockholders with annual reports containing consolidated financial statements certified by an independent registered public accounting firm. We also maintain a website at www.tokaipharma.com. Our website is not a part of this prospectus.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Tokai Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Tokai Pharmaceuticals, Inc. and its subsidiary (a development stage company) at December 31, 2013 and 2012, and the results of their operations and their cash flows for the years then ended and, cumulatively, for the period from March 26, 2004 (date of inception) to December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Oversight Board (United States), which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
May 2, 2014

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,		June 30,	Pro Forma June 30,
	2012	2013	2014	2014
			(unaudited)	
Assets				
Current assets:				
Cash and cash equivalents	$ 11,691	$ 31,753	$ 21,150	$ 21,150
Prepaid expenses and other current assets	235	425	589	589
Total current assets	11,926	32,178	21,739	21,739
Property and equipment, net	16	29	36	36
Deferred offering costs	—	30	1,524	1,524
Restricted cash	20	50	50	50
Other Assets	—	—	71	71
Total assets	$ 11,962	$ 32,287	$ 23,420	$ 23,420
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	$ 764	$ 5	$ 1,216	$ 1,216
Accrued expenses	1,254	2,204	2,472	2,472
Total current liabilities	2,018	2,209	3,688	3,688
Total liabilities	2,018	2,209	3,688	3,688
Commitments and contingencies (Note 11)				
Redeemable convertible preferred stock (Series A, B-1, B-2, C, D-1, D-2, D-3 and E), $0.001 par value; 98,693,763 and 155,586,141 shares authorized at December 31, 2012 and 2013, respectively, and 155,586,141 shares authorized at June 30, 2014 (unaudited); 98,693,750 and 155,586,141 shares issued and outstanding at December 31, 2012 and 2013, respectively, and 155,586,141 shares issued and outstanding at June 30, 2014 (unaudited); aggregate liquidation preference of $83,528 at December 31, 2013 and June 30, 2014 (unaudited); no shares issued or outstanding pro forma at June 30, 2014 (unaudited)	49,845	85,345	85,345	—
Stockholders' equity (deficit):				
Common stock, $0.001 par value; 112,182,244 and 173,018,331 shares authorized at December 31, 2012 and 2013, respectively, and 178,408,438 shares authorized at June 30, 2014 (unaudited); 4,864,773 and 5,164,837 shares issued and outstanding at December 31, 2012 and 2013, respectively, and 5,251,501 shares issued and outstanding at June 30, 2014 (unaudited); 160,837,642 shares issued and outstanding pro forma at June 30, 2014 (unaudited)	5	5	5	161
Additional paid-in capital	7,424	7,783	8,135	93,324
Deficit accumulated during the development stage	(47,330)	(63,055)	(73,753)	(73,753)
Total stockholders' equity (deficit)	(39,901)	(55,267)	(65,613)	19,732
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 11,962	$ 32,287	$ 23,420	$ 23,420

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period From Inception (March 26, 2004) to December 31, 2013	Cumulative Period From Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014		
			(unaudited)			(unaudited)
Revenue	$ —	$ —	$ —	$ —	$ —	$ —
Operating expenses:						
Research and development	7,370	12,201	5,148	7,948	49,366	57,314
General and administrative	2,279	3,548	1,687	2,829	13,457	16,286
Total operating expenses	9,649	15,749	6,835	10,777	62,823	73,600
Loss from operations	(9,649)	(15,749)	(6,835)	(10,777)	(62,823)	(73,600)
Other income (expense):						
Interest income	—	—	—	—	216	216
Interest expense	—	—	—	—	(302)	(302)
Other income (expense), net	—	24	—	79	263	342
Total other income, net	—	24	—	79	177	256
Net loss and comprehensive loss	(9,649)	(15,725)	(6,835)	(10,698)	(62,646)	(73,344)
Accretion of redeemable convertible preferred stock to redemption value	(34)	(94)	(79)	—	(3,359)	(3,359)
Accrual of dividend on redeemable convertible preferred stock	—	—	—	—	(347)	(347)
Modifications of redeemable convertible preferred stock	—	—	—	—	9,925	9,925
Net loss attributable to common stockholders	$ (9,683)	$ (15,819)	$ (6,914)	$ (10,698)	$ (56,427)	$ (67,125)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.97)	$ (3.63)	$ (1.96)	$ (2.05)		
Weighted average common shares outstanding, basic and diluted	3,261,143	4,355,914	3,533,578	5,215,188		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		$ (0.12)		$ (0.07)		
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		128,050,265		160,801,329		

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share data)

	Series A, B-1, B-2, C, D-1, D-2, D-3 and E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Stockholder Receivable	Deficit Accumulated During the Development Stage	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value				
Balances at Inception (March 26, 2004)	—	$ —	—	$ —	$ —	$ —	$ —	$ —
Issuance of common stock	—	—	4,224,513	4	54	—	—	58
Issuance of common stock upon exercise of stock options	—	—	32,151	—	1	—	—	1
Repurchase and forfeiture of unvested restricted stock	—	—	(1,044,248)	(1)	(32)	—	—	(33)
Issuance of Series A, Series B-2 and Series D-1, D-2 and D-3 redeemable convertible preferred stock, net of issuance costs of $693	47,119,526	30,272	—	—	—	—	—	—
Conversion of promissory notes and accrued interest into Series B-1 and B-2 and Series C redeemable convertible preferred stock	16,878,182	6,970	—	—	—	—	—	—
Modification of Series A redeemable convertible preferred stock in 2007	—	45	—	—	—	—	(45)	(45)
Modification of Series A and Series B-1 and B-2 redeemable convertible preferred stock in 2009	—	(9,970)	—	—	9,970	—	—	9,970
Accrual of Series A preferred stock cumulative dividend	—	347	—	—	—	—	(347)	(347)
Accretion of Series A, Series B-1 and B-2 and Series D-1 and D-3 redeemable convertible preferred stock to redemption value	—	3,231	—	—	(3,214)	—	(17)	(3,231)
Cancellation of warrants	—	—	—	—	125	—	—	125
Forgiveness of accrued interest on convertible promissory note in 2009	—	—	—	—	94	—	—	94
Loans to stockholders	—	—	—	—	—	(350)	—	(350)
Collection of loans to stockholders	—	—	—	—	—	130	—	130
Reserve for loan to stockholder	—	—	—	—	—	220	—	220
Stock-based compensation expense	—	—	—	—	248	—	—	248
Net loss	—	—	—	—	—	—	(37,272)	(37,272)
Balances at December 31, 2011	63,997,708	30,895	3,212,416	3	7,246	—	(37,681)	(30,432)
Issuance of Series D-3 redeemable convertible preferred stock, net of issuance costs of $34	34,696,042	18,916	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	29,778	—	4	—	—	4
Issuance of common stock	—	—	1,622,579	2	(2)	—	—	—
Stock-based compensation expense	—	—	—	—	210	—	—	210
Accretion of Series D-3 redeemable convertible preferred stock to redemption value	—	34	—	—	(34)	—	—	(34)
Net loss	—	—	—	—	—	—	(9,649)	(9,649)
Balances at December 31, 2012	98,693,750	49,845	4,864,773	5	7,424	—	(47,330)	(39,901)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of $94	56,892,391	35,406	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	1,652,218	1	214	—	—	215
Repurchase and forfeiture of unvested restricted stock	—	—	(1,352,154)	(1)	1	—	—	—
Stock-based compensation expense	—	—	—	—	238	—	—	238
Accretion of Series E redeemable convertible preferred stock to redemption value	—	94	—	—	(94)	—	—	(94)
Net loss	—	—	—	—	—	—	(15,725)	(15,725)
Balances at December 31, 2013	155,586,141	85,345	5,164,837	5	7,783	—	(63,055)	(55,267)
Issuance of common stock upon exercise of stock options	—	—	86,664	—	12	—	—	12
Stock-based compensation expense	—	—	—	—	340	—	—	340
Net loss	—	—	—	—	—	—	(10,698)	(10,698)
Balances at June 30, 2014 (unaudited)	155,586,141	$ 85,345	5,251,501	$ 5	$ 8,135	$ —	$ (73,753)	$ (65,613)

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period From Inception (March 26, 2004) to December 31, 2013	Cumulative Period From Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014		
			(unaudited)			(unaudited)
Cash flows from operating activities:						
Net loss	$ (9,649)	$ (15,725)	$ (6,835)	$ (10,698)	$ (62,646)	$ (73,344)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock-based compensation expense	210	238	90	340	696	1,036
Non-cash interest expense	—	—	—	—	299	299
Depreciation expense	9	10	3	11	65	76
Reserve for (release of reserve for) loan to stockholder	—	—	—	(79)	220	141
Loss on disposal of property and equipment	—	—	—	—	5	5
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets	139	(190)	37	(164)	(425)	(589)
Accounts payable	(119)	(759)	621	507	5	512
Accrued expenses	77	950	410	(43)	2,204	2,161
Other assets	—	—	—	(71)	—	(71)
Net cash used in operating activities	(9,333)	(15,476)	(5,674)	(10,197)	(59,577)	(69,774)
Cash flows from investing activities:						
Purchases of property and equipment	(8)	(23)	(3)	(18)	(99)	(117)
Change in restricted cash	—	(30)	(30)	—	(50)	(50)
Net cash used in investing activities	(8)	(53)	(33)	(18)	(149)	(167)
Cash flows from financing activities:						
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	18,775	35,406	19,921	—	84,594	84,594
Proceeds from issuance of convertible promissory notes, net of issuance costs	—	—	—	—	6,890	6,890
Proceeds from issuance of common stock	—	—	—	—	58	58
Proceeds from exercise of common stock options	4	215	215	12	220	232
Loans made to stockholders	—	—	—	—	(350)	(350)
Collection of loans made to stockholders	—	—	—	79	130	209
Repurchase of common stock at cost	—	—	—	—	(33)	(33)
Payments of initial public offering costs	—	(30)	—	(479)	(30)	(509)
Net cash provided by (used in) financing activities	18,779	35,591	20,136	(388)	91,479	91,091
Net increase (decrease) in cash and cash equivalents	9,438	20,062	14,429	(10,603)	31,753	21,150
Cash and cash equivalents at beginning of period	2,253	11,691	11,691	31,753	—	—
Cash and cash equivalents at end of period	$ 11,691	$ 31,753	$ 26,120	$ 21,150	$ 31,753	$ 21,150
Supplemental disclosure cash flow information:						
Cash paid for interest	$ —	$ —	$ —	$ —	$ 3	$ 3
Supplemental disclosure of non-cash investing and financing activities:						
Accretion of redeemable convertible preferred stock to redemption value	$ 34	$ 94	$ 79	$ —	$ 3,359	$ 3,359
Accrual of dividend on redeemable convertible preferred stock	$ —	$ —	$ —	$ —	$ 347	$ 347
Modifications of redeemable convertible preferred stock	$ —	$ —	$ —	$ —	$ 9,925	$ 9,925
Issuance of warrant in connection with convertible notes	$ —	$ —	$ —	$ —	$ 125	$ 125
Forgiveness of interest	$ —	$ —	$ —	$ —	$ 94	$ 94
Warrant cancellation	$ —	$ —	$ —	$ —	$ 125	$ 125
Conversion of convertible promissory notes and accrued interest and advance from stockholder to shares of redeemable convertible preferred stock	$ 141	$ —	$ —	$ —	$ 6,970	$ 6,970
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ —	$ —	$ 1,015	$ —	$ 1,015

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the "Company") (a development stage company) was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company's lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate. Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management, in-licensing technology and raising capital. Accordingly, the Company is considered to be in the development stage.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Galeterone, which is currently under development, and any product candidates that the Company may seek to develop in the future will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance-reporting capabilities.

Galeterone is in the development stage. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative cash flows and has a deficit accumulated during the development stage of $63,055 as of December 31, 2013. The Company expects that its existing cash and cash equivalents as of December 31, 2013 will enable the Company to fund its operating expenses and capital expenditure requirements through at least December 31, 2014. In addition, the Company expects that its cash and cash equivalents as of June 30, 2014 (unaudited) will be sufficient to fund its operating expenses and capital expenditure requirements through at least June 30, 2015 (unaudited). The future viability of the Company is largely dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

The Company is seeking to complete an initial public offering of its common stock. If the gross proceeds from the initial public offering are at least $40,000, subject to a minimum per share price for the shares of common stock sold in the initial public offering, the Company's outstanding redeemable convertible preferred stock will automatically convert into shares of common stock upon the completion of the Company's initial public offering.

In the event the Company does not complete an initial public offering, the Company expects to seek additional funding through a combination of equity offerings, debt financings, marketing and distribution

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to the Company on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain sufficient funding, it may have to curtail the development of galeterone, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense, which could adversely affect its business prospects.

The accompanying consolidated financial statements and footnotes include Diotima Pharmaceuticals, Inc. ("Diotima"), a variable interest entity in which the Company has a variable financial interest and is the primary beneficiary but has no ownership interest. In September 2010, the Company formed and incorporated Diotima, which has since operated as a stand-alone company with limited activity. In November 2010, the Company contributed certain assets to Diotima in exchange for all of the issued and outstanding shares of common and preferred stock of Diotima (see Note 8). All significant intercompany balances and transactions between the Company and Diotima have been eliminated in consolidation.

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

At December 31, 2013 and June 30, 2014, the Company is considered a development stage enterprise. Until planned principal operations have commenced and significant revenue is generated, financial statements prepared in accordance with GAAP are required to report cumulative statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows from the date of inception.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of common stock, redeemable convertible preferred stock and stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Interim Financial Information

The accompanying consolidated balance sheet as of June 30, 2014, the consolidated statements of operations and comprehensive loss and consolidated statements of cash flows for the six months ended June 30, 2013 and 2014 and for the cumulative period from inception (March 26, 2004) to June 30, 2014, and the consolidated statement of redeemable convertible preferred stock and stockholders' deficit for the six months ended June 30, 2014 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2014 and the results of its operations and its cash flows for the six

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

months ended June 30, 2013 and 2014 and for the cumulative period from inception (March 26, 2004) to June 30, 2014. The financial data and other information disclosed in these notes related to the six months ended June 30, 2013 and 2014 and the cumulative period from inception (March 26, 2004) to June 30, 2014 are unaudited. The results for the six months ended June 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period.

Unaudited Pro Forma Information

The accompanying unaudited pro forma consolidated balance sheet as of June 30, 2014 has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into 155,586,141 shares of common stock as if the Company's proposed initial public offering (see Note 1) had occurred on June 30, 2014. In the accompanying consolidated statements of operations, unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the six months ended June 30, 2014 have been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as if the Company's proposed initial public offering (see Note 1) had occurred on the later of January 1, 2013 or the issuance date of the redeemable convertible preferred stock.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has all cash and cash equivalents balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

- Level 2 — Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents of $1,311 as of December 31, 2012 and 2013 and June 30, 2014 (unaudited) were carried at fair value based on Level 2 inputs. The carrying values of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as other assets until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering or as a reduction to the carrying value of preferred stock issued. As of December 31, 2013 and June 30, 2014 (unaudited), the Company had recorded $30 and $1,524, respectively, of deferred offering costs in the accompanying consolidated balance sheet in contemplation of a probable 2014 equity financing. Should the equity financing no longer be considered probable of being consummated, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. The Company did not record any deferred offering costs as of December 31, 2012.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over a three-year estimated useful life for computer equipment, which is the only type of property and equipment the Company holds. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Research and Development Costs

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including manufacturing expenses and external costs of outside vendors engaged to conduct both pre-clinical studies and clinical trials.

The Company has entered into various research and development contracts with research institutions and other companies both inside and outside of the United States. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing costs. This process involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated costs incurred for the services for which the Company has not yet been invoiced. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions, while the graded vesting method is applied to all grants with both service and performance conditions.

For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. No revenue has been generated since inception, and all tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for the years ended December 31, 2012 and 2013, the six months ended June 30, 2013 and 2014 (unaudited), the cumulative period from inception (March 26, 2004) to December 31, 2013 and the cumulative period from inception (March 26, 2004) to June 30, 2014 (unaudited).

Carrying Value of Redeemable Convertible Preferred Stock

The Company recognizes changes in the redemption values of its outstanding redeemable convertible preferred stock immediately as they occur and adjusts the carrying value of the redeemable convertible preferred stock to equal the redemption value at the end of each reporting period as if the end of each reporting period were the redemption date.

Reductions in the carrying value of each series of redeemable convertible preferred stock are only recorded to the extent that the Company has previously recorded increases in the carrying value of the security.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Net Income (Loss) Per Share

The Company follows the two-class method when computing net income (loss) per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options and unvested restricted common stock. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014 (unaudited).

Recently Issued and Adopted Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board, (the "FASB"), issued Accounting Standards Update No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this guidance remove all incremental financial reporting requirements for development stage entities. Among other changes, this guidance will no longer require development stage entities to present inception-to-date information about income statement line items, cash flows, and equity transactions. These presentation and disclosure requirements will no longer be required for the first annual period beginning after December 15, 2014 for public companies. Early application is permitted for interim and annual periods for which financial statements have not yet been issued or made available for issuance. Effective upon the Company's adoption of this guidance, the Company will no longer disclose inception-to-date information currently included in its consolidated statements of operations and comprehensive loss, of cash flows, and of redeemable convertible preferred stock and stockholders' deficit and the related notes thereto.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

3. Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2012 and 2013 and June 30, 2014 (unaudited):

	December 31,		June 30,
	2012	2013	2014
			(unaudited)
Computer equipment	$ 67	$ 72	$ 86
	67	72	86
Less: Accumulated depreciation	(51)	(43)	(50)
	$ 16	$ 29	$ 36

Depreciation expense was $9 and $10 for the years ended December 31, 2012 and 2013, respectively, $3 and $11 for the six months ended June 30, 2013 and 2014 (unaudited), respectively, $65 for the cumulative period from inception (March 26, 2004) through December 31, 2013 and $76 for the cumulative period from inception (March 26, 2004) through June 30, 2014 (unaudited).

4. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2012 and 2013 and June 30, 2014 (unaudited):

	December 31,		June 30,
	2012	2013	2014
			(unaudited)
Accrued research and development expenses	$ 766	$1,370	$ 1,595
Accrued payroll and related expenses	291	436	320
Accrued professional fees	146	338	511
Accrued other	51	60	46
	$1,254	$2,204	$ 2,472

5. Convertible Promissory Notes

In March 2007, the Company issued a convertible promissory note in the aggregate principal amount of $2,935 (the "Series B Note") to one of its existing stockholders. The Series B Note accrued interest at an annual rate of 6% payable at maturity. In May 2007, the total outstanding principal and accrued interest on the Series B note of $3,050 converted into 798,067 and 80,117 shares of the Company's Series B-1 and B-2 redeemable convertible preferred stock, respectively (see Note 6).

In October 2008 and February 2009, the Company issued $2,000 and $2,000 in aggregate principal amount, respectively, of convertible promissory notes (collectively, the "Series C Notes") to certain existing holders of

the Company's Series B-2 redeemable convertible preferred stock. The Series C Notes accrued interest at an annual rate of 6% and were due at any time on or after April 14, 2010 upon the written demand of the holders of at least 60% of the aggregate principal amount under all Series C Notes then outstanding. The Company incurred financing costs of $45 related to the issuance of the Series C Notes. In connection with the issuance of the Series C Notes, the Company also issued warrants to the holders of the Series C Notes for the purchase of an aggregate of 572,683 shares of Series C redeemable convertible preferred stock at a purchase price of $0.25 per warrant share (the "Series C Warrants"). At the date of issuance, the Series C Warrants were valued using the Black-Scholes option-pricing model, which resulted in a total fair value of $125 at the date of issuance. The Series C Warrants were remeasured at December 31, 2008 using the Black-Scholes option-pricing model and again upon cancellation of the Series C Warrants in May 2009. There was no significant change in the value of the Series C Warrants from October 2008 through May 2009. Issuance costs and the value of the Series C Warrants were recorded initially as deferred financing costs included in other assets on the consolidated balance sheet and amortized to interest expense. The Company recorded $90 of interest expense during 2008 and 2009 related to the amortization of these deferred financing costs.

In May 2009, the aggregate outstanding principal of $4,000 on the Series C Notes were converted into an aggregate of 15,999,998 shares of Series C redeemable convertible preferred stock at a conversion price of $0.25 per share, the outstanding Series C Warrants were cancelled and the accrued interest on the Series C Notes payable was forgiven. As the holders of the Series C Notes were also the Company's majority stockholders, the Company considered the cancellation of the Series C Warrants and forgiveness of interest to represent contributed capital and, accordingly, recorded $125 and $94 for the cancellation of the Series C Warrants and forgiveness of interest, respectively, as additional paid-in capital.

6. Redeemable Convertible Preferred Stock

As of December 31, 2013 and June 30, 2014 (unaudited), the Company's certificate of incorporation, as amended and restated (the "Certificate of Incorporation"), authorizes the Company to issue 155,586,141 shares of preferred stock, $0.001 par value per share.

The Company has issued Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2 and Series D-3, and Series E redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). The Series C, D and E redeemable convertible preferred stock are collectively referred to as the "Senior Preferred Stock." The Redeemable Preferred Stock is classified outside of stockholders' equity (deficit) because the shares contain redemption features that are not solely within the control of the Company.

During 2004, 2005 and 2007, the Company issued a total of 4,500,000 shares of Series A redeemable convertible preferred stock at an issuance price equal to $0.50 per share and received aggregate gross proceeds of $2,250. In connection with these preferred stock financings, the Company paid total issuance costs of $20. Holders of the Series A redeemable convertible preferred stock were initially entitled to cumulative dividends of $0.04 per share.

During 2007, the outstanding principal and accrued interest of $3,050 on the Series B Note was converted into 798,067 shares of Series B-1 redeemable convertible preferred stock at $3.383176 per share and 80,117 shares of Series B-2 redeemable convertible preferred stock at $4.365388 per share, respectively (see Note 5). The Company issued an additional 1,423,702 shares of Series B-2 redeemable convertible preferred stock in 2007 for aggregate gross proceeds of $6,215. The Company incurred issuance costs of $240 relating to the sale and issuance of these shares of Series B-2 redeemable convertible preferred stock.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

In May 2007, in connection with the authorization and issuance of the Series B-1 and Series B-2 redeemable convertible preferred stock, the rights and preferences of the Series A redeemable convertible preferred stock were modified such that the holders of Series A were no longer entitled to cumulative dividends but instead became entitled to non-cumulative dividends when and if declared by the Company's board of directors. In addition, the maximum participation amount of the Series A redeemable convertible preferred stock upon liquidation was increased from 200% to 300% of the Series A liquidation preference. The modification of these rights and preferences resulted in a transfer of value between common and preferred stockholders and was treated as a deemed dividend to the Company's preferred stockholders. Accordingly, the Company recorded the deemed dividend of $45, representing the decrease in fair value of the Company's common stock as a result of the modification, by increasing the carrying value of the Series A redeemable convertible preferred stock by $45 and increasing accumulated deficit, as the Company had no additional paid-in capital.

As the Company immediately accretes the carrying value of its redeemable convertible preferred stock to redemption value at the end of each reporting period as if the end of the reporting period were the redemption date, as of December 31, 2007, the Company reduced the carrying value of the Series A redeemable convertible preferred stock by $347, which represented the amount of cumulative dividends recorded through the modification date to which holders of Series A redeemable convertible preferred stock were no longer entitled upon liquidation or redemption as a result of the modification.

In May 2009, the aggregate outstanding principal of $4,000 on the Series C Notes was converted into an aggregate of 15,999,998 shares of Series C redeemable convertible preferred stock at a conversion price of $0.25 per share, and the accrued interest on the Series C Notes payable was forgiven (see Note 5). In 2009, the Company issued 29,294,828 shares of Series D redeemable convertible preferred stock at $0.54617142 per share to new and existing investors for gross proceeds of $16,000. The Company incurred issuance costs of $209 in connection with the sale and issuance of these shares of Series D redeemable convertible preferred stock.

In connection with the issuance of the Series C and Series D redeemable convertible preferred stock in 2009, the rights and preferences of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock outstanding were modified such that the liquidation and redemption price of the Series A was increased from $0.50 per share to $0.70 per share, the liquidation and redemption price of the Series B-1 was decreased from $3.38 to $0.70 per share, and the liquidation and redemption price of the Series B-2 was decreased from $4.365388 to $0.70 per share. In addition, certain voting rights were modified and the maximum participation amount for the holders of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock was eliminated. The holders of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock also waived adjustment to the conversion prices of the Series A and Series B redeemable convertible preferred stock that should have occurred as a result of anti-dilution provisions due to the issuance price of the Series C redeemable convertible preferred stock.

Due to the significant change in the fair value of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock as a result of the modification, such changes were, for accounting purposes only, treated by the Company as extinguishments and reissuances of these securities. Accordingly, the Company recorded an adjustment to remove the carrying value of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock with a corresponding adjustment to additional paid-in capital. The Company recorded the adjustment to additional paid-in capital because the holders of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock were also the majority shareholders of the Series C and Series D redeemable convertible preferred stock. Subsequently, the Company recorded the reissuance of the modified

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Series A, Series B-1 and Series B-2 redeemable convertible preferred stock at their respective fair values with a corresponding entry to additional paid-in capital. The extinguishment and reissuance of these securities resulted in a net decrease to the carrying values of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock of $1,395, $2,461 and $6,114, respectively, as well as an aggregate net capital contribution of $9,970 recorded as additional paid-in capital.

As the Company immediately accretes the carrying value of its redeemable convertible preferred stock to redemption value at the end of each reporting period as if the end of the reporting period were the redemption date, the Company recorded an entry of $3,380 as of December 31, 2009 to increase the carrying values of each series of outstanding redeemable convertible preferred stock to their respective redemption values

In May 2010, the Company issued 3,661,846 shares of Series D redeemable convertible preferred stock to certain existing investors at $0.54617142 per share for gross proceeds of $2,000. The Company incurred issuance costs of $30 in connection with the sale and issuance of these shares of Series D redeemable convertible preferred stock. In November 2010, all outstanding shares of Series D redeemable convertible preferred stock were exchanged for 29,294,828 shares of Series D-1 redeemable convertible preferred stock and 3,661,846 shares of Series D-2 redeemable convertible preferred stock. The Company treated this exchange as an extinguishment of the Series D redeemable convertible preferred stock and the issuance of Series D-1 and D-2 preferred stock at their respective fair values. As the rights and preferences of the shares exchanged were identical, the Company determined that the fair value of the Series D-1 and Series D-2 redeemable convertible preferred stock was the same as the carrying value of the Series D redeemable convertible preferred stock at the time of the exchange. As a result, there was no change in the aggregate carrying values of these securities.

In November 2010, in connection with the distribution of all outstanding shares of convertible preferred stock of Diotima, which was a wholly owned subsidiary of the Company, to holders of the Company's Series A, Series B-1, Series B-2, Series C and Series D-1 redeemable convertible preferred stock on a pro rata basis (see Note 8), the liquidation and redemption amounts of each of the Company's outstanding shares of Series A, Series B-1, Series B-2, Series C and Series D-1 redeemable convertible preferred stock were decreased by $0.0419 per share. Accordingly, the Company recorded an adjustment to decrease the aggregate carrying value of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock by $285, or $0.0419 per share, to reflect their adjusted redemption values. Although the liquidation preferences of the Series C and D-1 redeemable convertible preferred stock were decreased as a result of the distribution, the downward adjustments to their carrying values was limited to $80, representing the amount of accretion previously recorded by the Company related to the Series C and D-1 redeemable convertible preferred stock.

During 2011, the Company issued 8,239,150 shares of Series D-3 redeemable convertible preferred stock to certain existing investors at $0.54617142 per share for gross proceeds of $4,500. The Company incurred issuance costs of $194 in connection with the sale and issuance of these shares of Series D-3 redeemable convertible preferred stock.

During 2012, the Company issued 34,696,042 shares of Series D-3 redeemable convertible preferred stock to certain existing investors at $0.54617142 per share for gross proceeds of $18,950. The Company incurred issuance costs of $34 in connection with the sale and issuance of these shares of Series D-3 redeemable convertible preferred stock.

In May and October 2013, the Company issued an aggregate of 56,892,391 shares of Series E redeemable convertible preferred stock to existing and new investors at $0.62398475 per share for gross proceeds of $35,500.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

The Company incurred issuance costs of $94 in connection with the sale and issuance of these shares of Series E redeemable convertible preferred stock.

Redeemable Preferred Stock consisted of the following as of December 31, 2012:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	4,500,000	4,500,000	$ 2,961	$ 2,961	4,500,000
Series B-1 redeemable convertible preferred stock	798,067	798,067	525	525	798,067
Series B-2 redeemable convertible preferred stock	1,503,819	1,503,819	989	989	1,503,819
Series C redeemable convertible preferred stock	15,999,998	15,999,998	3,330	3,920	15,999,998
Series D-1 redeemable convertible preferred stock	29,294,828	29,294,828	14,773	16,000	29,294,828
Series D-2 redeemable convertible preferred stock	3,661,846	3,661,846	2,000	2,000	3,661,846
Series D-3 redeemable convertible preferred stock	42,935,205	42,935,192	23,450	23,450	42,935,192
	98,693,763	98,693,750	$ 48,028	$49,845	98,693,750

Redeemable Preferred Stock consisted of the following as of December 31, 2013 and as of June 30, 2014 (unaudited):

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	4,500,000	4,500,000	$ 2,961	$ 2,961	4,500,000
Series B-1 redeemable convertible preferred stock	798,067	798,067	525	525	798,067
Series B-2 redeemable convertible preferred stock	1,503,819	1,503,819	989	989	1,503,819
Series C redeemable convertible preferred stock	15,999,998	15,999,998	3,330	3,920	15,999,998
Series D-1 redeemable convertible preferred stock	29,294,828	29,294,828	14,773	16,000	29,294,828
Series D-2 redeemable convertible preferred stock	3,661,846	3,661,846	2,000	2,000	3,661,846
Series D-3 redeemable convertible preferred stock	42,935,192	42,935,192	23,450	23,450	42,935,192
Series E redeemable convertible preferred stock	56,892,391	56,892,391	35,500	35,500	56,892,391
	155,586,141	155,586,141	$ 83,528	$85,345	155,586,141

The holders of the Redeemable Preferred Stock have the following rights and preferences:

Voting Rights

The holders of Redeemable Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of all Redeemable Preferred Stock, with the exception of holders of Series C redeemable convertible preferred stock, have the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Preferred Stock could convert on the record date for determination of stockholders entitled to vote. Holders of Series C redeemable convertible preferred stock are entitled to cast 0.45773175 of a vote for each share of common stock into which one share of Series C redeemable convertible preferred stock is convertible.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Dividends

The holders of all Redeemable Preferred Stock are entitled to receive dividends at an annual rate of 8% of the Original Issue Price of the applicable series when and if declared by the Company's board of directors, provided that the holders of the Series A redeemable convertible preferred stock are entitled to receive the greater of 8% of the original issuance price of the Series A redeemable convertible preferred stock or $0.04 per share when and if declared by the Company's board of directors. Dividends are non-cumulative, and holders of Redeemable Preferred Stock holders are not entitled to any accruing dividends. In addition, any dividends declared by the Company's board of directors are required to be paid: first, to the holders of the Senior Preferred Stock; second, to the holders of Series B-1 and B-2 redeemable convertible preferred stock; and last, to the holders of Series A redeemable convertible preferred stock. The Original Issue Price ("OIP") for the Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2, Series D-3 and Series E redeemable convertible preferred stock is equal to $0.50, $3.383176, $4.365388, $0.25, $0.54617142, $0.54617142, $0.54617142 and $0.62398475 per share, respectively, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Redeemable Preferred Stock. As of December 31, 2013 and June 30, 2014 (unaudited), no dividends had been declared by the Company's board of directors.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company (each, a "Liquidation Event"), the holders of Series C, Series D and Series E redeemable convertible preferred stock (collectively, the "Senior Preferred Stockholders") are entitled to be paid out of the assets of the Company prior to any payments made to the holders of Series A, Series B-1 or Series B-2 redeemable convertible preferred stock, and the holders of Series B-1 and B-2 redeemable convertible preferred stock are entitled to be paid out of any remaining assets prior to the holders of the Series A redeemable convertible preferred stock.

Based on the liquidation preferences under the Certificate of Incorporation and assuming sufficient assets available for distribution to the Company's stockholders, upon a Liquidation Event, holders of Redeemable Preferred Stock would be entitled to receive $0.6581 per share for Series A redeemable convertible preferred stock, $0.6581 per share for Series B-1 and B-2 redeemable convertible preferred stock, $0.2081 per share for Series C redeemable convertible preferred stock, $0.5043 per share for Series D-1 redeemable convertible preferred stock, $0.54617142 per share for Series D-2 and D-3 redeemable convertible preferred stock and $0.62398475 per share for Series E redeemable convertible preferred stock (in each case, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization).

In the event that the assets available for distribution to the Company's stockholders are not sufficient to permit payment in full to the holders of Redeemable Preferred Stock, the holders of the Senior Preferred Stock are entitled to receive such amount prior to and in preference of the holders of the Series B-1 and B-2 redeemable convertible preferred stock and Series A redeemable convertible preferred stock, and the holders of Series B-1 and B-2 redeemable convertible preferred stock are entitled to receive such amount prior to and in preference of the holders of Series A redeemable convertible preferred stock.

In the event that the assets available for distribution to the Company's stockholders are not sufficient to permit payment to any class of holders in order of preference and in the full amount to which they are entitled, the assets available for distribution are distributed on a pro rata basis. After the payment of all preferential amounts to the holders of the Senior Preferred Stock, the Series B redeemable convertible preferred stock and the Series A

redeemable convertible preferred stock, any remaining assets available for distribution will be distributed among the holders of the Redeemable Preferred Stock and the holders of the Company's common stock on a pro rata basis based on the number of shares held by each holder on an as converted to common stock basis.

Conversion

Each share of Redeemable Preferred Stock is convertible at the option of the stockholder at any time without the payment of additional consideration, or will automatically be converted into shares of common stock at the applicable conversion ratio then in effect, upon the closing of a firm commitment underwritten public offering with gross proceeds of at least $40,000 and a minimum price per share to the public or upon the vote or written consent of the holders of at least 75% of the outstanding shares of the Senior Preferred Stockholders voting together as a single class. The conversion ratio of the Redeemable Preferred Stock is determined by dividing the OIP of the applicable series by the Conversion Price (as defined in the Certificate of Incorporation) of the applicable series with the exception of Series B redeemable convertible preferred stock, which is calculated by dividing $0.54617142 by the Conversion Price. The Conversion Price is subject to adjustment as set forth in the Certificate of Incorporation. As of December 31, 2013 and June 30, 2014 (unaudited), the Conversion Price for the Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2, Series D-3 and Series E redeemable convertible preferred stock is equal to $0.50, $0.54617142, $0.54617142, $0.25, $0.54617142, $0.54617142, $0.54617142 and $0.62398475 per share, respectively. As of December 31, 2013 and June 30, 2014 (unaudited), all shares of Redeemable Preferred Stock are convertible into shares of the Company's common stock on a one-for-one basis.

Redemption Rights

At any time on or after May 10, 2018, shares of each of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock are subject to mandatory redemption by the Company in three equal annual installments beginning 60 days after receipt of a notice of redemption from the holders of at least 60% of the combined voting power of the holders of the outstanding Series A, Series B-1 and Series B-2 redeemable convertible preferred stock, voting as a single class. As of December 31, 2013 and June 30, 2014 (unaudited), the redemption price for the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock is equal to $0.6581 per share, subject to appropriate adjustment for any stock splits, stock dividends, combinations or any other similar recapitalization affecting such shares, plus any dividends declared but unpaid thereon.

At any time on or after May 10, 2018, shares of the Senior Preferred Stock are subject to mandatory redemption by the Company in three equal annual installments beginning 60 days after receipt of a notice of redemption from the holders of at least 75% of the combined voting power of holders of the outstanding Senior Preferred Stock. As of December 31, 2013 and June 30, 2014 (unaudited), the redemption price for the Series C, Series D-1, Series D-2, Series D-3 and Series E convertible preferred stock is equal to $0.2081, $0.5043, $0.54617142, $0.54617142 and $0.62398475 per share, respectively, subject to appropriate adjustment for any stock splits, stock dividends, combinations or any other similar recapitalization affecting such shares, plus any dividends declared but unpaid thereon.

Reissuance

Shares of any Redeemable Preferred Stock that are redeemed or converted will be retired or canceled and may not be reissued by the Company.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

7. Common Stock

As of December 31, 2013 and June 30, 2014 (unaudited), the Certificate of Incorporation authorizes the Company to issue 173,018,331 and 178,408,438 shares, respectively, of common stock, $0.001 par value per share.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

As of December 31, 2013 and June 30, 2014 (unaudited), the Company had reserved 167,853,596 and 173,157,039 shares of common stock, respectively, for the conversion of the outstanding shares of Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2, Series D-3 and Series E redeemable convertible preferred stock (see Note 6) and the exercise of outstanding stock options and the number of shares of common stock remaining available for grant under the Company's Amended and Restated 2007 Stock Option Plan (see Note 9).

8. Diotima Distribution

In September 2010, the Company formed and incorporated Diotima, a wholly owned subsidiary of the Company (see Note 1). In November 2010, the Company entered into a contribution agreement with Diotima (the "Contribution Agreement"), pursuant to which the Company assigned rights to develop and commercialize certain compounds that were unrelated to the Company's core operations to Diotima in exchange for all outstanding shares of common and preferred stock of Diotima. The book value of the assets contributed to Diotima was $0. Effective in November 2010, the Company distributed to stockholders of the Company who were record holders as of May 21, 2010, on a pro rata basis, all of the issued and outstanding shares of common and preferred stock of Diotima (the "Diotima Spin-off").

In connection with the Diotima Spin-off, the Company entered into various agreements with Diotima. Under the terms of these agreements, the Company has funded the payment of license and license maintenance fees related to intellectual property licenses held by Diotima. As a result of this funding activity, the Company has determined that Diotima is a variable interest entity, in which the Company has a variable financial interest and is the primary beneficiary but has no ownership interest. Accordingly, the Company has continued to consolidate Diotima subsequent to the Diotima Spin-off. Diotima has had limited activity. Expenses incurred by Diotima for the years ended December 31, 2012 and 2013 and for the cumulative period from the incorporation of Diotima in 2010 to December 31, 2013 were $85, $60 and $233, respectively. Expenses incurred by Diotima for the six months ended June 30, 2013 and 2014 (unaudited) and for the cumulative period from the incorporation of Diotima in 2010 to June 30, 2014 (unaudited) were $58, $8 and $241, respectively. In 2014, the license agreements relating to these compounds were terminated. Additionally, in April 2014, the board of directors and stockholders of Diotima approved the dissolution of Diotima, and Diotima was dissolved.

9. Stock-Based Awards

2007 Stock Incentive Plan

The Company's 2007 Stock Incentive Plan (as amended, the "2007 Plan") provides for the Company to sell or issue restricted common stock or to grant stock options for the purchase of common stock to employees, members of the board of directors and consultants of the Company. The 2007 Plan is administered by the board of directors,

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years.

Stock options granted under the 2007 Plan with service-based vesting conditions generally vest over four years and expire after ten years, although options have been granted with vesting terms of less than four years.

The total number of shares of common stock that may be issued under the 2007 Plan was 16,653,382 shares as of December 31, 2013, of which 497,693 shares remained available for future issuance as of December 31, 2013. As of June 30, 2014 (unaudited), the total number of shares of common stock that may be issued under the 2007 Plan was 22,043,489 shares, of which 459,555 shares remained available for issuance as of June 30, 2014 (unaudited).

As required by the 2007 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as determined by the Company as of the date of grant. The Company values its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded group of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table sets forth the assumptions that the Company used to determine the fair value of the stock options granted, presented on a weighted average basis:

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Risk-free interest rate	0.79%	1.72%	1.71%	1.87%
Expected term (in years)	6.07	5.98	5.99	5.89
Expected volatility	65.5%	79.7%	79.6%	79.2%
Expected dividend yield	0%	0%	0%	0%

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

The following table summarizes the Company's stock option activity from January 1, 2012 through June 30, 2014:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2011	8,057,970	$ 0.12	9.3	$ 74
Granted	1,037,923	0.13		
Exercised	(29,778)	0.13		
Forfeited	(609,675)	0.11		
Outstanding as of December 31, 2012	8,456,440	$ 0.12	8.5	$ 52
Granted	8,235,182	0.17		
Exercised	(1,652,218)	0.13		
Forfeited	(3,269,642)	0.13		
Outstanding as of December 31, 2013	11,769,762	$ 0.15	8.8	$ 2,346
Granted (unaudited)	5,487,720	0.53		
Exercised (unaudited)	(86,664)	0.14		
Forfeited (unaudited)	(59,475)	0.15		
Outstanding as of June 30, 2014 (unaudited)	17,111,343	$ 0.27	8.7	$ 5,941
Options vested and expected to vest as of December 31, 2013	9,909,215	$ 0.15	8.6	$ 1,992
Options exercisable as of December 31, 2013	3,452,365	$ 0.12	7.5	$ 790
Options vested and expected to vest as of June 30, 2014 (unaudited)	15,187,034	$ 0.28	8.7	$ 5,098
Options exercisable as of June 30, 2014 (unaudited)	4,928,771	$ 0.15	7.6	$ 2,300

As of December 31, 2013 and June 30, 2014 (unaudited), outstanding options for the purchase of 1,730,184 shares of common stock at an exercise price of $0.15 per share have performance-based vesting conditions that have been deemed to be not probable of vesting.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was $1 and $33 for the years ended December 31, 2012 and 2013, respectively, and $33 and $34 for the six months ended June 30, 2013 and 2014, respectively (unaudited).

The Company received cash proceeds from the exercise of stock options of $4 and $215 during the years ended December 31, 2012 and 2013, respectively, and $215 and $12 during the six months ended June 30, 2013 and 2014, respectively (unaudited).

The weighted average grant date fair value of stock options granted during the years ended December 31, 2012 and 2013 was $0.08 and $0.12 per share, respectively, and $0.10 and $0.36 per share for the six months ended June 30, 2013 and 2014, respectively (unaudited).

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Restricted Common Stock

The 2007 Plan provides for the award of restricted common stock. The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award.

The table below summarizes the Company's restricted stock activity since January 1, 2012:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2011	28,679	$ —
Issued	1,622,579	0.13
Vested	(190,089)	0.12
Forfeited	—	—
Unvested restricted common stock as of December 31, 2012	1,461,169	$ 0.13
Issued	—	—
Vested	(109,015)	0.12
Forfeited	(1,352,154)	0.13
Unvested restricted common stock as of December 31, 2013	—	$ —

The aggregate intrinsic value of restricted stock awards is calculated as the difference between the price paid for the restricted stock awards and the fair value of the Company's common stock for those restricted stock awards that had a purchase price lower than the fair value of the Company's common stock. The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2012 and 2013 was $23 and $14, respectively, and during the six months ended June 30, 2013 (unaudited) was $14. As of December 31, 2013 and June 30, 2014 (unaudited), there were no unvested restricted stock awards subject to repurchase.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its statements of operations:

	Year Ended December 31,		Six Months Ended June 30,		Cumulative Period From Inception (March 26, 2004) to December 31, 2013	Cumulative Period From Inception (March 26, 2004) to June 30, 2014
	2012	2013	2013	2014		
			(unaudited)			(unaudited)
Research and development	$ 87	$ 91	$ 41	$ 136	$ 263	$ 399
General and administrative	123	147	49	204	433	637
	$ 210	$ 238	$ 90	$ 340	$ 696	$ 1,036

As of December 31, 2013, the Company had an aggregate of $645 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.95 years. As of June 30, 2014 (unaudited), the Company had an aggregate of $2,238 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.20 years.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

10. Net Loss Per Share and Unaudited Pro Forma Net Loss Per Share

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014 (unaudited):

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Numerator:				
Net loss	$ (9,649)	$ (15,725)	$ (6,835)	$ (10,698)
Accretion of redeemable convertible preferred stock to redemption value	(34)	(94)	(79)	—
Net loss attributable to common stockholders	$ (9,683)	$ (15,819)	$ (6,914)	$ (10,698)
Denominator:				
Weighted average common shares outstanding, basic and diluted	3,261,143	4,355,914	3,533,578	5,215,188
Net loss per share attributable to common stockholders, basic and diluted	$ (2.97)	$ (3.63)	$ (1.96)	$ (2.05)

The Company excluded the following common stock equivalents, outstanding as of December 31, 2012 and 2013 and as of June 30, 2013 and 2014 (unaudited), from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014 (unaudited) because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods:

	December 31,		June 30,	
	2012	2013	2013	2014
			(unaudited)	
Stock options to purchase common stock	8,456,440	11,769,762	11,123,802	17,111,343
Unvested restricted common stock	1,461,169	—	—	—
Redeemable convertible preferred stock (as converted to common stock)	98,693,750	155,586,141	130,745,804	155,586,141
	108,611,359	167,355,903	141,869,606	172,697,484

Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the six months ended June 30, 2014 gives effect to adjustments arising upon the closing of the proposed initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the adjustments to the carrying value of Redeemable Preferred Stock to equal redemption value because it assumes that the conversion of Redeemable Preferred Stock into common stock had occurred on the later of January 1, 2013 or the issuance date of the Redeemable Preferred Stock.

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2013 and the six months ended June 30, 2014 gives effect to the automatic conversion upon the closing of the proposed initial public offering of all outstanding shares of Redeemable Preferred Stock as of December 31, 2013 and June 30, 2014 into 155,586,141 shares of common stock as if the conversion had occurred on the later of January 1, 2013 or the issuance date of the Redeemable Preferred Stock.

The computation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders is as follows:

	Year Ended December 31, 2013	Six Months Ended June 30, 2014
		(unaudited)
Numerator:		
Net loss	$ (15,725)	$ (10,698)
Pro forma net loss attributable to common stockholders	$ (15,725)	$ (10,698)
Denominator:		
Weighted average common shares outstanding, basic and diluted	4,355,914	5,215,188
Pro forma adjustment for assumed automatic conversion of all outstanding shares of redeemable convertible preferred stock upon the closing of the proposed initial public offering	123,694,351	155,586,141
Pro forma weighted average common shares outstanding, basic and diluted	128,050,265	160,801,329
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ (0.12)	$ (0.07)

11. Commitments and Contingencies

Leases

The Company leases its office space and obtains certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. Payments under this service agreement include monthly rent and certain fee-for-service charges.

During the years ended December 31, 2012 and 2013, the Company recognized $341 and $366, respectively, of rental expense related to office space. For the cumulative period from inception (March 26, 2004) to December 31, 2013, the Company recognized $1,557 of rental expense related to office space. For the six months ended June 30, 2013 and 2014 (unaudited), the Company recognized $173 and $209, respectively, of rental expense related to office space. For the cumulative period from inception (March 26, 2004) to June 30, 2014 (unaudited), the Company recognized $1,766 of rental expense related to office space.

Intellectual Property Licenses

In May 2006, the Company entered into a master license agreement with the University of Maryland, Baltimore ("UMB"). Pursuant to the license agreement, UMB granted an exclusive worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

import certain anti-androgen steroids including galeterone for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted the Company a first option to receive an exclusive license to UMB's rights in certain improvements to the licensed products. The Company has exercised the option and acquired exclusive rights to licensed improvements under three amendments to the license agreement.

In consideration for the rights granted, the Company made an upfront payment to UMB of $20 following the execution of the license agreement and a payment of $10 following the execution of each of the amendments in 2009, 2012 and 2013. In addition, the Company paid UMB a $50 milestone payment in 2009 upon the submission of an investigational new drug application ("IND") for galeterone and a $40 milestone payment in 2013 upon the issuance of the first patent related to UMB's prodrug patent application.

The Company is obligated to pay UMB an annual maintenance fee of $10 each year until the first commercial sale of a product developed using the licensed technology. The Company is also obligated to make an additional $50 milestone payment to UMB for each additional IND filed for a licensed product and a $100 milestone payment upon the approval of each NDA for a licensed product by the U.S. Food and Drug Administration. Because the achievement of these milestones has not occurred as of December 31, 2013 or June 30, 2014 (unaudited), no liabilities for such milestone payments have been recorded in the Company's consolidated financial statements.

The Company must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. The royalty obligations are subject to specified reductions in the event that additional licenses need to be obtained from third parties or in the event of specified competition from third-party products licensed by UMB. Minimum annual royalty payments to UMB are $50 beginning in the year following the year in which the first commercial sale occurs. The Company must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents. As of December 31, 2013 and June 30, 2014 (unaudited), the Company has not yet developed a commercial product using the licensed technologies, and it has not entered into any sublicense agreements for the technologies. In connection with this license agreement, the Company incurred license, milestone and maintenance fees of $60 and $20 for the years ended December 31, 2012 and 2013, respectively, and $210 for the cumulative period from inception (March 26, 2004) to December 31, 2013. In connection with this license agreement, the Company incurred license, milestone and maintenance fees of $10 in each of the six months ended June 30, 2013 and 2014 (unaudited) and $220 for the cumulative period from inception (March 26, 2004) to June 30, 2014 (unaudited).

The Company also had two license agreements for compounds and indications unrelated to its core strategy that were assigned to Diotima in November 2010 (see Note 8). Under the terms of the Contribution Agreement with Diotima, the Company funded the payment of annual license maintenance fees for the years ended December 31, 2011, 2012 and 2013. In early 2014, the Company, on behalf of Diotima, notified the licensors that they were terminating the two license agreements. In connection with these license agreements, the Company incurred license and maintenance fees of $50 for each of the years ended December 31, 2012 and 2013 and $1,710 for the cumulative period from inception (March 26, 2004) to December 31, 2013. The Company incurred license and maintenance fees of $50 for the six months ended June 30, 2013 (unaudited). There were no license or maintenance fees associated with these licenses incurred by the Company during the six months ended June 30, 2014 (unaudited).

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

The Company also entered into a license agreement in 2006 for certain technologies, under which the Company paid a total of $100 prior to the license agreement being terminated effective December 31, 2008.

Advisor Agreement

The Company is obligated to pay a fee to a financial advisor equal to the greater of $500 and 1% of the gross proceeds of an initial public offering of the Company's common stock, upon the closing of such event, in connection with strategic and financial advisory services unrelated to the offering.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2013 or June 30, 2014 (unaudited).

12. Income Taxes

During the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014 (unaudited), the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2012	2013
Federal statutory income tax rate	(34.0)%	(34.0)%
Federal and state research and development tax credit	(1.2)	(0.7)
State taxes, net of federal benefit	(5.4)	(5.6)
Stock-based compensation expense	0.6	0.4
Other	—	0.1
Change in deferred tax asset valuation allowance	40.0	39.8
Effective income tax rate	0.0%	0.0%

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Net deferred tax assets as of December 31, 2012 and 2013 consisted of the following:

	December 31,	
	2012	2013
Current deferred tax assets:		
Accrued expenses	$ 43	$ 201
Total current deferred tax assets	43	201
Noncurrent deferred tax assets:		
Capitalized research and development expenses	14,455	19,250
Net operating loss carryforwards	2,862	3,989
Research and development tax credit carryforwards	718	889
Other	60	73
Total noncurrent deferred tax assets	18,095	24,201
Total gross deferred tax assets	18,138	24,402
Valuation allowance	(18,138)	(24,402)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2012 and 2013 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,	
	2012	2013
Valuation allowance as of beginning of year	$ 14,129	$ 18,138
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	4,009	6,264
Valuation allowance as of end of year	$ 18,138	$ 24,402

As of December 31, 2013, the Company had net operating loss carryforwards for federal and state income tax purposes of $10,471 and $8,116, respectively, which begin to expire in 2024 and 2014, respectively. As of December 31, 2013, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $610 and $422, respectively, which begin to expire in 2025 and 2023, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382 of the Code, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Code, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the

time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

As of December 31, 2012 and 2013, the Company's gross deferred tax asset balance of $18,138 and $24,402, respectively, was comprised principally of capitalized research and development expenses, net operating loss carryforwards, and research and development tax credit carryforwards. During the years ended December 31, 2012 and 2013, gross deferred tax assets increased due to additional net operating loss carryforwards, research and development tax credits generated and additional research and development expenses capitalized for tax purposes. During the six months ended June 30, 2014 (unaudited), the Company's gross deferred tax assets increased by approximately $4,300 due to the operating losses incurred by the Company during that period.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2012 and 2013 and June 30, 2014 (unaudited). Management reevaluates the positive and negative evidence at each reporting period.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2012 or 2013 or June 30, 2014 (unaudited).

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2010 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

13. 401(k) Plan

The Company has a 401(k) plan available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the Board of Directors. To date, the Company has not made any contributions to the plan.

14. Qualifying Therapeutic Discovery Project Program

In 2010, the Company received $244 for a research project under the Qualifying Therapeutic Discovery Project Credit program under the Patient Protection and Affordable Care Act, covering 50% of qualifying expenses incurred. The Company recorded the proceeds received as other income in its consolidated statements of operations for the cumulative period from inception (March 26, 2004) to December 31, 2013 and for the cumulative period from inception (March 26, 2004) to June 30, 2014 (unaudited).

Tokai Pharmaceuticals, Inc.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

15. Related Party Transactions

In 2005, the Company loaned $250 to and entered into a promissory note with an advisor and stockholder of the Company that accrued interest at 2.92% per annum and was due in 2007. In 2007, unpaid principal and interest in the amount of $220 was deemed uncollectable by the Company, and as a result, was fully reserved for by the Company. As of December 31, 2013, no payments had been received by the Company, and the unpaid principal and interest balance remained fully reserved. Subsequent to December 31, 2013, the Company started to receive repayment of this note. The Company is recording payments received as other income in 2014 as cash is received. As a result, the Company recorded other income of $79 for the six months ended June 30, 2014 (unaudited), representing cash collected during that period.

In May 2009, the Company loaned $100 to and entered into a promissory note with an officer of the Company. The note and accrued interest was fully paid in 2011.

16. Subsequent Events

For its consolidated financial statements as of December 31, 2013 and for the year then ended, the Company evaluated subsequent events through May 2, 2014, the date on which those financial statements were issued.

In February 2014, the Company effected an increase in the number of authorized shares of its common stock to 177,408,438 shares and an increase in the number of shares of common stock available for issuance under the 2007 Plan to 21,043,489 shares.

In April 2014, the Company effected an increase in the number of authorized shares of its common stock to 178,408,438 shares and an increase in the number of shares of common stock available for issuance under the 2007 Plan to 22,043,489 shares.

17. Subsequent Events (unaudited)

For its interim consolidated financial statements as of June 30, 2014 and for the six months then ended, the Company evaluated subsequent events through August 11, 2014, the date on which those financial statements were issued.

Table of Contents

Tokai Pharmaceuticals, Inc.

Shares

Common Stock

Preliminary Prospectus

, 2014

Until , 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

BMO Capital Markets • Stifel • William Blair

Janney Montgomery Scott

Part II
Information not required in prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with this offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the FINRA filing fee.

	Amount
Securities and Exchange Commission registration fee	$ 9,660
FINRA filing fee	11,750
NASDAQ Global Market listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	$ *

* To be completed by amendment

Item 14. Indemnification of Directors and Officers

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Upon the closing of this offering, our certificate of incorporation will provide that none of our directors shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon the closing of this offering, our certificate of incorporation will provide that we will indemnify each person who was or is a party or threatened to be made a party to or is involved in any threatened, pending or completed action, suit or proceeding by reason of the fact that he or she is or was a director or officer of us or is

or was serving at our request as a director or officer of another corporation, partnership, joint venture, trust or other enterprise to the fullest extent permitted by the Delaware General Corporation Law. Upon the closing of this offering, our certificate of incorporation will provide that expenses must be advanced to these indemnitees under certain circumstances.

The indemnification provisions contained in our certificate of incorporation that will be effective as of the closing date of this offering are not exclusive. In addition, we intend to enter into indemnification agreements with each of our directors and officers. Each indemnification agreement will provide that we will, among other things, indemnify our directors and executive officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

In addition, we maintain standard policies of insurance under which coverage is provided to our directors and officers against losses arising from claims made by reason of breach of duty or other wrongful act, and to us with respect to payments which may be made by us to such directors and officers pursuant to the above indemnification provisions or otherwise as a matter of law. In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended (the "Securities Act") against certain liabilities.

Item 15. Recent Sale of Unregistered Securities.

Set forth below is information regarding shares of common stock and redeemable convertible preferred stock issued, and options granted, by us within the past three years that were not registered under the Securities Act. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Redeemable Convertible Preferred Stock

In September and December 2011 and July 2012, we issued and sold an aggregate of 42,935,192 shares of our Series D-3 redeemable convertible preferred stock at a purchase price per share of $0.54617142 for an aggregate purchase price of $23,449,975. All outstanding shares of Series D-3 redeemable convertible preferred stock will automatically convert into an aggregate of 42,935,192 shares of common stock upon the closing of this offering.

In May and October of 2013, we issued and sold an aggregate of 56,892,391 shares of our Series E redeemable convertible preferred stock at a purchase price per share of $0.62398475 for an aggregate purchase price of $35,499,985. All outstanding shares of Series E redeemable convertible preferred stock will automatically convert into an aggregate of 56,892,391 shares of common stock upon the closing of this offering.

No underwriters were involved in the foregoing sales of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

(b) Stock Option Grants

Between August 11, 2011 and August 11, 2014, we granted options to purchase an aggregate of 20,721,236 shares of common stock, with exercise prices ranging from $0.13 to $0.62 per share, to employees, directors and consultants pursuant to our 2007 Stock Incentive Plan, as amended. Between August 11, 2011 and August 11, 2014, we issued an aggregate of 1,768,660 shares of common stock upon the exercise of options for aggregate consideration of $229,669.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the securities described in paragraphs (a) and (b) of this Item 15 are deemed restricted securities for purposes of the Securities Act. All of the certificates representing such securities included appropriate legends setting forth that the securities have not been registered and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on the 11th day of August, 2014.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie P. Morrison
Jodie P. Morrison
President and Chief Executive Officer

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jodie P. Morrison and John S. McBride, and each of them, his/her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for him/her and in his/her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he/she might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or his/her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jodie P. Morrison Jodie P. Morrison	President and Chief Executive Officer *(Principal Executive Officer)*	August 11, 2014
/s/ John S. McBride John S. McBride	Chief Operating Officer *(Principal Financial and Accounting Officer)*	August 11, 2014
/s/ Seth L. Harrison Seth L. Harrison	Chairman	August 11, 2014
/s/ Reinhard J. Ambros Reinhard J. Ambros	Director	August 11, 2014
/s/ Timothy J. Barberich Timothy J. Barberich	Director	August 11, 2014
/s/ David A. Kessler David A. Kessler	Director	August 11, 2014

Table of Contents

Signature	Title	Date
/s/ Campbell Murray Campbell Murray	Director	August 11, 2014
/s/ Joseph A. Yanchik, III Joseph A. Yanchik, III	Director	August 11, 2014

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
1.1*	Underwriting Agreement
3.1	Seventh Amended and Restated Certificate of Incorporation of the Registrant, as amended
3.2*	Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering
3.3	Amended and Restated Bylaws of the Registrant
3.4*	Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering
4.1*	Specimen certificate evidencing shares of common stock
5.1*	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
10.1	Fifth Amended and Restated Investor Rights Agreement, dated as of May 13, 2013, among the Registrant and the other parties thereto
10.2+	2007 Stock Incentive Plan, as amended
10.3+	Form of Incentive Stock Option Agreement under 2007 Stock Incentive Plan
10.4+	Form of Nonstatutory Stock Option Agreement under 2007 Stock Incentive Plan
10.5*+	2014 Stock Incentive Plan to be effective upon the closing of this offering
10.6*+	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan
10.7*+	Form of Nonstatutory Stock Option Agreement under 2014 Stock Incentive Plan
10.8+	Amended and Restated Employment Agreement, dated as of July 16, 2014, between the Registrant and Jodie P. Morrison
10.9+	Employment Agreement, dated as of September 7, 2011, between the Registrant and Martin D. Williams
10.10+	Separation Agreement, dated as of March 27, 2013, between the Registrant and Martin D. Williams, as amended April 3, 2013
10.11+	Employment Agreement, dated as of July 19, 2012, between the Registrant and Adrian Senderowicz, M.D.
10.12+	Separation Agreement, dated as of March 27, 2013, between the Registrant and Adrian Senderowicz, M.D., as amended April 2, 2013
10.13*+	Form of Director and Officer Indemnification Agreement
10.14†	Master License Agreement, dated as of May 19, 2006, between the Registrant and the University of Maryland, Baltimore, as amended by First Amendment, dated as of March 3, 2009, Second Amendment, dated as of April 10, 2012, and Third Amendment, dated as of October 28, 2013
10.15+	Employment Agreement, dated as of January 30, 2014, between the Registrant and John S. McBride
10.16+	Employment Agreement, dated as of April 7, 2014, between the Registrant and Karen J. Ferrante, M.D.
10.17*	2014 Employee Stock Purchase Plan to be effective upon the closing of this offering
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)

* To be filed by amendment.
† Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.
\+ Indicates management contract or plan.

Exhibit 3.1

SEVENTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TOKAI PHARMACEUTICALS, INC.

Tokai Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the present name of the Corporation is Tokai Pharmaceuticals, Inc., a Delaware corporation.

2 That the name under which the Corporation was originally incorporated is Tokai Pharmaceuticals, Inc., and the date of filing of the Corporation's original certificate of incorporation with the Delaware Secretary of State is March 26, 2004. The Corporation's certificate of incorporation was amended and restated with the Delaware Secretary of State on April 27, 2004, May 30, 2007, October 14, 2008, May 6, 2009, November 15, 2010 and September 9, 2011.

3. That the Board of Directors duly adopted resolutions proposing to amend and restate the Sixth Amended and Restated Certificate of Incorporation of the Corporation, declaring said amendment and restatement to be advisable and in the best interests of the Corporation and its stockholders, and authorizing the appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed Seventh Amended and Restated Certificate of Incorporation is as follows:

RESOLVED, that the Sixth Amended and Restated Certificate of Incorporation of the Corporation be amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is Tokai Pharmaceuticals, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 173,018,331 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 155,586,141 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock"), of which 4,500,000 shares have been designated as Series A Convertible Preferred Stock ("Series A Preferred Stock"), 798,067 shares have been designated as Series B-1 Convertible Preferred Stock ("Series B-1 Preferred Stock"), 1,503,819 shares have been designated as Series B-2 Convertible Preferred Stock ("Series B-2 Preferred Stock," and together with the Series B-1 Preferred Stock, the "Series B Preferred Stock,"), 15,999,998 shares have been designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), 29,294,828 shares have been designated as Series D-1 Convertible Preferred Stock ("Series D-1 Preferred Stock"), 3,661,846 shares have been designated as Series D-2 Convertible Preferred Stock ("Series D-2 Preferred Stock"), 42,935,192 shares have been designated as

Series D-3 Convertible Preferred Stock ("Series D-3 Preferred Stock," and together with the Series D-1 Preferred Stock and the Series D-2 Preferred Stock, the "Series D Preferred Stock"), and 56,892,391 shares have been designated as Series E Convertible Preferred Stock ("Series E Preferred Stock"). The Series C Preferred Stock, the Series D Preferred Stock and the Series E Preferred Stock are collectively referred to as the "Senior Preferred Stock," and the Senior Preferred Stock and the Series A Preferred Stock and the Series B Preferred Stock are collectively referred to as the "Preferred Stock."

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of the Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. AUTHORIZATION OF PREFERRED STOCK

Preferred Stock may be issued from time to time in one or more series, each of such series to consist of such number of shares and to have such terms, rights, powers and preferences, and the qualifications and limitations with respect thereto, as stated or expressed herein.

C. PREFERRED STOCK

Unless otherwise indicated, references to "Sections" or "Subsections" in this Part C of this Article Fourth refer to sections and subsections of Part C of this Article Fourth.

1. Dividends.

1.1 The holders of the Senior Preferred Stock shall be entitled to receive, out of any funds legally available therefor, when and if declared by the Board of Directors, dividends at an annual rate of eight percent (8%) of the Series C Original Issue Price, Series D-1 Original Issue Price, Series D-2 Original Issue Price, Series D-3 Original Issue Price or Series E Original Issue Price (each as defined below), as applicable, per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such series of Senior Preferred Stock). The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of the Senior Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Senior Preferred Stock in an amount at least equal to the greater of (i) eight percent (8%) of the Series C Original Issue Price, Series D-1 Original Issue

Price, Series D-2 Original Issue Price, Series D-3 Original Issue Price or Series E Original Issue Price, as applicable, per share of Senior Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such series of Senior Preferred Stock) per year from and after the date of the issuance of such share of Senior Preferred Stock (to the extent not previously paid) and (ii) (A) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Senior Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of such share of Senior Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Senior Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the Series C Original Issue Price, Series D-1 Original Issue Price, Series D-2 Original Issue Price, Series D-3 Original Issue Price or Series E Original Issue Price, as applicable; provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Senior Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Senior Preferred Stock dividend. The foregoing dividend shall not be cumulative and holders of Senior Preferred Stock shall not be entitled to any accruing dividends.

1.2 The holders of the Series B Preferred Stock shall be entitled to receive, out of any funds legally available therefor, when and if declared by the Board of Directors, dividends at an annual rate of eight percent (8%) of the Series B-1 Original Issue Price or Series B-2 Original Issue Price (each as defined below), as applicable, per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such series of Series B Preferred Stock). The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock and dividends on shares of Senior Preferred Stock pursuant to Subsection 1.1 above) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of the Series B Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Series B Preferred Stock in an amount at least equal to the greater of (i) eight percent (8%) of the Series B-1 Original Issue Price or Series B-2 Original Issue Price, as applicable, per share of Series B Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such series of Series B Preferred Stock) per year from and after the date of the issuance of such share of Series B Preferred Stock (to the extent not previously paid) and (ii) (A) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Series B Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of such share of Series B Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Series B Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the Series B-1 Original Issue Price or Series B-2 Original Issue Price, as applicable; provided that, if the Corporation

declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Series B Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Series B Preferred Stock dividend. The foregoing dividend shall not be cumulative and holders of Series B Preferred Stock shall not be entitled to any accruing dividends.

1.3 The holders of the Series A Preferred Stock shall be entitled to receive, out of any funds legally available therefor, when and if declared by the Board of Directors, dividends at an annual rate of eight percent (8%) of the Series A Original Issue Price (as defined below) per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock). The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock, dividends on shares of Senior Preferred Stock pursuant to Subsection 1.1 above and dividends on shares of Series B Preferred Stock pursuant to Subsection 1.2 above) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of the Series A Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Series A Preferred Stock in an amount at least equal to the greater of (i) $0.04 per share of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) per year from and after the date of the issuance of such share of Series A Preferred Stock (to the extent not previously paid) and (ii) (A) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Series A Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of such share of Series A Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Series A Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the Series A Original Issue Price; provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Series A Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Series A Preferred Stock dividend. The foregoing dividend shall not be cumulative and holders of Series A Preferred Stock shall not be entitled to any accruing dividends.

1.4 The “Series E Original Issue Price” shall mean $0.62398475 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series E Preferred Stock. The “Series D-3 Original Issue Price” shall mean $0.54617142 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D-3 Preferred Stock. The “Series D-2 Original Issue Price” shall mean $0.54617142 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D-2 Preferred Stock. The “Series D-1 Original Issue Price” shall mean $0.54617142 per share, and the “Series D-1 Adjusted Original Issue Price” shall mean $0.5043 per share, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D-1 Preferred Stock. The “Series C Original Issue Price” shall mean $0.25 per share, and the “Series C Adjusted Original Issue Price” shall mean $0.2081 per share,

each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock. The "Series B-1 Original Issue Price" shall mean $3.383176 per share, and the "Series B-1 Adjusted Original Issue Price" shall mean $0.6581 per share, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-1 Preferred Stock. The "Series B-2 Original Issue Price" shall mean $4.365388 per share, and the "Series B-2 Adjusted Original Issue Price" shall mean $0.6581 per share, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-2 Preferred Stock. The "Series A Original Issue Price" shall mean $0.50 per share, and the "Series A Adjusted Original Issue Price" shall mean $0.6581 per share, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Senior Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Senior Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of Common Stock, Series A Preferred Stock or Series B Preferred Stock by reason of their ownership thereof, an amount equal to the Series C Adjusted Original Issue Price, the Series D-1 Adjusted Original Issue Price, the Series D-2 Original Issue Price, the Series D-3 Original Issue Price and the Series E Original Issue Price, as applicable, plus any dividends declared but unpaid on each share of Series C Preferred Stock, Series D-1 Preferred Stock, Series D-2 Preferred Stock, Series D-3 Preferred Stock or Series E Preferred Stock, as applicable. If upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Senior Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Senior Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares of Senior Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 Preferential Payments to Holders of Series B Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, after the payment of all preferential amounts required to be paid to the holders of shares of Senior Preferred Stock, but before any payment shall be made to the holders of Common Stock or Series A Preferred Stock by reason of their ownership thereof, the Series B-1 Adjusted Original Issue Price or the Series Adjusted B-2 Original Issue Price, as applicable (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock), plus any dividends declared but unpaid on each share of Series B-1 Preferred Stock or Series B-2 Preferred Stock, as applicable. If upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series B Preferred Stock the full amount to which they shall be entitled under this Subsection 2.2, the holders of shares of Series B Preferred Stock shall share ratably (after the payment of all preferential amounts required to be paid to the holders of shares of Senior Preferred Stock) in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares of Series B Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.3 Preferential Payments to Holders of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, after the payment of all preferential amounts required to be paid to the holders of shares of Senior Preferred Stock and Series B Preferred Stock, but before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, the Series A Adjusted Original Issue Price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) plus any dividends declared but unpaid on the Series A Preferred Stock. If upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A Preferred Stock the full amount to which they shall be entitled under this Subsection 2.3, the holders of shares of Series A Preferred Stock shall share ratably (after the payment of all preferential amounts required to be paid to the holders of shares of Senior Preferred Stock and Series B Preferred Stock) in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares of Series A Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.4 Distribution of Remaining Assets. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of the shares of Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock pursuant to the terms of the Certificate of Incorporation immediately prior to such dissolution, liquidation or winding up of the Corporation. The aggregate amount that a holder of a share of (i) Senior Preferred Stock is entitled to receive under Subsections 2.1 and 2.4 is hereinafter referred to as the "Senior Liquidation Amount," (ii) Series B Preferred Stock is entitled to receive under Subsections 2.2 and 2.4 is hereinafter referred to as the "Series B Liquidation Amount" and (iii) Series A Preferred Stock is entitled to receive under Subsections 2.3 and 2.4 is hereinafter referred to as the "Series A Liquidation Amount."

2.5 Deemed Liquidation Events.

2.5.1 Definition. Each of the following events shall be considered a "Deemed Liquidation Event" unless the holders of shares of Senior Preferred Stock representing at least seventy-five percent (75%) of the combined voting power of the outstanding shares of Senior Preferred Stock, voting as a single class in accordance with Subsection 3.1, elect otherwise by written notice sent to the Corporation at least three business days prior to the effective date of any such event:

(a) a merger or consolidation in which

(i) the Corporation is a constituent party or

(ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation;

except any such merger or consolidation involving the Corporation or a subsidiary in which (A) the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, a majority, by voting power, of the capital stock of

(1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation (provided that, for the purpose of this Subsection 2.5.1, all shares of Common Stock issuable upon exercise of Options (as defined below) outstanding immediately prior to such merger or consolidation or upon conversion of Convertible Securities (as defined below) outstanding immediately prior to such merger or consolidation shall be deemed to be outstanding immediately prior to such merger or consolidation and, if applicable, converted or exchanged in such merger or consolidation on the same terms as the actual outstanding shares of Common Stock are converted or exchanged) and (B) the surviving or resulting corporation (or, if the surviving or resulting corporation is a wholly owned subsidiary, its parent) does not have a class of securities that is, or has been within ninety (90) days prior to such merger or consolidation, tradable on a public market or exchange; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.5.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.5.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the "Merger Agreement") provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1, 2.2, 2.3 and 2.4.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.5.1(a)(ii) or 2.5.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within 90 days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the 90th day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the holders of shares of Senior Preferred Stock representing at least seventy-five percent (75%) of the combined voting power of the outstanding shares of Senior Preferred Stock, acting together as a single class in accordance with Subsection 3.1, so request in a written instrument delivered to the Corporation not later than 120 days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors), together with any other assets of the Corporation available for distribution to its stockholders (the "Available Proceeds"), to the extent legally available therefor, on the 150th day after such Deemed Liquidation Event, to redeem all outstanding shares of Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock at a price per share equal to the Series A Liquidation Amount, Series B Liquidation Amount and Senior Liquidation Amount, as applicable. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, (A) if the Available Proceeds are not sufficient to redeem all outstanding shares of Senior Preferred Stock, the Corporation shall redeem, prior to any redemption of any Series A Preferred Stock or Series B Preferred Stock, a pro rata portion of each holder's shares of Senior Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts that would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall

redeem the remaining shares of Senior Preferred Stock to have been redeemed as soon as practicable after the Corporation has funds legally available therefor, (B) if the Available Proceeds are not sufficient (after redemption of all the shares of Senior Preferred Stock as provided in clause A above) to redeem all outstanding shares of Series B Preferred Stock (after the redemption of the Senior Preferred Stock as provided in clause A above), the Corporation shall redeem, prior to any redemption of any Series A Preferred Stock, a pro rata portion of each holder's shares of Series B Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts that would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares of Series B Preferred Stock to have been redeemed as soon as practicable after the Corporation has funds legally available therefor and (C) if the Available Proceeds are not sufficient (after redemption of all the shares of Senior Preferred Stock and Series B Preferred Stock) to redeem all outstanding shares of Series A Preferred Stock, the Corporation (after the redemption of the Senior Preferred Stock as provided in clause A above and the Series B Preferred Stock as provided in clause B above) shall redeem a pro rata portion of each holder's shares of Series A Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts that would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares of Series A Preferred Stock to have been redeemed as soon as practicable after the Corporation has funds legally available therefor. The provisions of Subsections 6.2 through 6.4 shall apply, with such necessary changes in the details thereof as are necessitated by the context, to the redemption of the Senior Preferred Stock, Series B Preferred Stock and Series A Preferred Stock pursuant to this Subsection 2.5.2(b). Prior to the distribution or redemption provided for in this Subsection 2.5.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

2.5.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. The value of such property, rights or securities shall be determined in good faith by the Board of Directors.

2.5.4 Allocation of Escrow. In the event of a Deemed Liquidation Event pursuant to Subsection 2.5.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is placed into escrow and/or is payable to the stockholders of the Corporation subject to contingencies, the Merger Agreement shall provide that (a) the portion of such consideration that is not placed in escrow and not subject to any contingencies (the "Initial Consideration") shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1, 2.2, 2.3 and 2.4 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event and (b) any additional consideration which becomes payable to the stockholders of the Corporation upon release from escrow or satisfaction of contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1, 2.2, 2.3 and 2.4 after taking into account the previous payment of the Initial Consideration as part of the same transaction.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), (i) each holder of outstanding shares of Series A Preferred Stock, Series B Preferred Stock, Series D Preferred Stock and Series E Preferred Stock, respectively, shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of

Series A Preferred Stock, Series B Preferred Stock, Series D Preferred Stock and Series E Preferred Stock, as applicable, held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter and (ii) except as otherwise expressly provided in the Certificate of Incorporation, each holder of outstanding shares of Series C Preferred Stock shall be entitled to cast 0.45773175 of a vote for each share of Common Stock into which the shares of Series C Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, holders of these series of Preferred Stock shall vote together with the holders of Common Stock as a single class.

3.2 Election of Directors.

(a) The holders of record of the shares of Senior Preferred Stock, exclusively and voting as a single class in accordance with Subsection 3.1, shall be entitled to elect four (4) directors of the Corporation (the "Senior Preferred Directors"). Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the Senior Preferred Stock, given either at a special meeting of the holders of the Senior Preferred Stock duly called for that purpose or pursuant to a written consent of the holders of the Senior Preferred Stock. If the holders of shares of Senior Preferred Stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors pursuant to the first sentence of this Subsection 3.2(a), then any directorship not so filled shall remain vacant until such time as the holders of the Senior Preferred Stock or any remaining Senior Preferred Directors elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the holders of the Senior Preferred Stock or by any remaining Senior Preferred Directors.

(b) The holders of record of the shares of Preferred Stock and Common Stock (collectively, the "Capital Stock"), exclusively and voting together as a single class in accordance with Section 3.1, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing such directors, the presence in person or by proxy of the holders of a majority of the outstanding shares of the Capital Stock shall constitute a quorum for the purpose of electing such director. A vacancy in any directorship filled by the holders of the Capital Stock shall be filled only by vote or written consent in lieu of a meeting of the holders of the Capital Stock or by any remaining director or directors elected by the holders of the Capital Stock pursuant to this Subsection 3.2(b).

3.3 Senior Preferred Stock Protective Provisions. At any time when shares of Senior Preferred Stock representing at least ten percent (10%) of the maximum number of shares of Senior Preferred Stock ever issued (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such shares) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of shares representing at least seventy-five percent (75%) of the combined voting power of the then outstanding shares of Senior Preferred Stock, voting as a single class in accordance with Subsection 3.1, given in writing or by vote at a meeting; provided, however, that no written consent or vote of the holders of shares of Senior Preferred Stock shall be required hereunder with respect to any action if such action is undertaken as a condition to or as part of a Qualified Liquidation Event (as defined in Section 3.6):

(a) liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any Deemed Liquidation Event, or consent to any of the foregoing;

(b) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (i) redemptions of or dividends or distributions on the Preferred Stock as expressly authorized herein, (ii) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, and (iii) repurchases of stock from former employees, officers, directors or consultants of the Corporation or any subsidiary in connection with the cessation of such employment or engagement pursuant to the terms of any stock option or restricted stock agreement;

(c) acquire the stock or all or a substantial portion of the assets of any other entity for aggregate consideration that exceeds $300,000;

(d) incur indebtedness, including guaranties, letters of credit and capital leases by the Corporation, in excess of $200,000, in the aggregate, or enter into a material amendment to any instrument, document or agreement evidencing such indebtedness;

(e) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation;

(f) engage in a transaction with any holder of Senior Preferred Stock or any of their respective affiliates; provided, however, that this Subsection 3.3(f) shall not apply to (i) a financing transaction involving the issuance or sale of securities of the Corporation by the Corporation in which the holders of Senior Preferred Stock are offered rights to participate in accordance with the preemptive rights afforded to the holders of Senior Preferred Stock under Section 3 of the Fifth Amended and Restated Stockholders' Agreement, dated May 10, 2013, among the Corporation and the stockholders named therein, as amended from time to time (the "Stockholders Agreement"), and (ii) any compensation arrangement for any officer or director of the Corporation, including the issuance of restricted stock or stock options;

(g) create, or authorize the creation of, or issue or obligate itself to issue shares of, any new class or series of capital stock or increase the authorized number of shares of any class or series of capital stock;

(h) sell, lease, transfer, license or otherwise dispose of, in a single transaction or series of related transactions, any material intellectual property rights of the Corporation, other than non-exclusive licenses entered into in the ordinary course of business; or

(i) increase or decrease the size of the Board in a manner that is not contemplated by the Stockholders Agreement.

3.4 Series B Preferred Stock Protective Provisions. At any time when shares of Series B Preferred Stock representing at least ten percent (10%) of the maximum number of shares of Series B Preferred Stock ever issued (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class:

(a) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation in a manner that materially and adversely affects the powers,

preferences or rights of the Series B Preferred Stock in a manner unique to the Series B Preferred Stock; or

(b) increase or decrease the total number of authorized shares of Series B Preferred Stock.

3.5 Series A Preferred Stock Protective Provisions. At any time when at least 450,000 shares of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series A Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class:

(a) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation in a manner that materially and adversely affects the powers, preferences or rights of the Series A Preferred Stock in a manner unique to the Series A Preferred Stock; or

(b) increase or decrease the total number of authorized shares of Series A Preferred Stock.

3.6 Qualified Liquidation Event. A "Qualified Liquidation Event" means a Deemed Liquidation Event (a) that results in a total per share payment upon the closing of a Deemed Liquidation Event (including any amounts deposited into escrow) to holders of Series D-1 Preferred Stock of at least five (5) times the Series D-1 Adjusted Original Issue Price, a per share payment to the holders of Series D-2 Preferred Stock of at least five (5) times the Series D-2 Original Issue Price, a per share payment to the holders of Series D-3 Preferred Stock of at least five (5) times the Series D-3 Original Issue Price and a per share payment to the holders of Series E Preferred Stock of at least five (5) times the Series E Original Issue Price (b) in which the other party to the Deemed Liquidation Event is not a holder of Senior Preferred Stock or an affiliate of such holder and (c) that is approved by the Board of Directors, including at least two Senior Preferred Directors and either (i) at least two Independent Directors (as defined in the Stockholders Agreement) or (ii) all of the Independent Directors then serving on the Board of Directors. For purposes of this Certificate of Incorporation, the term "affiliate" with respect to a holder of Senior Preferred Stock means any person, entity or firm which, directly or indirectly, controls, is controlled by or is under common control with such holder and shall also include (I) any investment fund now or hereafter existing which is controlled by or under common control with one or more general partners of the holder or any individual controlling such general partner or which shares the same management company with such holder (an "Affiliated Fund"), (II) any entity of which the holder or Affiliated Fund is a partner, member or stockholder (other than through the ownership of 2% or less of the equity of an entity that is publicly traded), (III) any entity that has (or whose management company, if any, has) an officer, director or general partner that is an officer, director or general partner of the holder or an Affiliated Fund (an "Affiliated Entity"), and (IV) any partner, officer, director, member, stockholder, consultant or employee of the holder, an Affiliated Fund or an Affiliated Entity.

4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the "Conversion Rights"):

4.1 Right to Convert.

4.1.1 Conversion Ratio.

(a) Each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series A Original Issue Price by the Series A Conversion Price (as defined below) in effect at the time of conversion. As of the Series E Original Issue Date (as defined below), the "Series A Conversion Price" shall be equal to $0.50. Such Series A Conversion Price, and the rate at which shares of Series A Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(b) Each share of Series B Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing $0.54617142 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock) by the Series B Conversion Price (as defined below) in effect at the time of conversion. As of the Series E Original Issue Date, the "Series B Conversion Price" shall be equal to $0.54617142. Such Series B Conversion Price, and the rate at which shares of Series B Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(c) Each share of Series C Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series C Original Issue Price by the Series C Conversion Price (as defined below) in effect at the time of conversion. As of the Series E Original Issue Date, the "Series C Conversion Price" shall be equal to $0.25. Such Series C Conversion Price, and the rate at which shares of Series C Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(d) Each share of Series D-1 Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series D-1 Original Issue Price by the Series D-1 Conversion Price in effect at the time of conversion. As of the Series E Original Issue Date, the "Series D-1 Conversion Price" shall be equal to $0.54617142. Such Series D-1 Conversion Price, and the rate at which shares of Series D-1 Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(e) Each share of Series D-2 Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series D-2 Original Issue Price by the Series D-2 Conversion Price in effect at the time of conversion. As of the Series E Original Issue Date, the "Series D-2 Conversion Price" shall be equal to $0.54617142. Such Series D-2 Conversion Price, and the rate at which shares of Series D-2 Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(f) Each share of Series D-3 Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series D-3 Original Issue Price by the Series D-3 Conversion Price in effect at the time of conversion. As of the Series E Original Issue Date, the "Series D-3 Conversion Price" shall be equal to $0.54617142. Such Series D-3 Conversion Price, and the rate at which shares of Series D-3 Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(g) Each share of Series E Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Series E Original Issue Price by the Series E Conversion Price in effect at the time of conversion. As of the Series E Original Issue Date, the "Series E Conversion Price" shall be equal to $0.62398475. Such Series E Conversion Price, and the rate at which shares of Series E Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.1.2 Termination of Conversion Rights. In the event of a notice of redemption of any shares of Preferred Stock pursuant to Section 6, the Conversion Rights of the shares designated for redemption shall terminate at the close of business on the last full day preceding the date fixed for redemption, unless the redemption price is not fully paid on such redemption date, in which case the Conversion Rights for such shares shall continue until such price is paid in full. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.

4.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent), together with written notice that such holder elects to convert all or any number of the shares of the Preferred Stock represented by such certificate or certificates and, if applicable, any event on which such conversion is contingent. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of Common Stock to be issued. If required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing.

The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such certificates (or lost certificate affidavit and agreement) and notice shall be the time of conversion (the "Conversion Time"), and the shares of Common Stock issuable upon conversion of the shares represented by such certificate shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time, issue and deliver to such holder of Preferred Stock, or to such holder's nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof, a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, and cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and payment of any declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when any Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Certificate of Incorporation. Before taking any action that would cause an adjustment reducing the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of such series of Preferred Stock, the Corporation will take any corporate action that may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and nonassessable shares of Common Stock at such adjusted Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable.

4.3.3 Effect of Conversion. All shares of Preferred Stock that shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of the applicable series of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so

converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) "Option" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(b) "Series E Original Issue Date" shall mean the date on which the first share of Series E Preferred Stock was issued.

(c) "Convertible Securities" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) "Additional Shares of Common Stock" shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3, deemed to be issued) by the Corporation after the Series E Original Issue Date, other than the following shares of Common Stock, and shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (collectively "Exempted Securities"):

(i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on any shares of Preferred Stock;

(ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8;

(iii) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to the Corporation's 2007 Stock Incentive Plan;

(iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;

(v) shares of Common Stock offered to the public pursuant to a Qualified Public Offering; or

(vi) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other

financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing, real property leasing or technology acquisition transaction approved by the Board of Directors of the Corporation, including at least three Senior Preferred Directors.

4.4.2 No Adjustment of Conversion Price. No adjustment in the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as the case may be, shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of (a) a majority of the then outstanding shares of Series A Preferred Stock, (b) a majority of the then outstanding shares of Series B-1 Preferred Stock, (c) a majority of the then outstanding shares of Series B-2 Preferred Stock, (d) at least sixty percent (60%) of the then outstanding shares of Series C Preferred Stock, (e) at least seventy-five percent (75%) of the then outstanding shares of Series D-1 Preferred Stock, (f) at least seventy-five percent (75%) of the then outstanding shares of Series D-2 Preferred Stock, (g) at least seventy-five percent (75%) of the then outstanding shares of Series D-3 Preferred Stock and (h) at least sixty-five percent (65%) of the then outstanding shares of Series E Preferred Stock, as applicable, agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series E Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities that are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as the case may be, pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti- dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price, or Series E Conversion Price, as applicable, computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto), shall be readjusted to such Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable, as would have obtained had such revised terms been in effect upon the

original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of (1) increasing the Series A Conversion Price to an amount that exceeds the lower of (i) the Series A Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series A Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date, (2) increasing the Series B Conversion Price to an amount that exceeds the lower of (i) the Series B Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series B Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date, (3) increasing the Series C Conversion Price to an amount that exceeds the lower of (i) the Series C Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series C Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date, (4) increasing the Series D-1 Conversion Price to an amount that exceeds the lower of (i) the Series D-1 Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series D-1 Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date, (5) increasing the Series D-2 Conversion Price to an amount that exceeds the lower of (i) the Series D-2 Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series D-2 Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date, (6) increasing the Series D-3 Conversion Price to an amount that exceeds the lower of (i) the Series D-3 Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series D-3 Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date or (7) increasing the Series E Conversion Price to an amount that exceeds the lower of (i) the Series E Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series E Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities that are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as the case may be, pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable, then in effect, or because such Option or

Convertible Security was issued before the Series E Original Issue Date), are revised after the Series E Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) that resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price pursuant to the terms of Subsection 4.4.4, the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable, shall be readjusted to such Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as so adjusted, as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as the case may be, provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable, that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price Upon Issuance of Additional Shares of Common Stock.

(a) In the event the Corporation shall at any time after the Series E Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price in effect immediately prior to such issue, then each applicable Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = (CP_1 * (A + B)) \div (A + C)$$

For purposes of the foregoing formula, the following definitions shall apply:

(i) "CP_2" shall mean the applicable Conversion Price in effect immediately after such issue of Additional Shares of Common Stock;

(ii) "CP_1" shall mean the applicable Conversion Price in effect immediately prior to such issue of Additional Shares of Common Stock;

(iii) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(iv) "B" shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by the Series A Conversion Price, Series B Conversion Price, Series C Conversion Price, Series D-1 Conversion Price, Series D-2 Conversion Price, Series D-3 Conversion Price or Series E Conversion Price, as applicable); and

(v) "C" shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

(i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;

(ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation; and

(iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration that covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation.

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

(i) the total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of

such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price or the Series E Conversion Price, as the case may be, pursuant to the terms of Subsection 4.4.4, and such issuance dates occur within a period of no more than 90 days from the first such issuance to the final such issuance, then, upon the final such issuance, the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price or the Series E Conversion Price, as applicable, shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series E Original Issue Date effect a subdivision of the outstanding Common Stock, the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of each such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series E Original Issue Date combine the outstanding shares of Common Stock, the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series E Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price, respectively, then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such

issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing, (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price, respectively, shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) no such adjustment shall be made if the holders of Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, as the case may be, simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, respectively, had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series E Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock, as the case may be, shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock, respectively, had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.5, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, as the case may be) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock, as applicable, shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property that a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock, as applicable, immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock, as applicable, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any

securities or other property thereafter deliverable upon the conversion of the Series A Preferred Stock, Series B Preferred Stock and Senior Preferred Stock.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price or the Series E Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than 10 days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, as applicable, a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, as applicable, is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than 10 days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Series A Conversion Price, the Series B Conversion Price, the Series C Conversion Price, the Series D-1 Conversion Price, the Series D-2 Conversion Price, the Series D-3 Conversion Price and the Series E Conversion Price, as applicable, then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property that then would be received upon the conversion of Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock, as applicable.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of any series of Preferred Stock) fix the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Series A Preferred Stock, Series B Preferred Stock or Senior Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Series A Preferred Stock, the Series B Preferred Stock, the Senior Preferred Stock and the Common Stock. Such notice shall be sent at least 10 days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, (i) at a price per share to the public, which when multiplied by the total number of shares of Common Stock then outstanding or then issuable upon conversion of outstanding Preferred Stock immediately prior to the consummation of the offering, exceeds $75,000,000 and (ii) which results in at least $40,000,000 of gross proceeds to the Corporation (a "Qualified Public Offering") or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of shares of the Senior Preferred Stock, representing at least seventy-five percent (75%) of the combined voting power of the outstanding shares of the Senior Preferred Stock, voting together as a single class in accordance with Section 3.1 (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Mandatory Conversion Time"), (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate for each series of Preferred Stock and (ii) such shares may not be reissued by the Corporation.

5.2 Procedural Requirements. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer; in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender the certificates for such shares at or prior to such time), except only the rights of the holders thereof, upon surrender of their certificate or certificates (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and the surrender of the certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof, together with cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

5.3 Special Mandatory Conversion. In the event that:

(a) pursuant to Section 2.2 or Section 2.3 of the Series E Convertible Preferred Stock Purchase Agreement, dated on or about the date of filing of this Seventh Amended and Restated Certificate of Incorporation, among the Corporation and the purchasers of Series E Preferred Stock named therein (the "Purchase Agreement"), the Corporation issues and sells additional shares of

Series E Preferred Stock at the Second Closing or the Third Closing, as the case may be (each as defined in the Purchase Agreement) (each a "Mandatory Offering");

(b) the Corporation shall have delivered a written notice to each Purchaser (as defined in the Purchase Agreement): (i) stating that the Corporation will be issuing and selling additional shares of Series E Preferred Stock in such Mandatory Offering and (ii) indicating the number of shares of Series E Preferred Stock that such Purchaser is obligated to purchase at such Mandatory Offering pursuant to the Purchase Agreement (the "Allocated Shares"); and

(c) such Purchaser does not purchase his, her or its Allocated Shares at such Mandatory Offering (such Purchaser being referred to herein as a "Non-Participating Purchaser"),

then, upon the closing of such Mandatory Offering (the "Special Mandatory Conversion Time"), all shares of Preferred Stock held by such Non-Participating Purchaser shall automatically and without further action on the part of the Corporation or such Non-Participating Purchaser be converted into one-tenth ($1/10^{th}$) the number of shares of Common Stock into which such shares of Preferred Stock are then otherwise convertible (a "Special Mandatory Conversion"). Each Non-Participating Purchaser shall surrender his, her or its certificate or certificates for all such shares of Preferred Stock (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer; in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to this Subsection 5.3, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Special Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender the certificates for such shares at or prior to such time), except only the rights of the holders thereof, upon surrender of their certificate or certificates (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.3. As soon as practicable after the Special Mandatory Conversion Time and the surrender of the certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof, together with cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D-1 Preferred Stock, Series D-2 Preferred Stock, Series D-3 Preferred Stock or Series E Preferred Stock, as applicable, accordingly.

6. Redemption.

6.1 Redemption.

6.1.1 Shares of Senior Preferred Stock shall be redeemed by the Corporation out of funds lawfully available therefor at a price equal to the Series C Adjusted Original Issue Price, Series D-1 Adjusted Original Issue Price, Series D-2 Original Issue Price, Series D-3 Original Issue Price or Series E Original Issue Price, as applicable, plus any dividends declared but unpaid thereon

(the "Senior Redemption Price"), in three annual installments commencing 60 days after receipt of a written notice by the Corporation at any time on or after May 10, 2018, from the holders of shares of Senior Preferred Stock representing at least seventy-five percent (75%) of the combined voting power of the outstanding Senior Preferred Stock, voting as a single class in accordance with Subsection 3.1, which notice requests redemption of all shares of Senior Preferred Stock (the date of each such installment being referred to as a "Senior Preferred Redemption Date").

6.1.2 Shares of Series A Preferred Stock and Series B Preferred Stock shall be redeemed by the Corporation out of funds lawfully available therefor at a price equal to $0.6581 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock or the Series B Preferred Stock, as applicable) plus any dividends declared but unpaid thereon (the "Series A/B Redemption Price", and together with the Senior Redemption Price, the "Redemption Price"), in three annual installments commencing 60 days after receipt of a written notice by the Corporation at any time on or after May 10, 2018, from the holders of shares of Series A Preferred Stock and Series B Preferred Stock representing at least sixty percent (60%) of the combined voting power of the outstanding Series A Preferred Stock and Series B Preferred Stock, voting as a single class, which notice requests redemption of all shares of Series A Preferred Stock and Series B Preferred Stock (the date of each such installment being referred to as a "Series A/B Redemption Date" and collectively with the Senior Preferred Redemption Date, the "Redemption Dates").

6.1.3 On each Redemption Date, the Corporation shall redeem, on a pro rata basis in accordance with the number of shares of each series of Preferred Stock owned by each holder, that number of outstanding shares of such series of Preferred Stock determined by dividing (i) the total number of shares of such series of Preferred Stock outstanding immediately prior to such Redemption Date by (ii) the number of remaining Redemption Dates (including the Redemption Date to which such calculation applies). Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, (A) if the Corporation does not have sufficient funds legally available to redeem on any Redemption Date all shares of Senior Preferred Stock to be redeemed on such Redemption Date, the Corporation shall redeem on such Redemption Date a pro rata portion of each holder's shares of Senior Preferred Stock to the fullest extent of such funds, based on the respective amounts that would otherwise be payable in respect of the shares to be redeemed if the legally available funds were sufficient to redeem all such shares, and shall redeem the remaining shares of Senior Preferred Stock to have been redeemed on such Redemption Date as soon as practicable after the Corporation has funds legally available therefor, (B) the Corporation shall not redeem any shares of Series A Preferred Stock or Series B Preferred Stock unless and until (x) all shares of Senior Preferred Stock then outstanding have been redeemed pursuant to this Section 6 or (y) the Corporation has sufficient funds legally available, reserved and set aside to redeem all shares of Senior Preferred Stock then outstanding at the applicable Redemption Price, and (C) if the Corporation does not have sufficient funds legally available to redeem on any Redemption Date all shares of Series A Preferred Stock and Series B Preferred Stock to be redeemed on such Redemption Date (after giving effect to the preceding clause (B)), the Corporation shall redeem on such Redemption Date, a pro rata portion of each holder's shares of Series A Preferred Stock and Series B Preferred Stock to the fullest extent of such funds, based on the respective amounts that would otherwise be payable in respect of the shares to be redeemed if the legally available funds were sufficient to redeem all such shares, and shall redeem the remaining shares of Series A Preferred Stock and Series B Preferred Stock to have been redeemed as soon as practicable after the Corporation has funds legally available therefor.

6.2 Redemption Notice. Written notice of a mandatory redemption (the "Redemption Notice") shall be sent to each holder of record of Series A Preferred Stock and Series B Preferred Stock or Senior Preferred Stock, as applicable, not less than 40 days prior to each Redemption Date. Each Redemption Notice shall state:

(a) the number of shares of Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice;

(b) the Redemption Date and the Redemption Price for shares of Preferred Stock to be redeemed;

(c) the date upon which the holder's right to convert such shares terminates (as determined in accordance with Subsection 4.1); and

(d) that the holder is to surrender to the Corporation, in the manner and at the place designated, such holder's certificate or certificates representing the shares of Preferred Stock to be redeemed.

6.3 Surrender of Certificates; Payment. On or before the applicable Redemption Date, each holder of shares of Preferred Stock to be redeemed on such Redemption Date, unless such holder has exercised such holder's right to convert such shares as provided in Section 4, shall surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the Redemption Price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder .

6.4 Rights Subsequent to Redemption. If the Redemption Notice shall have been duly given, and if on the applicable Redemption Date the Redemption Price payable upon redemption of the shares of Preferred Stock to be redeemed on such Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor, then notwithstanding that the certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of their certificate or certificates therefor.

7. Redeemed or Otherwise Acquired Shares. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

8. Waiver. Any of the rights, powers, preferences and other terms of the Series A Preferred Stock set forth herein may be waived on behalf of all holders of Series A Preferred Stock by the affirmative written consent or vote of the holders of a majority of the shares of Series A Preferred Stock then outstanding. Any of the rights, powers, preferences and other terms of the Series B Preferred Stock set forth herein may be waived on behalf of all holders of Series B Preferred Stock by the affirmative written consent or vote of the holders of a majority of the shares of Series B Preferred Stock then outstanding. Any of the rights, powers, preferences and other terms of the Senior Preferred Stock set forth herein may be waived on behalf of all holders of Senior Preferred Stock by the affirmative written consent or vote of the holders of at least seventy-five percent (75%) of the combined voting power of the

shares of Senior Preferred Stock then outstanding, voting as a single class in accordance with Subsection 3.1.

9. Preemptive Rights. Each holder of Preferred Stock shall be entitled to the preemptive rights provided for in Section 3 of the Stockholders Agreement on, and subject to, the terms set forth therein to the extent that such holder is a party to the Stockholders Agreement and entitled to such preemptive rights thereunder.

10. Notices. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: In furtherance of and not in limitation of powers conferred by statute, it is further provided:

A. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

B. Election of directors need not be by written ballot.

C. The Board of Directors is expressly authorized to adopt, amend, alter or repeal the Bylaws of the Corporation.

SIXTH: Except to the extent that the General Corporation Law of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment.

SEVENTH: The Corporation shall provide indemnification as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the

Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) that the Court of Chancery of Delaware shall deem proper.

3. Indemnification for Expenses of Successful Party. Notwithstanding any other provisions of this Article, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article SEVENTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith.

4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not

be required to indemnify Indemnitee under this Article SEVENTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner that would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

5. Advance of Expenses. Subject to the provisions of Section 6 of this Article SEVENTH, in the event of any action, suit, proceeding or investigation of which the Corporation receives notice under this Article, any expenses (including attorneys' fees) incurred by or on behalf of an Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article; and further provided that no such advancement of expenses shall be made under this Article SEVENTH if it is determined (in the manner described in Section 6) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article SEVENTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article SEVENTH (and none of the circumstances described in Section 4 of this Article SEVENTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article SEVENTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. The right to indemnification or advancement of expenses as granted by this Article shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article SEVENTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation.

8. Limitations. Notwithstanding anything to the contrary in this Article, except as set forth in Section 7 of this Article SEVENTH, the Corporation shall not indemnify an Indemnitee pursuant to this Article SEVENTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. Notwithstanding anything to the contrary in this Article, the Corporation shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, Indemnitee shall promptly refund such indemnification payments to the Corporation to the extent of such insurance reimbursement.

9. Subsequent Amendment. No amendment, termination or repeal of this Article or of the relevant provisions of the General Corporation Law of Delaware or any other applicable laws shall affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

10. Corporate Opportunity. Pursuant to Section 122(17) of the General Corporation Law of Delaware, the Corporation renounces any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "Excluded Opportunity" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee or consultant of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, "Covered Persons"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in connection with such Covered Person's capacity as a director of the Corporation.

11. Other Rights. The indemnification and advancement of expenses provided by this Article shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article.

12. Partial Indemnification. If an Indemnitee is entitled under any provision of this Article to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), judgments, fines or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), judgments, fines or amounts paid in settlement to which Indemnitee is entitled.

13. Insurance. The Corporation shall purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation,

partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him in any such capacity, or arising out of his status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of Delaware.

14. Savings Clause. If this Article or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), judgments, fines and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article that shall not have been invalidated and to the fullest extent permitted by applicable law.

15. Definitions. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

EIGHTH: The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Seventh Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Seventh Amended and Restated Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

* * *

4. That this Seventh Amended and Restated Certificate of Incorporation was approved by the holders of the requisite number of shares of the Corporation in accordance with Section 228 of the General Corporation Law.

5. That this Seventh Amended and Restated Certificate of Incorporation has been duly adopted in accordance with Section 242 and 245 of the General Corporation Law.

[Signature page follows]

IN WITNESS WHEREOF, this Seventh Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of the Corporation on this 10th day of May, 2013.

By: /s/ Jodie P. Morrison
Jodie P. Morrison
Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
SEVENTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
TOKAI PHARMACEUTICALS, INC.

Pursuant to Section 242
of the General Corporation Law of
the State of Delaware

Tokai Pharmaceuticals, Inc. (hereinafter called the "Corporation"), organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

The Board of Directors of the Corporation (hereinafter called the "Board"), acting in accordance with Section 242 of the General Corporation Law of the State of Delaware, duly adopted a resolution at a meeting of the Board of Directors setting forth an amendment to the Corporation's Seventh Amended and Restated Certificate of Incorporation, (the "Certificate of Incorporation"), and declaring said amendment to be advisable. Said amendment has been duly approved by the written consent of the Corporation's stockholders in accordance with Sections 228 and 242 of the General Corporation Law of the State of Delaware. The resolution setting forth the amendment to the Certificate of Incorporation is as follows:

RESOLVED: That the Certificate of Incorporation be and hereby is amended by deleting the first paragraph of Article FOURTH in its entirety and substituting therefor the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 177,408,438 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 155,586,141 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock"), of which 4,500,000 shares have been designated as Series A Convertible Preferred Stock ("Series A Preferred Stock"), 798,067 shares have been designated as Series B-l Convertible Preferred Stock ("Series B-l Preferred Stock"), 1,503,819 shares have been designated as Series B-2 Convertible Preferred Stock ("Series B-2 Preferred Stock," and together with the Series B-l Preferred Stock, the "Series B Preferred Stock,"), 15,999,998 shares have been designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), 29,294,828 shares have been designated as Series D-l Convertible Preferred Stock ("Series D-l Preferred Stock"), 3,661,846 shares have been designated as Series D-2 Convertible Preferred Stock ("Series D-2 Preferred Stock"), 42,935,192 shares have been designated as Series D-3 Convertible Preferred Stock ("Series D-3 Preferred Stock," and together with the Series D-l Preferred Stock and the Series D-2 Preferred Stock, the "Series D Preferred Stock"), and 56,892,391 shares have been designated as Series E Convertible Preferred Stock ("Series E Preferred Stock"). The Series C Preferred Stock, the Series D Preferred Stock and the Series E Preferred Stock are collectively referred to as the "Senior Preferred Stock," and the Senior Preferred Stock and the Series A Preferred Stock and the Series B Preferred Stock are collectively referred to as the "Preferred Stock."

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation to be signed by its Chief Executive Officer on this 27th day of February, 2014.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie P. Morrison
By: Jodie P. Morrison
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT
OF
SEVENTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
TOKAI PHARMACEUTICALS, INC.

Pursuant to Section 242
of the General Corporation Law of
the State of Delaware

Tokai Pharmaceuticals, Inc. (hereinafter called the "Corporation"), organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

The Board of Directors of the Corporation (hereinafter called the "Board"), acting in accordance with Section 242 of the General Corporation Law of the State of Delaware, duly adopted a resolution at a meeting of the Board of Directors setting forth an amendment to the Corporation's Seventh Amended and Restated Certificate of Incorporation, (the "Certificate of Incorporation"), and declaring said amendment to be advisable. Said amendment has been duly approved by the written consent of the Corporation's stockholders in accordance with Sections 228 and 242 of the General Corporation Law of the State of Delaware. The resolution setting forth the amendment to the Certificate of Incorporation is as follows:

RESOLVED: That the Certificate of Incorporation be and hereby is amended by deleting the first paragraph of Article FOURTH in its entirety and substituting therefor the following:

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 178,408,438 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 155,586,141 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock"), of which 4,500,000 shares have been designated as Series A Convertible Preferred Stock ("Series A Preferred Stock"), 798,067 shares have been designated as Series B-1 Convertible Preferred Stock ("Series B-1 Preferred Stock"), 1,503,819 shares have been designated as Series B-2 Convertible Preferred Stock ("Series B-2 Preferred Stock," and together with the Series B-1 Preferred Stock, the "Series B Preferred Stock,"), 15,999,998 shares have been designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), 29,294,828 shares have been designated as Series D-1 Convertible Preferred Stock ("Series D-1 Preferred Stock"), 3,661,846 shares have been designated as Series D-2 Convertible Preferred Stock ("Series D-2 Preferred Stock"), 42,935,192 shares have been designated as Series D-3 Convertible Preferred Stock ("Series D-3 Preferred Stock," and together with the Series D-1 Preferred Stock and the Series D-2 Preferred Stock, the "Series D Preferred Stock"), and 56,892,391 shares have been designated as Series E Convertible Preferred Stock ("Series E Preferred Stock"). The Series C Preferred Stock, the Series D Preferred Stock and the Series E Preferred Stock are collectively referred to as the "Senior Preferred Stock," and the Senior Preferred Stock and the Series A Preferred Stock and the Series B Preferred Stock are collectively referred to as the "Preferred Stock."

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation to be signed by its Chief Executive Officer on this 17th day of April, 2014.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie P. Morrison
Name: Jodie P. Morrison
Title: Chief Executive Officer

Exhibit 3.3

AMENDED AND RESTATED BY-LAWS
OF
TOKAI PHARMACEUTICALS, INC.

TABLE OF CONTENTS

ARTICLE I

STOCKHOLDERS

1.1 Place of Meetings. All meetings of stockholders shall be held at such place as may be designated from time to time by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President or, if not so designated, at the principal office of the corporation. The Board of Directors may, in its sole discretion, determine that a meeting shall not be held at any place, but may instead be held solely by means of remote communication in a manner consistent with the General Corporation Law of the State of Delaware.

1.2 Annual Meeting. The annual meeting of stockholders for the election of directors and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President (which date shall not be a legal holiday in the place where the meeting is to be held).

1.3 Special Meetings. Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President, and may not be called by any other person or persons. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

1.4 Notice of Meetings. Except as otherwise provided by law, notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. Without limiting the manner by which notice otherwise may be given to stockholders, any notice shall be effective if given by a form of electronic transmission consented to (in a manner consistent with the General Corporation Law of the State of Delaware) by the stockholder to whom the notice is given. The notices of all meetings shall state the place , if any, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called. If notice is given by mail, such notice shall be deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If notice is given by electronic transmission, such notice shall be deemed given at the time specified in Section 232 of the General Corporation Law of the State of Delaware.

1.5 Voting List. The Secretary shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. If the meeting is to be held at a physical location (and not solely by means of remote communication), then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the

information required to access such list shall be provided with the notice of the meeting. The list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

1.6 Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these By-laws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

1.7 Adjournments. Any meeting of stockholders may be adjourned from time to time to any other time and to any other place at which a meeting of stockholders may be held under these By-laws by the chairman of the meeting or by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place, if any, of the adjourned meeting, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting.

1.8 Voting and Proxies. Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders, or to express consent or dissent to corporate action without a meeting, may vote or express such consent or dissent in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote or act for such stockholder by a proxy executed or transmitted in a manner permitted by the General Corporation Law of the State of Delaware by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted or acted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.

1.9 Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented at the meeting and voting affirmatively or negatively on such matter), except when a different vote is required by law, the Certificate of Incorporation or these By-laws. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

1.10 Conduct of Meetings.

(a) Chairman of Meeting. Meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in the Chairman's absence by the Vice Chairman of the Board, if any, or in the Vice Chairman's absence by the Chief Executive Officer, or in the Chief Executive Officer's absence, by the President, or in the President's absence by a Vice President, or in the absence of all of the foregoing persons by a chairman designated by the Board of Directors, or in the absence of such designation by a chairman chosen by vote of the stockholders at the meeting. The Secretary shall act as secretary of the meeting, but in the Secretary's absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

(b) Rules, Regulations and Procedures. The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem appropriate including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

1.11 Action without Meeting.

(a) Taking of Action by Consent. Any action required or permitted to be taken at any annual or special meeting of stockholders of the corporation may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote on such action were present and voted. Except as otherwise provided by the Certificate of Incorporation, stockholders may act by written consent to elect directors; provided, however, that, if such consent is less than unanimous, such action by written consent may be in lieu of holding an annual meeting only if all of the directorships to which directors could be elected at an annual meeting held at the effective time of such action are vacant and are filled by such action.

(b) Electronic Transmission of Consents. A telegram, cablegram or other electronic transmission consenting to an action to be taken and transmitted by a stockholder or proxyholder, or by a person or persons authorized to act for a stockholder or proxyholder, shall be deemed to be written, signed and dated for the purposes of this section, provided that any such telegram, cablegram or other electronic transmission sets forth or is delivered with information from which the corporation can determine (i) that the telegram, cablegram or other electronic transmission was transmitted by the stockholder or proxyholder or by a person or persons authorized to act for the stockholder or proxyholder and (ii) the date on which such stockholder or proxyholder or authorized person or persons transmitted such telegram, cablegram or electronic transmission. The date on which such telegram, cablegram or electronic transmission is transmitted shall be deemed to be the date on which such consent was signed. No consent given by telegram, cablegram or other electronic transmission shall be deemed to have been

delivered until such consent is reproduced in paper form and until such paper form shall be delivered to the corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be made by hand or by certified or registered mail, return receipt requested. Notwithstanding the foregoing limitations on delivery, consents given by telegram, cablegram or other electronic transmission may be otherwise delivered to the principal place of business of the corporation or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded if, to the extent and in the manner provided by resolution of the Board of Directors. Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

(c) Notice of Taking of Corporate Action. Prompt notice of the taking of corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for such meeting had been the date that written consents signed by a sufficient number of holders to take the action were delivered to the corporation.

ARTICLE II

DIRECTORS

2.1 General Powers. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation.

2.2 Number, Election and Qualification. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the corporation shall be established from time to time by the stockholders or the Board of Directors. The directors shall be elected at the annual meeting of stockholders by such stockholders as have the right to vote on such election. Election of directors need not be by written ballot. Directors need not be stockholders of the corporation.

2.3 Chairman of the Board; Vice Chairman of the Board. The Board of Directors may appoint from its members a Chairman of the Board and a Vice Chairman of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chairman of the Board, such Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chairman of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these By-laws. If the Board of Directors appoints a Vice Chairman of the Board, such Vice Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors. Unless otherwise provided by the Board of Directors, the Chairman of the Board or, in the Chairman's absence, the Vice Chairman of the Board, if any, shall preside at all meetings of the Board of Directors.

2.4 Tenure. Each director shall hold office until the next annual meeting of stockholders and until a successor is elected and qualified, or until such director's earlier death, resignation or removal.

2.5 Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2.2 of these By-laws shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a

quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

2.6 Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting of the Board of Directors duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.

2.7 Removal. Except as otherwise provided by the General Corporation Law of the State of Delaware, any one or more or all of the directors of the corporation may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except that the directors elected by the holders of a particular class or series of stock may be removed without cause only by vote of the holders of a majority of the outstanding shares of such class or series.

2.8 Vacancies. Subject to the rights of holders of any series of Preferred Stock to elect directors, unless and until filled by the stockholders, any vacancy or newly-created directorship on the Board of Directors, however occurring, may be filled by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director. A director elected to fill a vacancy shall be elected for the unexpired term of such director's predecessor in office, and a director chosen to fill a position resulting from a newly-created directorship shall hold office until the next annual meeting of stockholders and until a successor is elected and qualified, or until such director's earlier death, resignation or removal.

2.9 Resignation. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal office or to the Chairman of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event.

2.10 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.

2.11 Special Meetings. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chairman of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.

2.12 Notice of Special Meetings. Notice of the date, place, if any, and time of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (a) in person or by telephone at least 24 hours in advance of the meeting, (b) by sending written notice by reputable overnight courier, telecopy, facsimile or electronic transmission, or delivering written notice by hand, to such director's last known business, home or electronic transmission address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

2.13 Meetings by Conference Communications Equipment. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference telephone or other

communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.

2.14 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission, and the written consents or electronic transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

2.15 Committees. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these By-laws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these By-laws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

2.16 Compensation of Directors. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

ARTICLE III

OFFICERS

3.1 Titles. The officers of the corporation shall consist of a Chief Executive Officer, a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, including one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.

3.2 Election. The Chief Executive Officer, President, Treasurer and Secretary shall be elected by the Board of Directors at its first meeting following each annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.

3.3 Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.

3.4 Tenure. Except as otherwise provided by law, by the Certificate of Incorporation or by these By-laws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.

3.5 Resignation and Removal. Any officer may resign by delivering a written resignation to the corporation at its principal office or to the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.

3.6 Vacancies. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of Chief Executive Officer, President, Treasurer and Secretary. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.

3.7 President; Chief Executive Officer. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and supervision of the business of the corporation subject to the direction of the Board of Directors, and shall perform all duties and have all powers that are commonly incident to the office of chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

3.8 Vice Presidents. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

3.9 Secretary and Assistant Secretaries. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more

than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chairman of the meeting shall designate a temporary secretary to keep a record of the meeting.

3.10 Treasurer and Assistant Treasurers. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these By-laws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

3.11 Salaries. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.

3.12 Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

ARTICLE IV

CAPITAL STOCK

4.1 Issuance of Stock. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.

4.2 Stock Certificates; Uncertificated Shares. The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of the corporation's stock shall be uncertificated shares. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these By-laws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated shares, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

4.3 Transfers. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these By-laws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these By-laws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these By-laws.

4.4 Lost, Stolen or Destroyed Certificates. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.

4.5 Record Date. The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders or to express consent (or dissent) to corporate action without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not precede the date on which the resolution fixing the record date is adopted, and such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 10 days after the date of adoption of a record date for a consent without a meeting, nor more than 60 days prior to any other action to which such record date relates.

If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. If no record date is fixed, the record date for determining stockholders entitled to express consent to corporate action without a meeting, when no prior action by the Board of Directors is necessary, shall be the day on which the first consent is properly delivered to the corporation. If no record date is fixed, the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

4.6 Regulations. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

ARTICLE V

GENERAL PROVISIONS

5.1 Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of January of each year and end on the last day of December in each year.

5.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.

5.3 Waiver of Notice. Whenever notice is required to be given by law, by the Certificate of Incorporation or by these By-laws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to notice required to be given to such person. Neither the business nor the purpose of any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

5.4 Voting of Securities. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation.

5.5 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.

5.6 Certificate of Incorporation. All references in these By-laws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as amended and in effect from time to time.

5.7 Severability. Any determination that any provision of these By-laws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these By-laws.

5.8 Pronouns. All pronouns used in these By-laws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

ARTICLE VI

AMENDMENTS

6.1 By the Board of Directors. These By-laws may be altered, amended or repealed, in whole or in part, or new by-laws may be adopted by the Board of Directors.

6.2 By the Stockholders. These By-laws may be altered, amended or repealed, in whole or in part, or new by-laws may be adopted by the affirmative vote of the holders of a majority of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at any annual meeting of stockholders, or at any special meeting of stockholders, provided notice of such alteration, amendment, repeal or adoption of new by-laws shall have been stated in the notice of such special meeting.

Exhibit 10.1

FIFTH AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT

This FIFTH AMENDED AND RESTATED INVESTOR RIGHTS AGREEMENT, dated as of May 13, 2013 (this "Agreement"), among TOKAI PHARMACEUTICALS, INC., a Delaware corporation (the "Issuer"), and the investors in the Issuer named in Schedule I hereto (collectively, the "Investors"), amending and restating the Fourth Amended and Restated Investor Rights Agreement, dated as of September 9, 2011, as amended (the "Fourth Amended and Restated Investor Rights Agreement"), among the Issuer and certain of the Investors.

WHEREAS, the Issuer and certain of the Investors (the "Series E Investors") have entered into a Series E Convertible Preferred Stock Purchase Agreement, dated as of the date hereof (the "Purchase Agreement"), pursuant to which the Series E Investors shall purchase from the Issuer shares of the Issuer's Series E Convertible Preferred Stock, $0.001 par value per share ("Series E Preferred Stock");

WHEREAS, the Issuer and certain Investors are parties to the Fourth Amended and Restated Investor Rights Agreement and the Issuer and such Investors desire to amend and restate the Fourth Amended and Restated Investor Rights Agreement in order to take into account the issuance of the Series E Preferred Stock, such amendment being a condition precedent to the execution, delivery and performance of the Purchase Agreement;

WHEREAS, the execution of this Agreement is a condition to the closing of the transactions contemplated by the Purchase Agreement; and

WHEREAS, as an inducement to the Series E Investors to consummate the transactions contemplated by the Purchase Agreement, the Issuer has agreed to enter into this Agreement; and

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements herein contained, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Definitions. For purposes of this Agreement, the following terms have the following respective meanings:

"Additional Shares" means shares of Common Stock (i) acquired by the Investors or (ii) issued or issuable to the Investors upon conversion or exercise of any security of the Issuer other than by conversion of the Preferred Shares, provided that (a) in the case of clause (i) such shares of Common Stock are, at the time of their acquisition, "restricted securities" as such term is defined in Rule 144 or otherwise subject to the restrictions on resale of Rule 144 and (b) in the case of clause (ii), such security is a "restricted security" at the time of acquisition or is otherwise subject to restrictions on resale under Rule 144.

"Affiliate" means, with respect to a particular person or entity, persons or entities controlling, controlled by or under common control with that person or entity, as well as any officers, directors and majority-owned entities of that person or entity and of its other Affiliates and, with respect to any Investor that is part of the Satter Family, as defined in the Stockholders Agreement, any other member of the Satter Family. The term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as applied to any person, means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of such person, whether through the ownership of voting securities or other ownership interest, by contract or otherwise.

"Agreement" shall have the meaning given it in the first paragraph of this Agreement.

"Certificate of Incorporation" means the Issuer's Seventh Amended and Restated Certificate of Incorporation, as it may be amended or restated from time to time.

"Common Stock" means the Common Stock, $0.001 par value per share, of the Issuer.

"Company Sale" means a Deemed Liquidation Event (as such term is defined in the Certificate of Incorporation).

"Confidential Information" means any information that is labeled as confidential, proprietary or secret that an Investor obtains from the Issuer pursuant to financial statements, reports and other materials provided by the Issuer to such Investor pursuant to this Agreement or pursuant to visitation or inspection rights granted hereunder.

"Conversion Shares" means the shares of Common Stock issued or issuable upon conversion of the Preferred Shares.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, or any successor federal statute, and the rules and regulations thereunder that shall be in effect at the time. Any reference to a particular section thereof shall include a reference to the corresponding section, if any, of any such successor federal statute, and the rules and regulations thereunder.

"FINRA" means the Financial Industry Regulatory Authority.

"GAAP" means United States generally accepted accounting principles.

"Holder" means any holder of Registrable Securities or Preferred Shares, including a Holder that has received Registrable Securities pursuant to Section 4.3.

"Investor" shall have the meaning given it in the first paragraph of this Agreement.

"Issuer" shall have the meaning given it in the first paragraph of this Agreement.

"Material Adverse Effect" means any material adverse effect on the business, assets, properties or financial condition of the Issuer.

"Person" means any natural person, firm, partnership, association, corporation, company, trust, business trust, governmental entity or other entity.

"Preferred Shares" mean any shares of Series A Preferred Stock, Series B-1 Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock.

"Prospectus" means the prospectus included in any Registration Statement (including, without limitation, a prospectus that discloses information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and all other amendments and supplements to the prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such prospectus.

"Purchase Agreement" shall have the meaning given it in the first recital hereof.

"Qualified Public Offering" means a Qualified Public Offering as such term is defined in Article FOURTH, Part C, Subsection 5.1 of the Certificate of Incorporation.

"Registrable Securities" means (a) the Shares, (b) the Additional Shares, (c) any securities issued or issuable with respect to any Shares or Additional Shares referred to in the foregoing clauses (a) and (b), (i) upon any conversion or exchange thereof, (ii) by way of stock dividend or other distribution, stock split or reverse stock split, or (iii) in connection with a combination of shares, recapitalization, merger, consolidation, exchange offer or other reorganization. As to any particular Registrable Securities, once issued such securities shall cease to be Registrable Securities when (A) a Registration Statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such Registration Statement, (B) such securities shall have been distributed to a third party in reliance upon Rule 144, (C) subject to the provisions of Section 4.1(b)(ii), such securities shall have been otherwise transferred, new certificates for such securities not bearing a legend restricting further transfer shall have been delivered by the Issuer and subsequent disposition of such securities shall not require registration or qualification of such securities under the Securities Act or any similar state law then in force, (D) such securities shall have been acquired by the Issuer, (E) at such time, following a Qualified Public Offering, as such securities become eligible for sale by the Holder thereof without being subject to notice requirements or volume or manner of sale limitations pursuant to Rule 144 under the Securities Act or (F) upon any transfer in any manner to a person or entity that is not entitled, pursuant to Section 4.3, to the rights under this Agreement. In determining the number of Registrable Securities outstanding at any time or whether the Holders of the requisite number of Registrable Securities have taken any action hereunder and in calculating the number of Registrable Securities for all purposes under this Agreement, (i) the Preferred Shares shall be deemed to have been converted at the then existing conversion price and (ii) such calculation shall include the number of shares of Common Stock then deliverable upon conversion of the Preferred Shares.

"Registration Expenses" means all fees and expenses incident to the performance of or compliance with the provisions of Section 2 of this Agreement, whether or not any registration statement is filed or becomes effective, including, without limitation, all (i) registration and filing fees (including, without limitation, (A) fees with respect to filings required to be made with FINRA in connection with an underwritten offering, (B) fees and expenses of compliance with state securities or blue sky laws (including, without limitation, fees and disbursements of counsel for the underwriter or underwriters in connection with blue sky qualifications of the Registrable Securities and determination of the eligibility of the Registrable Securities for investment under the laws of such jurisdictions as provided in Section 2.3(e)), and (C) fees and other expenses associated with the listing of the Shares and any Additional Shares on a registered national securities exchange), (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities and of printing Prospectuses), (iii) fees and disbursements of all independent registered public accounting firms referred to in Section 2.3 (including, without limitation, the reasonable expenses of any special audit and "cold comfort" letters required by or incident to such performance), (iv) the fees and expenses of any "qualified independent underwriter" or other independent appraiser participating in an offering pursuant to Rule 2720 of the FINRA Rules of Conduct, (v) fees and expenses of all attorneys, advisers, appraisers and other persons retained by the Issuer or any Subsidiary of the Issuer, (vi) the expenses relating to printing and distributing all registration statements, underwriting agreements, securities sales agreements, indentures and any other documents necessary in order to comply with this Agreement and (vii) the reasonable out-of-pocket expenses of the Holders of the Registrable Securities being registered in such registration incurred in connection therewith including, without limitation, the reasonable fees and disbursements of not more than one counsel chosen by the Holders of a majority of the then-outstanding Registrable Securities to be included in such Registration Statement; provided, however, that if a registration under Section 2.1 is withdrawn at the request of the Investors requesting such registration (other than, prior to the end of the applicable

period specified in Section 2.3(b), as a result of information concerning a Material Adverse Effect that is made known to the Investors after the date on which such registration was requested and if the requesting Investors elect not to have such registration counted as a registration requested under Section 2.1) the Investors shall pay the Registration Expenses of such registration pro rata in accordance with the number of their Registrable Securities that would otherwise have been included in such registration. "Registration Expenses" shall not include any underwriting discounts or commissions or any transfer taxes payable in respect of the sale of Registrable Securities by the Holders thereof.

"Registration Statement" means any registration statement of the Issuer that covers any of the Registrable Securities pursuant to the provisions of this Agreement, and all amendments and supplements to any such registration statement, including post-effective amendments, in each case including the Prospectus, and all exhibits and all material incorporated by reference or deemed to be incorporated by reference in such registration statement (other than a registration statement on Form S-8 or Form S-4, or their successors, or any other form for a similar limited purpose, or any registration statement covering only securities proposed to be issued in exchange for securities or assets of another corporation).

"Rule 144" means Rule 144 (or any successor provision) under the Securities Act.

"Rule 145" means Rule 145 (or any successor provision) under the Securities Act.

"SEC" means the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act or the Exchange Act.

"Securities Act" means the Securities Act of 1933, as amended, or any successor federal statute, and the rules and regulations thereunder that shall be in effect at the time. Any reference to a particular section thereof shall include a reference to the corresponding section, if any, of any such successor federal statute, and the rules and regulations thereunder.

"Senior Preferred Designee" means a Senior Preferred Designee as such term is defined in Section 1(a)(iii) of the Stockholders Agreement.

"Senior Preferred Stock" means the Series C Preferred Stock, the Series D Preferred Stock and the Series E Preferred Stock.

"Senior Registrable Securities" means shares of Common Stock issued or issuable upon conversion of the Senior Preferred Stock that are Registrable Securities.

"Senior Required Securities" means shares representing a majority of the Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of the Certificate of Incorporation) or, following the automatic conversion of each series of Preferred Stock under Section 5.1 of the Certificate of Incorporation, the shares of Common Stock issued upon conversion of the Senior Preferred Stock (voting as a single class based upon the number of votes to which each such share was entitled prior to such conversion into Common Stock).

"Series A Preferred Stock" means the Series A Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series B-1 Preferred Stock" means the Series B-1 Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series B-2 Preferred Stock" means the Series B-2 Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series C Preferred Stock" means the Series C Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series D Preferred Stock" means the Series D-1 Preferred Stock, the Series D-2 Preferred Stock and the Series D-3 Preferred Stock.

"Series D-1 Preferred Stock" means the Series D-1 Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series D-2 Preferred Stock" means the Series D-2 Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series D-3 Preferred Stock" means the Series D-3 Convertible Preferred Stock, $0.001 par value per share, of the Issuer.

"Series E Preferred Stock" has the meaning given it in the first recital hereof.

"Shares" means the Conversion Shares.

"Significant Holder" means any Holder holding at least 8,000,000 Preferred Shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Shares).

"Special Registration" means the registration of shares of equity securities and/or options or other rights in respect thereof to be offered solely to directors, members of management, employees, consultants or sales agents, distributors or similar representatives of the Issuer or its direct or indirect Subsidiaries, solely on Form S-8 or Form S-4 or any successor form.

"Stockholders Agreement" means the Fifth Amended and Restated Stockholders Agreement by and among the Issuer, the Investors and the Common Stockholders named therein, dated as of the date hereof, as amended from time to time.

"Subsidiary" means, with respect to any Person, any other Person, a majority of the outstanding voting stock or other equity interests of which is owned, directly or indirectly, by that Person.

"underwritten registration" or "underwritten offering" means a registration in which securities of the Issuer (including Registrable Securities) are sold to an underwriter for re-offering to the public.

2. Registration.

2.1 Demand Registration.

(a) Requests. Subject to the provisions of Section 2.7, at any time or from time to time after the earlier of (i) the four year anniversary of the date hereof or (ii) 180 days following the effective date of the initial public offering of the Common Stock, a Holder or the Holders of (x) at least seventy-five percent (75%) of the combined voting power of the issued and outstanding Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of

the Certificate of Incorporation) in the case of clause (i) of this sentence or (y) the Senior Required Securities in the case of clause (ii) of this sentence shall have the right to make written requests that the Issuer effect a registration under the Securities Act with respect to at least 20% of the outstanding Registrable Securities, or any lesser percentage of the outstanding Registrable Securities if the reasonably anticipated aggregate offering price to the public would exceed $10,000,000; provided, however, in the event that Novartis (as defined in the Stockholders Agreement) or any of its Affiliates holding Senior Preferred Stock is determined by the Board of Directors of the Issuer to not be a Financial Fund (as defined in the Stockholders Agreement), such Holder shall not be entitled to request registration under this Section 2.1(a) and the percentage of Senior Preferred Stock required to request registration under this Section 2.1(a) shall be reduced by the percentage of Senior Preferred Stock held by such Holder. Such requests shall specify the intended method of disposition thereof by such Holder, including whether the registration requested is for an underwritten offering. The Issuer shall not be required to effect a registration pursuant to this Section 2.l(a) on more than two occasions during the term of this Agreement provided, however, that if the Issuer is not entitled to use Commission Form S-3 due to the Issuer's failure to comply with its filing obligations under the Exchange Act, the Holders shall be entitled to additional S-1 Registrations under Section 2.1(a) notwithstanding the foregoing limitation; except that in no event shall the Issuer be required to effect any registration on more than one occasion during any 12-month period. Nothing in this Agreement shall prevent any Holder from making a request under Section 2.1(a) or 2.1(b) prior to converting the Preferred Shares. The Issuer shall not be required to file any Registration Statement pursuant to this Section 2.1(a) if at the time of any request to register Registrable Securities pursuant to this Section 2.1(a), the Issuer furnishes to the requesting Holder or Holders a certificate signed by the Chief Executive Officer (or, if none, the President) of the Issuer stating that the Issuer has a good faith intent to engage in a firmly underwritten public offering within 90 days of such request, such right to delay a request to be exercised by the Issuer not more than once in any twelve- month period.

(b) Form S-3 Registration. If at any time the Issuer is eligible to file a Registration Statement under the Securities Act on Form S-3 (or any successor short form registration statement), a Holder or Holders of the Senior Required Securities shall have the right to make written requests that the Issuer effect a registration under the Securities Act on Form S-3 of all or part of the Registrable Securities of the Holder making such request, which requests shall specify the intended method of disposition thereof by such Holder, including whether (i) the registration requested is for an underwritten offering and (ii) the Registration Statement covering such Registrable Securities shall provide for the sale by the Holder thereof of the Registrable Securities from time to time on a delayed or a continuous basis under Rule 415 under the Securities Act; provided, however, in the event that Novartis or any of its Affiliates holding Senior Preferred Stock is determined by the Board of Directors of the Issuer to not be a Financial Fund, such Holder shall not be entitled to request registration under this Section 2.1(b) and the percentage of Senior Preferred Stock required to request registration under this Section 2.1(b) shall be reduced by the percentage of Senior Preferred Stock held by such Holder. The Issuer shall not be required to file any such Registration Statement (i) if the reasonably anticipated aggregate price to the public of the offering would not exceed $7,500,000 (unless the request is for all remaining Registrable Securities) or (ii) if at the time of any request to register Registrable Securities pursuant to this Section 2.1(b), the Issuer furnishes to the requesting Holder or Holders a certificate signed by the Chief Executive Officer (or, if none, the President) of the Issuer stating that the Issuer has a good faith intent to engage in a firmly underwritten public offering within 90 days of such request, such right to delay a request to be exercised by the Issuer not more than once in any twelve-month period. No requested registration under this Section 2.1(b) shall constitute a "demand" registration for purposes of Section 2.1(a). So long as the provisions and requirements of this Section 2.l(b) are satisfied and subject to the other provisions of this Agreement, there shall be no limit on the number of times a Holder or Holders may make a written request that the Issuer effect a registration hereunder except that the Issuer

shall not be required to effect a registration pursuant to this Section 2.l(b) on more than two occasions during any 12-month period.

(c) Obligation to Effect Registration. Within 20 days after receipt by the Issuer of any request for registration pursuant to Section 2.1(a) or 2.1(b), the Issuer shall promptly give written notice of such requested registration to all Holders, and thereupon will use its best efforts to effect the registration under the Securities Act of:

(i) the Registrable Securities that the Issuer has been so requested to register pursuant to Section 2.1(a) or 2.1(b), and

(ii) all other Registrable Securities that the Issuer has been requested to register by the Holders thereof by written request given to the Issuer within 10 days after the Issuer has given such written notice (which request shall specify the intended method of disposition of such Registrable Securities), all to the extent required to permit the disposition (in accordance with the intended methods thereof as aforesaid) of the Registrable Securities so to be registered.

(d) Effective Registration Statement. A registration requested pursuant to Section 2.1(a) or 2.1(b) shall not be deemed to have been effected unless the Registration Statement for such registration is declared effective by the SEC and remains effective for the period specified in Section 2.3(b). Notwithstanding the preceding sentence, a registration requested pursuant to Section 2.1(a) or 2.1(b) that does not become effective after the Issuer has filed a Registration Statement with respect thereto by reason of the refusal to proceed of the Holders of Registrable Securities requesting the registration, or by reason of a request by the Holders of (x) at least seventy-five percent (75%) of the combined voting power of the issued and outstanding Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of the Certificate of Incorporation) in the case of a registration requested pursuant to Section 2.1(a)(i) or (y) the Senior Required Securities in the case of a registration requested pursuant to Section 2.1(a)(ii) for which registration is being requested that such registration be withdrawn, shall be deemed to have been effected by the Issuer at the request of such Holders.

(e) Pro Rata Allocation. If the Holders of (x) at least seventy-five percent (75%) of the combined voting power of the issued and outstanding Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of the Certificate of Incorporation) in the case of a registration requested pursuant to Section 2.1(a)(i) or (y) the Senior Required Securities in the case of a registration requested pursuant to Section 2.1(a)(ii) or 2.1(b) determine, based on consultation with the managing underwriters or, in an offering that is not underwritten, with an investment banker, that the number of securities to be sold in any such offering should be limited due to market conditions or otherwise, Holders of Registrable Securities proposing to sell their securities in such registration shall be entitled to include in such registration:

(i) first, all Senior Registrable Securities requested to be included by the Holders, allocated pro rata based on the number of Senior Registrable Securities as to which registration was requested by such Holders;

(ii) second, to the extent that the number of shares registered pursuant to clause (i) above is less than the number of securities to be sold in such offering, the remaining Registrable Securities requested to be included by the Holders, pro rata based on the number of such Registrable Securities as to which registration was requested by such Holders.

(f) Inclusion of Other Securities in Demand Registration.

(i) The Issuer may, subject to the remainder of this Section 2.l(f), elect to include in any Registration Statement made pursuant to Section 2.1(a) or 2.1(b), authorized but unissued shares of Common Stock, or shares of Common Stock held as treasury stock, provided, however that in the event that (i) such Registration Statement was made pursuant to Section 2.1(a), (ii) the Issuer elects to include such shares of Common Stock in such Registration Statement and (iii) the number of shares requested pursuant to Section 2.1(a) is reduced pursuant to Section 2.1(f)(ii), then the registration made with regard to such Registration Statement will not be deemed to be one of the two allowable registration requests permitted to be made pursuant to Section 2.1(a).

(ii) If any Registration Statement made pursuant to Section 2.1(a) or 2.1(b) involves an underwritten offering and the managing underwriter of such offering (or, in connection with an offering that is not underwritten, an investment banker) shall advise the Issuer that the number of securities requested to be included in such registration exceeds the largest number that can be sold in an orderly manner in such offering within a price range acceptable to the selling Holders, the Issuer shall include in such registration:

(A) first, all shares of Common Stock requested to be included in such registration by the selling Holders subject to Section 2.1(e);

(B) second, to the extent that the number of securities to be registered pursuant to clause (A) above is less than the largest number that can be sold in an orderly manner in such offering within a price range acceptable to the selling Holders, securities that the Issuer proposes to register; and

(C) third, to the extent that the number of shares registered pursuant to clauses (A) and (B) above is less than the largest number that can be sold in an orderly manner in such offering within a price range acceptable to the selling Holders, the securities requested to be included by any other holders.

The securities to be included in any such registration pursuant to clause (C) shall be allocated on a pro rata basis among all holders requesting that securities be included in such registration pursuant to such clause on the basis of the number of securities requested to be included by such holders.

2.2 Piggyback Registration. If the Issuer at any time proposes to register any Common Stock under the Securities Act (other than pursuant to a Registration Statement relating solely to the sale of securities on Form S-4 with respect to any merger, consolidation or acquisition, pursuant to Section 2.1 or pursuant to a Special Registration), whether or not for sale for its own account, and the registration form to be used may be used for the registration of Registrable Securities, it shall give prompt written notice to all Holders of its intention to do so and, upon the written request of any Holder given to the Issuer within 10 days after the Issuer has given any such notice (which request shall specify the Registrable Securities intended to be disposed of by such Holder and the intended method of disposition thereof), the Issuer will use its best efforts to effect the registration under the Securities Act of all Registrable Securities that the Issuer has been so requested to register by the Holders thereof, to the extent required to permit the disposition (in accordance with the intended methods thereof as aforesaid) of the Registrable Securities so to be registered, provided that:

(a) if, at any time after giving written notice of its intention to register any Common Stock and prior to the effective date of the Registration Statement filed in connection with such registration, the Issuer shall determine for any reason not to register such Common Stock, the Issuer may, at its election, give written notice of such determination to each Holder that was previously notified of such registration and, thereupon, shall not register any Registrable Securities in connection with such registration (but shall nevertheless pay the Registration Expenses in connection therewith), without prejudice, however, to the rights of any Holders to request that a registration be effected under Section 2.1; and

(b) if the Issuer shall be advised in writing by the managing underwriters (or, in connection with an offering that is not underwritten, by an investment banker) that due to marketing factors, the number of securities requested to be included in such registration exceeds the number of such securities that can be sold in such offering in an orderly manner within a price range that is acceptable to the Issuer, the Issuer shall include in such registration:

(i) first, all shares of Common Stock that the Issuer proposes to register for its own account or the account of the holder or holders initially requesting or demanding such registration;

(ii) second, to the extent that the number of shares registered pursuant to clause (i) above is less than the largest number that can be sold in an orderly manner in such offering within a price range acceptable to the Issuer, the Registrable Securities requested to be included by the Holders subject to Section 2.1(e);

(iii) third, to the extent that the number of shares registered pursuant to clauses (i) and (ii) above is less than the largest number that can be sold in an orderly manner in such offering within a price range acceptable to the Issuer, the securities requested to be included by any other holders,

and the Issuer shall so provide in any registration agreement hereinafter entered into with respect to any of its securities.

The securities to be included in any such registration pursuant to clause (ii) or (iii) shall be allocated on a pro rata basis among all holders requesting that securities be included in such registration pursuant to such clause on the basis of the number of securities requested to be included by such holders (in the case of clause (ii), subject to Section 2.1(e)).

Subject to Section 2.5, no registration effected under this Section 2.2 shall relieve the Issuer from its obligation to effect registrations upon request under Section 2.1. Nothing in this Agreement shall prevent any Holder from making a request under this Section 2.2 prior to converting the Preferred Shares.

2.3 Registration Procedures. If and whenever the Issuer is required to use its best efforts to effect the registration of any Registrable Securities under the Securities Act as provided in Sections 2.1 and 2.2, the Issuer shall:

(a) prepare and file with the SEC, as soon as practicable, a Registration Statement with respect to such securities, make all required filings with FINRA and use its best efforts to cause such Registration Statement to become effective at the earliest possible date;

(b) prepare and file with the SEC such amendments and supplements to such Registration Statement and the Prospectus used in connection therewith and such other documents as may

be necessary to keep such Registration Statement effective until the earlier of (i) 30 days after the effective date of such Registration Statement (360 days in the case of a shelf registration pursuant to Section 2.1 (b)) or (ii) the consummation of the disposition by the Holders of all the Registrable Securities covered by such Registration Statement, and otherwise comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement;

(c) furnish to counsel (if any) selected by the Holders of a majority of the Registrable Securities covered by such Registration Statement and to counsel for the underwriters in any underwritten offering copies of all documents proposed to be filed with the SEC in connection with such registration a reasonable time prior to the proposed filing thereof and give reasonable consideration in good faith to any comments of such Holders, counsel and underwriters;

(d) furnish to each seller of Registrable Securities, without charge, such reasonable number of conformed copies of such Registration Statement and of each such amendment and supplement thereto (in each case, including all exhibits (including exhibits incorporated by reference), financial statements, schedules and all documents incorporated therein, deemed to be incorporated therein by reference or filed therewith, except that the Issuer shall not be obligated to furnish any seller of securities with more than two copies of such exhibits and documents), such number of copies of the Prospectus included in such Registration Statement (including each preliminary prospectus and any summary prospectus) in conformity with the requirements of the Securities Act, and such other documents, as such seller may reasonably request in order to facilitate the disposition of the securities owned by such seller;

(e) use its best efforts to register or qualify and cooperate with the Holders of Registrable Securities, the underwriters and their respective counsels in connection with the registration or qualification (or exemption from such registration or qualification) of the securities covered by such Registration Statement under such other securities or blue sky laws of such jurisdictions as each seller shall request; provided, that where Registrable Securities are offered other than through an underwritten offering, the Issuer agrees to cause its counsel to perform blue sky investigations and file registrations and qualifications required to be filed pursuant to this Section 2.3(e)); keep each such registration or qualification (or exemption therefrom) effective during the period such Registration Statement is required to be effective hereunder and do any and all other acts and things that may be necessary or advisable to enable such seller to consummate the disposition in such jurisdictions of the securities owned by such seller; provided, however, that the Issuer shall not be required in connection with this paragraph (e) to qualify as a foreign corporation or to execute a general consent to service of process in any jurisdiction or to amend its Certificate of Incorporation or Bylaws in a manner that the Board of Directors of the Issuer determines is inadvisable;

(f) (i) notify each Holder of Registrable Securities subject to such Registration Statement if such Registration Statement, at the time it or any amendment thereto became effective, (x) contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading upon discovery by the Issuer of such material misstatement or omission or (y) upon discovery by the Issuer of the happening of any event as a result of which the Issuer believes there would be such a material misstatement or omission, and, as promptly as practicable, prepare and file with the SEC a post-effective amendment to such Registration Statement and use best efforts to cause such post-effective amendment to become effective such that such Registration Statement, as so amended, shall not contain an untrue

statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and (ii) notify each Holder of Registrable Securities subject to such Registration Statement, at any time when a Prospectus relating thereto is required to be delivered under the Securities Act, if the Prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading upon discovery by the Issuer of such material misstatement or omission or upon discovery by the Issuer of the happening of any event as a result of which the Issuer believes there would be such a material misstatement or omission, and, as promptly as is practicable, prepare and furnish to such Holder a reasonable number of copies of a supplement to or an amendment of such Prospectus as may be necessary so that, as thereafter delivered to the purchasers of such securities, such Prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading and each such Holder of Registrable Securities shall immediately discontinue any sales of Registrable Securities pursuant to such Registration Statement until such Holder of Registrable Securities has received copies of a supplemented or amended Prospectus or until such Holder of Registrable Securities is advised in writing by the Issuer that the then current Prospectus may be used and has received copies of any additional or supplemental filings that are incorporated or deemed incorporated by reference in such Prospectus;

(g) otherwise use its best efforts to comply with all applicable rules and regulations of the SEC, and make available to its security holders, as soon as reasonably practicable, an earnings statement of the Issuer complying with the provisions of Section 11(a) of the Securities Act and Rule 158 promulgated under the Securities Act (or any similar rule promulgated under the Securities Act) no later than 45 days after the end of any 12-month period (or 90 days after the end of any 12-month period if such period is a fiscal year) (i) commencing at the end of any fiscal quarter in which Registrable Securities are sold to an underwriter or to underwriters in a firm commitment or best efforts underwritten offering and (ii) if not sold to an underwriter or to underwriters in such an offering, commencing on the first day of the first fiscal quarter of the Issuer after the effective date of the relevant Registration Statement, which statements shall cover said 12-month periods;

(h) promptly notify each Holder of any Registrable Securities covered by such Registration Statement, their counsel and the underwriters (i) when such Registration Statement, or any post-effective amendment to such Registration Statement, shall have become effective, or any amendment of or supplement to the Prospectus used in connection therewith shall have been filed, (ii) of any request by the SEC to amend such Registration Statement or to amend or supplement such Prospectus or for additional information, (iii) of the issuance by the SEC of any stop order suspending the effectiveness of such Registration Statement or of any order preventing or suspending the use of any preliminary prospectus or the initiation or threatening of any proceedings for any of such purposes, (iv) of the suspension of the qualification of such securities for offering or sale in any jurisdiction, or of the institution of any proceedings for any of such purposes and (v) if at any time when a Prospectus is to be required by the Securities Act to be delivered in connection with the sale of the Registrable Securities, the representations and warranties of the Issuer contained in any agreement (including the underwriting agreement contemplated in Section 2.4(b) below), to the knowledge of the Issuer, cease to be true and correct in any material respect;

(i) use its best efforts to prevent the issuance of any order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of a Prospectus or suspending the qualification (or exemption from qualification) of any of the Registrable Securities covered thereby for sale in any jurisdiction, and, if any such order is issued, to use its best efforts to obtain the withdrawal of any such order at the earliest possible moment;

(j) prior to the effective date of the Registration Statement, (i) provide the registrar or transfer agent for the Common Stock or such other Registrable Securities with printed

certificates for such securities in a form eligible for deposit with DTC and (ii) provide a CUSIP number for such securities;

(k) have the right, if the Board of Directors of the Issuer, in its good faith judgment, determines that any registration of Registrable Securities should not be made or continued because (x) it would materially interfere with any material financing, acquisition, corporation reorganization, merger, or other transaction involving the Issuer or any of its Subsidiaries or (y) it would require the disclosure of material nonpublic information, which disclosure would have a Material Adverse Effect (each a "Valid Business Reason"), (i) to postpone filing a Registration Statement until such Valid Business Reason no longer exists, but in no event for more than 60 days, and (ii) to cause any Registration Statement that has already been filed to be withdrawn and its effectiveness terminated or to postpone amending or supplementing such Registration Statement until such Valid Business Reason no longer exists, but in no event for more than 60 days (the "Postponement Period"); provided, however, that in no event shall the Issuer be permitted to postpone or withdraw a Registration Statement under this subsection (k) or otherwise within 60 days after the expiration of the Postponement Period;

(l) participate in marketing any Registrable Securities in connection with the registration of such securities under this Agreement (including, but not limited to, making available reasonably necessary personnel and participating in a road show) as would be customary for public offerings of this nature; and

(m) have the right, by furnishing to the requesting Holder or Holders a certificate signed by the Chief Executive Officer (or, if none, the President) of the Issuer stating that, in the good faith judgment of the Board of Directors of the Issuer, circumstances exist (other than the circumstances set forth in subparagraph (k)), such that it would be detrimental to the Issuer and its investors for a registration requested pursuant to Section 2.1 to be effected at such time, to direct that such request be delayed for a period not in excess of 180 days from the receipt of the request, such right to delay a request to be exercised by the Issuer not more than once in any twelve-month period (and not within 60 days of any Postponement Period).

The Issuer may require each Holder of any Registrable Securities as to which any registration is being effected to furnish to the Issuer such information regarding such Holder and the distribution of such securities as the Issuer may from time to time reasonably request in writing and as shall be required by law in connection therewith. Each such Holder agrees to furnish promptly to the Issuer all information required to be disclosed in order to make the information previously furnished to the Issuer by such Holder not materially misleading.

By the acquisition of Registrable Securities, each Holder shall be deemed to have agreed that upon receipt of any notice from the Issuer pursuant to Section 2.3(f) or (k), such Holder will promptly discontinue such Holder's disposition of Registrable Securities pursuant to the Registration Statement covering such Registrable Securities until such Holder shall have received, in the case of clause (i) of Section 2.3(f), notice from the Issuer that such Registration Statement has been amended, as contemplated by Section 2.3(f), or in the case of clause (ii) of Section 2.3(f), copies of the supplemented or amended Prospectus contemplated by Section 2.3(f); or, in the case of Section 2.3(k), until the time period specified has elapsed or such Holder has received notice from the Issuer that the Postponement Period has been terminated. If so directed by the Issuer, each Holder will deliver to the Issuer (at the Issuer's expense) all copies, other than permanent file copies, in such Holder's possession of the Prospectus covering such Registrable Securities at the time of receipt of such notice. In the event that the Issuer shall

give any such notice, the period mentioned in Section 2.3(b) shall be extended by the number of days during the period from and including the date of the giving of such notice to and including the date when the Issuer shall have sent to the Holder copies of the supplemented or amended Prospectus contemplated by Section 2.3(f).

2.4 Underwritten Offerings. The provisions of this Section 2.4 do not establish registration rights in addition to those set forth in Sections 2.1, 2.2 and 2.3, but instead set forth procedures applicable, in addition to those set forth in Sections 2.1 through 2.3, to any registration that is an underwritten offering.

(a) Underwritten Offerings Exclusive. Whenever a registration requested pursuant to Section 2.1 or 2.2 is for an underwritten offering, only securities that are to be distributed by the underwriters may be included in the registration.

(b) Underwriting Agreement. If requested by the underwriters for any underwritten offering by Holders pursuant to a registration requested under Section 2.1, the Issuer shall enter into an underwriting agreement with such underwriters for such offering, such agreement to be reasonably satisfactory in substance and form to the Issuer and to the underwriters and to contain such representations and warranties by the Issuer and such other terms and provisions as are customarily contained in agreements of this type, including, but not limited to, indemnities to the effect and to the extent provided in Section 2.8, provisions for the delivery of officers' certificates, opinions of counsel and accountants' "cold comfort" letters, and lock-up arrangements. The Holders of Registrable Securities to be distributed by such underwriters shall be parties to such underwriting agreement.

(c) Selection of Underwriters. Whenever a registration is for an underwritten offering, the Issuer shall have the right to select one or more underwriters to administer the offering; provided that the lead underwriter shall be an underwriter of nationally recognized standing.

2.5 Lock-Up Agreements. If and whenever the Issuer proposes to register any of its equity securities under the Securities Act in an initial public offering, each of the Holders, (i) if required by the managing underwriter and (ii) so long as all stockholders holding 5% or more to the total outstanding shares of Common Stock and Preferred Shares of the Issuer on a fully-diluted basis and all officers and directors of the Issuer are also restricted in their ability to transfer securities of the Issuer by terms at least as restrictive as those contained in this Section 2.5, agrees by acquisition of such Registrable Securities not to effect (other than pursuant to such registration) any public sale or distribution, including, but not limited to, any sale pursuant to Rule 144, of any Registrable Securities, any other equity securities of the Issuer or any securities convertible into or exchangeable or exercisable for any equity securities of the Issuer during the time periods specified by the managing underwriter (not to exceed 180 days), to the extent timely notified in writing by the Issuer or the managing underwriter. Each holder hereby agrees to enter into a customary agreement with the managing underwriter for the initial public offering to the effect set forth in the preceding sentence. If and whenever the Issuer is required to use its best efforts to effect the registration of any Registrable Securities under the Securities Act pursuant to Section 2.1 or 2.2, the Issuer, if required by the managing underwriter in an underwritten offering, shall not effect (other than pursuant to such registration or a Special Registration) any public sale or distribution of any other equity securities of the Issuer or any securities convertible into or exchangeable or exercisable for any equity securities of the Issuer during the 10 days prior to, and for 90 days (or 180 days in the case of an initial public offering)

after, the effective date of such registration, to the extent timely notified in writing by the managing underwriter. In addition, in such circumstances, the Issuer shall use its best efforts to cause its directors and officers and all holders of 5% or more of its equity securities (other than the Holders) not to effect (other than pursuant to such registration) any public sale or distribution, including, but not limited to, any sale pursuant to Rule 144, of any equity securities of the Issuer or any securities convertible into or exchangeable or exercisable for any equity securities of the Issuer during the 10 days prior to, and for 90 days (or 180 days in the case of an initial public offering) after, the effective date of such registration, to the extent timely notified in writing by the managing underwriter.

2.6 Preparation; Reasonable Investigation. In connection with the preparation and filing of each Registration Statement registering Registrable Securities under the Securities Act, the Issuer shall give the Holders of such Registrable Securities so to be registered and their underwriters or placement agents, if any, and their respective counsel and accountants, the opportunity to participate in the preparation of such Registration Statement, each Prospectus included therein or filed with the SEC, and each amendment thereof or supplement thereto, and shall, upon reasonable advance notice and during normal business hours, give one representative of the Investors such access to all pertinent financial, corporate and other documents and properties of the Issuer and its Subsidiaries, and such opportunities to discuss the business of the Issuer with its officers, directors, employees and the independent registered public accounting firm that has issued audit reports on its financial statements as shall be reasonably necessary, in the opinion of such Holders' and such underwriters' or placement agents' respective counsel, to conduct a reasonable investigation within the meaning of the Securities Act.

2.7 Other Registrations. If and whenever the Issuer is required to use its best efforts to effect the registration of any Registrable Securities under the Securities Act pursuant to Section 2.1 or 2.2, and if such registration shall not have been withdrawn or abandoned, the Issuer shall not be obligated to and shall not file any Registration Statement with respect to any of its securities (including Registrable Securities) under the Securities Act (other than a Special Registration), whether of its own accord or at the request or demand of any holder or holders of such securities, until a period of 180 days shall have elapsed from the effective date of such previous registration, provided that the Issuer shall not be prohibited from filing a registration statement by virtue of this Section 2.7 more than once in a 360 day period.

2.8 Indemnification.

(a) Indemnification by the Issuer. In the event of any registration of any Registrable Securities under the Securities Act pursuant to Section 2.1 or 2.2, the Issuer shall indemnify and hold harmless the seller of such securities, its directors, officers, and employees, each other person who participates as an underwriter, broker or dealer in the offering or sale of such securities and each other person, if any, who controls such seller or any such participating person within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all losses, claims, damages or liabilities, joint or several, to which such seller or any such director, officer, employee, participating person or controlling person may become subject under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of or are based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement under which such securities were registered under the Securities Act, any Prospectus or preliminary prospectus included therein, or any amendment or supplement thereto, or (ii) any omission or alleged omission to state a material fact required to be stated in any such Registration Statement, Prospectus, preliminary prospectus, amendment or supplement or necessary to make the statements therein not misleading; and the Issuer shall reimburse such seller and each such director, officer, employee, participating person and controlling person for any legal or any other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, liability, action or proceeding as such expenses are incurred; provided that the Issuer shall not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon an untrue statement or omission made in any such Registration Statement, Prospectus, preliminary prospectus, amendment or supplement in reliance upon and in conformity with written information furnished to the Issuer by such seller or participating person expressly for use in the preparation thereof.

(b) Indemnification by the Seller. In the event of any registration of any Registrable Securities under the Securities Act pursuant to Section 2.1 or 2.2, each of the prospective sellers of such securities, severally and not jointly, will indemnify and hold harmless the Issuer, each director of the Issuer, each officer of the Issuer who shall sign such Registration Statement, each other person who participates as an underwriter, broker or dealer in the offering or sale of such securities and each other person, if any, who controls the Issuer or such other participating person within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all losses, claims, damages or liabilities, joint or several, to which the Issuer or any such director, officer, participating person or controlling person may become subject under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement under which such securities were registered under the Securities Act, any Prospectus or preliminary prospectus included therein, or any amendment or supplement thereto, or any omission or alleged omission to state a material fact with respect to such seller required to be stated in any such Registration Statement, Prospectus, preliminary prospectus, amendment or supplement or necessary to make the statements therein not misleading if such statement or omission was made in reliance upon and in conformity with written information furnished to the Issuer by such seller expressly for use in the preparation of any such Registration Statement, Prospectus, preliminary prospectus, amendment or supplement; provided that the liability of each such seller shall be in proportion to and limited to the net amount received by such seller (after deducting any underwriting discount and expenses) from the sale of Registrable Securities pursuant to such Registration Statement.

(c) Notices of Claims, etc. Promptly after receipt by an indemnified party of notice of the commencement of any action or proceeding involving a claim referred to in the preceding paragraphs of this Section 2.8, such indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party hereunder, give prompt written notice to the latter of the commencement of such action, provided that the failure of any indemnified party to give notice as provided therein shall not relieve the indemnifying party of its obligations under the preceding paragraphs of this Section 2.8 unless the failure to provide prompt written notice shall cause actual prejudice to the indemnifying party. In case any such action is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party shall have the right to retain counsel reasonably satisfactory to such indemnified party to defend against such proceeding and shall pay the reasonable fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel and the payment of such fees by the indemnifying party, or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them or (iii) the indemnifying party has not retained counsel to defend such proceeding, in which case (under any of such clauses (i), (ii) or (iii)) it is understood that (x) the indemnifying party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate firm for all such indemnified parties and (y) such firm shall be designated in writing by the Holders of a majority of the Registrable Securities included in such Registration Statement in the case of parties indemnified pursuant to Section 2.8(a) and by the Issuer in the case of parties indemnified pursuant to Section 2.8(b). No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of such indemnified party, which consent shall not be unreasonably withheld, consent to entry of any judgment or enter into any settlement of any pending or threatened action in respect of which any indemnified party is or could have been a party and indemnity was sought hereunder by such indemnified party unless such judgment or settlement includes as an

unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

(d) Other Indemnification. Indemnification similar to that specified in the preceding paragraphs of this Section 2.8 (with appropriate modifications) shall be given by the Issuer and each seller of Registrable Securities with respect to any required registration or other qualification of such Registrable Securities under any federal or state law or regulation of governmental authority other than the Securities Act.

(e) Other Remedies. If for any reason the foregoing indemnity is unavailable, or is insufficient to hold harmless an indemnified party, other than by reason of the exceptions provided therein, then the indemnifying party shall contribute to the amount paid or payable by the indemnified party as a result of such losses, claims, damages, liabilities or expenses in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Issuer or the Holders of Registrable Securities covered by the Registration Statement in question and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Issuer and the Holders agree that it would not be just and equitable if contribution pursuant to this Section 2.8 were determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in the immediately preceding paragraph. The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in the immediately preceding paragraph of this Section 2.8 shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. No party shall be liable for contribution under this Section 2.8(e) except to the extent and under such circumstances as such party would have been liable to indemnify under this Section 2.8 if such indemnification were enforceable under applicable law.

(f) Officers and Directors. As used in this Section 2.8, the terms "officers" and "directors" shall include the partners of Holders that are partnerships and the members of Holders that are limited liability companies.

2.9 Expenses. The Issuer shall pay all Registration Expenses in connection with each registration of Registrable Securities pursuant to this Section 2. All other expenses shall be borne by the Holders participating in such registration.

2.10 Termination. All of the Issuer's obligations to register Registrable Securities under Sections 2.1 and 2.2 shall terminate upon the earliest of (a) five years after the closing of an initial public offering, (b) the date on which no Holder holds any Registrable Securities or (c) a Company Sale.

3. Covenants of the Issuer. The Issuer shall comply with the covenants set forth in Sections 3.1 through 3.7:

3.1 Financial Statements. The Issuer shall maintain a system of accounts in accordance with GAAP applied on a consistent basis, keep full and complete financial records, and, so long as the Issuer has not effected a Qualified Public Offering, the Issuer shall:

(a) furnish to each Significant Holder, within 120 days after the end of each fiscal year, an audited balance sheet of the Issuer as at the end of such year, together with related audited statements of operations and cash flows of the Issuer for such year, examined and reported upon by the Issuer's independent public accountants reasonably satisfactory to the Significant Holders, prepared in accordance with GAAP and certified by Chief Financial Officer of the Issuer;

(b) furnish to each Significant Holder, within 45 days after the end of each fiscal quarter, unaudited balance sheets and statements of operations and cash flows of the Issuer, such balance sheets to be as of the end of such quarter and such statements of operations and cash flows to be both for the year- to-date period as of the end of such quarter and for the quarter, prepared in accordance with GAAP and certified by the Chief Financial Officer of the Issuer, together with comparisons of actual results versus the results for comparable periods in the preceding fiscal year and versus the results from the Issuer's budget through such period;

(c) furnish to each Significant Holder, within 30 days after the end of each month, unaudited balance sheets and statements of operations and cash flows of the Issuer, such balance sheets to be as of the end of such month and such statements of operations and cash flows to be both for the year-to-date period as of the end of such month and for the month, prepared in accordance with GAAP and certified by the Chief Financial Officer of the Issuer, together with comparisons of actual results versus the results for comparable periods in the preceding fiscal year and versus the results from the Issuer's budget through such period;

(d) furnish to each Significant Holder such other information as the Holders may reasonably request in connection with any of the transactions entered into or proposed to be entered into by the Issuer that are not in the ordinary course of the Issuer's business; and

(e) except as may otherwise be agreed by the Board of Directors of the Issuer, including at least three Senior Preferred Designees, furnish to the Board of Directors of the Issuer and any Observer (as defined in the Stockholders Agreement) (i) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year, prepared on a monthly basis, (ii) notices of any pending or threatened litigation promptly upon becoming aware of such litigation, (iii) upon filing, copies of all filings made with the Securities and Exchange Commission and (iv) monthly, an updated capitalization table of the Issuer, setting forth the outstanding securities of the Issuer and the holders thereof as of the date of delivery of such table to the Board of Directors.

Notwithstanding the foregoing, the Issuer shall not be required to furnish the reports or other information contemplated by this Section 3.1 to Novartis or any of its Affiliates if such entity is determined by the Board of Directors of the Issuer not to be a Financial Fund.

3.2 Directors' Indemnification and Insurance. The Certificate of Incorporation or Bylaws of the Issuer shall at all times provide for indemnification of the directors and limitations on the liability of the directors to the fullest extent permitted under applicable state law. The Issuer will obtain and at all times maintain on reasonable business terms directors' and officers' liability insurance coverage.

3.3 Inspection. The Issuer shall, upon reasonable prior notice to the Issuer and during normal business hours, permit one authorized representative of any Investor to visit and inspect any of the properties of the Issuer, including its books of account, and to discuss its affairs, finances and accounts with its officers and independent accountants, all at reasonable times and at such Investor's expense; provided, that no action requested under this Section 3.3 shall unreasonably interfere with the normal business operations of the Issuer; provided, further, that the Issuer shall not be required to permit any action requested under this Section 3.3 by Novartis or any of its Affiliates if such entity is determined by the Board of Directors of the Issuer not to be a Financial Fund.

3.4 Stock Incentive Plans. The Issuer shall not, without the approval of the Board of Directors, including at least three Senior Preferred Designees, (i) create any stock option plan or similar stock option, equity participation or bonus arrangement or (ii) allocate, grant or otherwise award any capital stock or any securities convertible into, exercisable for or evidencing the right to purchase shares of capital stock to employees, directors or consultants of the Issuer. Unless otherwise approved by the Board of Directors, including at least three Senior Preferred Designees, all employees and consultants of the Issuer who purchase, receive options to purchase, or receive awards of shares of the Issuer's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months.

3.5 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge or use for any purpose, other than to monitor its investment in the Issuer, any Confidential Information, unless such Confidential Information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 3.5 by such Investor), (b) is or has been independently developed or conceived by the Investors without use of the Issuer's Confidential Information or (c) is or has been made known or disclosed to the Issuer by a third party without a breach of any obligation of confidentiality such third party may have to the Issuer; provided, however, that a Investor may disclose Confidential Information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Issuer, (ii) to any prospective purchaser of any Shares from such Investor as long as such prospective purchaser agrees to be bound by the provisions of this Section 3.5, (iii) to any Affiliate of such Investor, provided that such party is obligated not to disclose, divulge or use any Confidential Information to the same extent as the Investors, or (iv) as may otherwise be required by law, provided that the Investor takes reasonable steps to minimize the extent of any such required disclosure. Notwithstanding the foregoing, such information shall not be deemed confidential for the purpose of enforcing this Agreement.

3.6 Employees and Consultants. The Issuer hereby covenants and agrees that (a) each employee and officer hired by the Issuer shall sign a Nondisclosure and Developments Agreement substantially in the form attached to the Purchase Agreement as "Exhibit G" prior to the commencement of such person's employment with the Issuer and (b) each consultant engaged by the Issuer shall agree in writing to be bound by nondisclosure and assignment of inventions terms consistent with nondisclosure and assignment of inventions terms previously approved by the Board of Directors.

3.7 Registration Rights. The Issuer hereby covenants and agrees that it shall not hereafter grant to any Person any right to register or qualify stock of the Issuer under federal or state securities laws, unless it shall have first obtained the written consent of the Holder or Holders of the Senior Required Securities.

3.8 Compensation Arrangements. The Issuer hereby covenants and agrees that it shall not enter into any compensation arrangement, including the issuance of restricted stock or stock options, with any officer or director of the Issuer who is affiliated with a Series E Investor without the approval of the Board of Directors, including at least three Senior Preferred Designees.

3.9 Termination. All of the Issuer's obligations under Sections 3.1 through 3.8 shall terminate upon the earliest of (a) the closing of an initial public offering pursuant to an effective registration agreement under the Securities Act and (b) the date on which no Holder holds any Registrable Securities or (c) a Company Sale.

4. Miscellaneous.

4.1 Rule 144; Legended Securities; etc.

(a) After the earliest of (i) the closing of the sale of securities of the Issuer pursuant to a Registration Statement, (ii) the registration by the Issuer of a class of securities under Section 12 of the Exchange Act, or (iii) the issuance by the Issuer of an offering circular pursuant to Regulation A under the Securities Act, the Issuer agrees to:

(i) make and keep current public information about the Issuer available, as those terms are understood and defined in Rule 144;

(ii) use its best efforts to file with the SEC in a timely manner all reports and other documents required of the Issuer under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements); and

(iii) furnish to any holder of Registrable Securities upon request (i) a written statement by the Issuer as to its compliance with the reporting requirements of Rule 144 and of the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), (ii) a copy of the most recent annual or quarterly report of the Issuer, and (iii) such other reports and documents of the Issuer as such holder may reasonably request to avail itself of any similar rule or regulation of the SEC allowing it to sell any such securities without registration.

(b) The Issuer shall issue new certificates for Registrable Securities without a legend restricting further transfer if (i) such securities have been sold to the public pursuant to an effective Registration Statement under the Securities Act (other than Form S-8 if the Holder of such Registrable Securities is an Affiliate) or Rule 144, or (ii) (x) such issuance is otherwise permitted under the Securities Act, (y) the Holder of such shares has delivered to the Issuer an opinion of counsel, which opinion and counsel shall be reasonably satisfactory to the Issuer, to such effect and (z) the Holder of such shares expressly requests the issuance of such certificates in writing.

4.2 Entire Agreement; Amendments and Waivers. This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior agreements and understanding among them, including the Fourth Amended and Restated Investor Rights Agreement as to such subject matter. This Agreement may be amended, modified, changed, discharged, waived or terminated, and the Issuer may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Issuer shall have obtained the written consent to such amendment, modification, change, discharge, waiver, termination, action or omission to act, of (a) the Holders of at least a majority of the Registrable Securities, (b) the Holders of the Senior Required

Securities and (c) the holders of at least seventy-five percent (75%) of the combined voting power of the issued and outstanding Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of the Certificate of Incorporation); provided that no consent shall be required under clauses (a), (b) or (c) for any amendments to this Agreement that are effected as a condition to or as part of a Qualified Liquidation Event (as defined in the Certificate of Incorporation); provided further that the Company may amend this Agreement without the consent of the Investors solely to add investors that purchase Series E Preferred Stock pursuant to Section 2.4 of the Purchase Agreement to Schedule I (which investors shall be included in the definition of "Investors" hereunder upon executing and delivering to the Company a signature page to the Purchase Agreement). Notwithstanding the foregoing, (i) a waiver or consent to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of Holders whose securities are being sold pursuant to a Registration Statement and that does not directly or indirectly affect, impair, limit or compromise the rights of other Holders may be given by Holders of at least a majority of the Registrable Securities being sold by such Holders pursuant to such Registration Statement and (ii) this Agreement may not be amended, modified, changed, waived, discharged or terminated and the observance of any term hereunder may not be waived with respect to any Holder without the written consent of such Holder if such amendment, modification, waiver, discharge or termination uniquely applies to such Holder; provided, however, that the provisions of this sentence may not be amended, modified or supplemented except in accordance with the provisions of the immediately preceding sentence. No amendment, modification or discharge of this Agreement, and no waiver hereunder, shall be valid or binding unless set forth in writing. Any such waiver shall constitute a waiver only with respect to the specific matter described in such writing and shall in no way impair the rights of the party or parties granting such waiver in any other respect or at any other time.

4.3 Successors, Assigns and Transferees.

(a) This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective permitted successors, assigns and transferees. Any Holder may assign its rights applicable to the shares transferred hereunder to:

(i) successors, assigns and transferees of such Holder by merger or consolidation or otherwise by operation of law,

(ii) any transferee who acquires at least 20% of the Registrable Securities owned by a transferring Holder; or

(iii) any partner, member or stockholder or other Affiliate of a Holder.

(b) In addition, such assignment is conditioned upon: (i) such Investor or other Holder agreeing in writing with the transferee or assignee to assign such rights, and the Issuer receiving written notice from the assigning party at the time of such assignment stating the name and address of the assignee and identifying the capital stock of the Issuer as to which the rights in question are being assigned; and (ii) the transferee or assignee agreeing in writing to be bound by all of the terms and conditions of this Agreement.

4.4 Notices. Any notice required to be given hereunder shall be sufficient if in writing, and sent by facsimile transmission, by courier service (with proof of service), hand delivery or certified or registered mail (return receipt requested and first-class postage prepaid), addressed as set forth below:

(1) if to the Issuer, to it at:

Tokai Pharmaceuticals, Inc.
1 Broadway, 14th floor
Cambridge, MA 02142
Facsimile: (617) 977-8607
Attention: Chief Executive Officer

with a copy to:

WilmerHale
60 State Street
Boston, MA 02109
Facsimile: (617) 526-5000
Attention: Stuart M. Falber, Esq.

(2) if to any other Holder, to it at the address set forth next to its name on Schedule I.

or, in any case, at such other address or facsimile number as shall have been furnished in writing by such party to all of the other parties hereto. Any party may give any notice or other communication in connection herewith using any other means (including, but not limited to, messenger service, telex or ordinary mail), but no such notice or other communication shall be deemed to have been duly given unless and until it is actually received by the individual for whom it is intended.

4.5 No Inconsistent Agreements. The Issuer shall not hereafter enter into any agreement, or amend any existing agreement, with respect to its securities if such agreement would be inconsistent with the rights granted to the Holders by this Agreement.

4.6 Enforcement of Agreement,

(a) The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with its specific terms or was otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, this being in addition to any other remedy to which they are entitled at law or in equity.

(b) The prevailing party in any judicial action shall be entitled to receive from the other party reimbursement for the prevailing party's reasonable attorneys' fees and disbursements, and court costs.

4.7 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, the provision shall be interpreted to be only so broad as is enforceable.

4.8 Headings. Headings of this Agreement are for the convenience of the parties only, and shall be given no substantive or interpretive effect whatsoever.

4.9 Counterparts. This Agreement may be executed by the parties hereto in separate counterparts (and may be delivered by facsimile), each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute one and the same instrument. Each

counterpart may consist of a number of copies hereof each signed by less than all, but together signed by all, of the parties hereto.

4.10 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware without regard to its rules of conflict of laws.

4.11 No Third Party Beneficiaries. Except as provided in Section 2.8, nothing in this Agreement shall confer any rights upon any person or entity other than the parties hereto, each such party's respective successors and permitted assigns.

4.12 Effectiveness. This Agreement shall become effective when executed by (a) the Issuer; (b) the Holders of a majority of the Registrable Securities and the Holders of the Senior Required Securities, as such terms are defined in the Fourth Amended and Restated Investor Rights Agreement; and (c) the holders of at least seventy-five percent (75%) of the combined voting power of the issued and outstanding Senior Preferred Stock (voting as a single class in accordance with Article FOURTH, Part C, Subsection 3.1 of the Certificate of Incorporation, upon which time the Fourth Amended and Restated Investor Rights Agreement shall be amended and restated in its entirety to read as set forth herein and this Agreement shall be binding upon each of the parties to the Fourth Amended and Restated Investor Rights Agreement (and any successor, assignee or transferee of any such party), notwithstanding any failure by any such party to sign a counterpart signature page hereto.

4.13 Limitations on Liability. The limitations on liability of Queensland Biocapital Funds No. 1 and Queensland Biocapital Funds No. 2, as set forth in Exhibit A attached hereto, are incorporated by reference herein as if set forth in its entirety herein.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the undersigned has executed this Agreement or caused this Agreement to be executed on its behalf as of the date first written above.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie P. Morrison
Jodie P. Morrison
Chief Executive Officer

INVESTORS:

Counterpart signature pages attached.

SCHEDULE I

INVESTORS

Name of Investors

APPLE TREE PARTNERS II, L.P.
APPLE TREE PARTNERS II, L.P.- ANNEX
47 Hulfish Street, Suite 441
Princeton, NJ 08542
Attention: Seth Harrison

Novartis BioVentures Ltd.
Attn: Henri Simon Zivi
131 Front Street
Hamilton HM 12
Bermuda

But for mail, to:

Novartis BioVentures Ltd.
PO Box HM 2899
Hamilton HM LX Bermuda

With a copy to:

Novartis Venture Fund
Attn: Campbell Murray
Five Cambridge Center, Suite 603
Cambridge, MA 02142

and

Edwards Wildman Palmer LLP
Attn: Al Sokol
111 Huntington Avenue
Boston, MA 02199 USA

Muneer A. Satter Revocable Trust
The Satter Foundation
Satter Children's Trust I
Satter Family Trust
Kristen Hayler Hertel Revocable Trust
c/o Muneer A. Satter
Satter Investment Management, LLC
676 North Michigan Ave., Suite 4000
Chicago, IL 60611

QBF No. 1 Pty Ltd
QBF No. 2 Pty Ltd
ACN 100 826 686
L6 Central Plaza II, 66 Eagle Street
GPO Box 2242 Brisbane
QLD 4001 Australia

Jon B. Platt
393 Arbor Street
Lunenburg, MA 01462

Nickeli Holdings Pty. Ltd.
30 Wolseley Road
Mosman N.S.W. 2088
Australia

Warman Investments Pty. Ltd.
Level 1, 4-10 Bridge Street
Pymble 2073
Australia

R.B. Thomas Family Trust
R.B. Thomas Superannuation Fund
56 Coolong Road
Vaucluse N.S.W. 2030
Australia

Timothy J. Barberich
40 Elm Steet
Concord, MA 01742

Vial Superannuation Fund
67 Denbigh Road
Armadale, Melbourne
Victoria
Australia 3143

Neil Chatfield
4 Hillcrest Avenue
Kew, Victoria
Australia 3101

WS Investment Company, LLC (2013A)
650 Page Mill Road
Palo Alto, CA 94304

Namarong Investments Pty Ltd as Trustee
for the Hansen Investment Trust
40 Claremont Street
South Yarra VIC
Australia 3141

EXHIBIT A

LIMITATIONS OF LIABILITY OF QBF

1 Limited capacity

QBF No. 1 Pty Ltd ("QBFl") enters into this agreement only in its capacity as trustee of the Queensland BioCapital Fund No 1 and in no other capacity. A liability arising under or in connection with this agreement is limited to and can be enforced against QBF1 only to the extent to which it can be satisfied out of the property of the Queensland BioCapital Fund No 1. This limitation of QBF1's liability applies despite any other provisions of this agreement and extends to all liabilities and obligations of QBF1 in any way connected with any representation, warranty, conduct, omission, agreement or transaction related to this agreement.

2 Limited rights to sue

The parties may not sue QBF1 in any capacity other than as trustee of the Queensland BioCapital Fund No 1, including seeking the appointment of a receiver (except in relation to the property of Queensland BioCapital Fund No 1), a liquidator, an administrator or any similar persons to QBF1 or approve any liquidation, administration or arrangement of affecting QBF1 (except in relation to the property of Queensland BioCapital Fund No 1).

3 Exceptions

The provisions of clauses 1 and 2 shall not apply to any obligation or liability of QBF1 to the extent that it is not satisfied because under the constitution establishing the Queensland BioCapital Fund No 1 or by operation of law there is a reduction in the extent of QBF1's indemnification from the assets of the Queensland BioCapital Fund No 1 as a result of QBF1's fraud, negligence or breach of trust.

4 Limitation on authority

No attorney, agent, receiver and manager appointed in accordance with this agreement has authority to act on behalf of QBF1 in a way which exposes QBF1 to any personal liability in contravention of clauses 1 and 2, and no act or omission of any such person will be considered fraud, negligence or breach of trust of QBF1 for the purpose of clause 3.

5 Limited capacity

QBF No. 2 Pty Ltd ("QBF2") enters into this agreement only in its capacity as trustee of the Queensland BioCapital Fund No 2 and in no other capacity. A liability arising under or in connection with this agreement is limited to and can be enforced against QBF2 only to the extent to which it can be satisfied out of the property of the Queensland BioCapital Fund No 2. This limitation of QBF2's liability applies despite any other provisions of this agreement and extends to all liabilities and obligations of QBF2 in any way connected with any representation, warranty, conduct, omission, agreement or transaction related to this agreement.

6 Limited rights to sue

The parties may not sue QBF2 in any capacity other than as trustee of the Queensland BioCapital Fund No 2, including seeking the appointment of a receiver (except in relation to the property of Queensland BioCapital Fund No 2), a liquidator, an administrator or any similar persons to QBF2 or approve any liquidation, administration or arrangement of affecting QBF2 (except in relation to the property of Queensland BioCapital Fund No 2).

7 ***Exceptions***

The provisions of clauses 5 and 6 shall not apply to any obligation or liability of QBF2 to the extent that it is not satisfied because under the constitution establishing the Queensland BioCapital Fund No 1 or by operation of law there is a reduction in the extent of QBF2's indemnification from the assets of the Queensland BioCapital Fund No 2 as a result of QBF2's fraud, negligence or breach of trust.

8 ***Limitation on authority***

No attorney, agent, receiver and manager appointed in accordance with this agreement has authority to act on behalf of QBF2 in a way which exposes QBF2 to any personal liability in contravention of clauses 5 and 6, and no act or omission of any such person will be considered fraud, negligence or breach of trust of QBF2 for the purpose of clause 7.

Exhibit 10.2

TOKAI PHARMACEUTICALS, INC.

2007 STOCK INCENTIVE PLAN

1. Purpose

The purpose of this 2007 Stock Incentive Plan (the "Plan") of Tokai Pharmaceuticals, Inc. a Delaware corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to align their interests with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "Board").

2. Eligibility

All of the Company's employees, officers, directors, consultants and advisors are eligible to receive options, restricted stock, restricted stock units and other stock-based awards (each, an "Award") under the Plan. Each person who receives an Award under the Plan is deemed a "Participant".

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. To the extent permitted by applicable law, the Board may delegate to one or more officers of the Company the power to grant Awards to employees or officers of the Company or any of its present or future subsidiary corporations and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of the Awards to be granted by such officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to Awards that the officers may grant; provided further, however, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of

1934, as amended (the "Exchange Act")) or to any "officer" of the Company (as defined by Rule 16a-1 under the Exchange Act).]

4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 235,519 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "Option") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option which is not intended to be an Incentive Stock Option (as hereinafter defined) shall be designated a "Nonstatutory Stock Option".

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "Incentive Stock Option") shall only be granted to employees of Tokai Pharmaceuticals, Inc., any of Tokai Pharmaceuticals, Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or for any action taken by the Board pursuant to Section 9(f), including without limitation the conversion of an Incentive Stock Option to a Nonstatutory Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option and specify such exercise price in the applicable option agreement.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement.

(e) Exercise of Option. Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares

for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company following exercise either as soon as practicable or, subject to such conditions as the Board shall specify, on a deferred basis (with the Company's obligation to be evidenced by an instrument providing for future delivery of the deferred shares at the time or times specified by the Board).

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as the Board may otherwise provide in an option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) when the Common Stock is registered under the Exchange Act, by delivery of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board ("Fair Market Value"), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent permitted by applicable law and by the Board, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

(g) Substitute Options. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Options in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Options may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Options contained in the other sections of this Section 5 or in Section 2. Substitute Options shall not count against the overall share limit set forth in Section 4(a), except as may be required by reason of Section 422 and related provisions of the Code.

(h) Repricing of Options. The Board may, without stockholder approval, amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option. The Board may also, without stockholder approval, cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option.

6. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("Restricted Stock"), subject to the right of the Company to repurchase all or part of such shares at

their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. Instead of granting Awards for Restricted Stock, the Board may grant Awards entitling the recipient to receive shares of Common Stock to be delivered at the time such shares of Common Stock vest ("Restricted Stock Units") (Restricted Stock and Restricted Stock Units are each referred to herein as a "Restricted Stock Award").

(b) Terms and Conditions. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for repurchase (or forfeiture) and the issue price, if any.

(c) Stock Certificates. Any stock certificates issued in respect of a Restricted Stock Award shall be registered in the name of the Participant and, unless otherwise determined by the Board, deposited by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "Designated Beneficiary"). In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.

7. Other Stock-Based Awards

Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("Other Stock Unit Awards"), including without limitation stock appreciation rights and Awards entitling recipients to receive shares of Common Stock to be delivered in the future. Such Other Stock Unit Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock Unit Awards may be paid in shares of Common Stock or cash, as the Board shall determine. Subject to the provisions of the Plan, the Board shall determine the conditions of each Other Stock Unit Award, including any purchase price applicable thereto.

8. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share of each outstanding Option, (iii) the repurchase price per share subject to each outstanding Restricted Stock Award, and (iv) the terms of each other outstanding Award shall be appropriately adjusted by the Company (or substituted Awards may be made, if applicable) to the extent determined by the Board.

(b) Reorganization Events

(1) Definition. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any exchange of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock Awards. In connection with a Reorganization Event, the Board shall take any one or more of the following actions as to all or any outstanding Awards on such terms as the Board determines: (i) provide that Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that the Participant's unexercised Options or other unexercised Awards shall become exercisable in full and will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to a Participant equal to (A) the Acquisition Price times the number of shares of Common Stock subject to the Participant's Options or other Awards (to the extent the exercise price does not exceed the Acquisition Price) minus (B) the aggregate exercise price of all such outstanding Options or other Awards, in exchange for the termination of such Options or other Awards, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof) and (vi) any combination of the foregoing.

For purposes of clause (i) above, an Option shall be considered assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent value (as determined by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

To the extent all or any portion of an Option becomes exercisable solely as a result of clause (ii) above, the Board may provide that upon exercise of such Option the Participant shall receive shares subject to a right of repurchase by the Company or its successor at the Option exercise price; such repurchase right (x) shall lapse at the same rate as the Option would have become exercisable under its terms and (y) shall not apply to any shares subject to the Option that were exercisable under its terms without regard to clause (ii) above.

(3) Consequences of a Reorganization Event on Restricted Stock Awards. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to the Common Stock subject to such Restricted Stock Award. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, all restrictions

and conditions on all Restricted Stock Awards then outstanding shall automatically be deemed terminated or satisfied.

9. General Provisions Applicable to Awards

(a) Transferability of Awards. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. Each Participant shall pay to the Company, or make provision satisfactory to the Company for payment of, any taxes required by law to be withheld in connection with an Award to such Participant. Except as the Board may otherwise provide in an Award, for so long as the Common Stock is registered under the Exchange Act, Participants may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares surrendered to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements. The Company may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) Amendment of Award. The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option, provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the

Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to such Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the completion of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to this Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Code Section 409A. No Award shall provide for deferral of compensation that does not comply with Section 409A of the Code, unless the Board, at the time of grant, specifically provides that the Award is not intended to comply with Section 409A of the Code.

(g) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than such state.

AMENDMENT NO. 1 TO
2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The 2007 Stock Incentive Plan (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 441,346 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on June 26, 2008
Adopted by the Stockholders on June 30, 2008

AMENDMENT NO. 2
TO 2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The 2007 Stock Incentive Plan (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 1,855,096 shares of common stock, $0,001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on March 3, 2009
Adopted by the Stockholders on March 25, 2009

AMENDMENT NO. 3 TO
2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The 2007 Stock Incentive Plan (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 8,911,043 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on May 5, 2009
Adopted by the Stockholders on May 5, 2009

AMENDMENT NO. 4 TO
2007 STOCK INCENTIVE PLAN OF TOKAI PHARMACEUTICALS, INC.

The 2007 Stock Incentive Plan (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 12,709,571 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on September 7, 2011
Adopted by the Stockholders on September 9, 2011

AMENDMENT NO. 5 TO
2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The Amended and Restated 2007 Stock Incentive Plan dated April 9, 2010 (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 16,653,382 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock that are covered by the Plan and which are tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on May 10, 2013
Adopted by the Stockholders on May 10, 2013

2007 Plan Amendment

AMENDMENT NO. 6 TO
2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The Amended and Restated 2007 Stock Incentive Plan dated April 9, 2010 (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 21,043,489 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock that are covered by the Plan and which are tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on February 25, 2014
Adopted by the Stockholders on February 26, 2014

2007 Plan Amendment

AMENDMENT NO. 7 TO
2007 STOCK INCENTIVE PLAN
OF
TOKAI PHARMACEUTICALS, INC.

The Amended and Restated 2007 Stock Incentive Plan dated April 9, 2010 (the "2007 Plan") of Tokai Pharmaceuticals, Inc. is hereby amended as follows:

Section 4 of the 2007 Plan is deleted in its entirety and the following is substituted in its place:

"4. Stock Available for Awards. Subject to adjustment under Section 8, Awards may be made under the Plan for up to 22,043,489 shares of common stock, $0.001 par value per share, of the Company (the "Common Stock"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock that are covered by the Plan and which are tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "California Regulations"), based on the shares of the Company which are outstanding at the time the calculation is made."

Adopted by the Board of Directors on April 8, 2014
Adopted by the Stockholders on April 17, 2014

Exhibit 10.3

TOKAI PHARMACEUTICALS, INC.

Incentive Stock Option Agreement
Granted Under 2007 Stock Incentive Plan

1. Grant of Option.

This agreement evidences the grant by Tokai Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on [_____] (the "Grant Date") to [_____], an employee of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2007 Stock Incentive Plan, as amended (the "Plan"), a total of [_____] shares (the "Shares") of common stock, $0.001 par value per share, of the Company ("Common Stock") at an exercise price of $[_____] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [_____] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) This option shall become exercisable ("vest") as to [_____] of the shares underlying the option on [_____] and as to an additional [_____] of the original number of shares on the first day of each successive month thereafter until [_____].

(b) The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

(c) Notwithstanding anything herein to the contrary, if, on or prior to the first anniversary of the date of the consummation of a Change of Control Event (as defined below), the Participant's employment with the Company is terminated by the Company without Cause (as defined below) or the Participant resigns as an employee of the Company for Good Reason (as defined below), all of the Shares not already vested shall automatically vest and the option shall be exercisable in full upon the effective date of such termination or resignation.

(d) For the purposes of this option, a "Change of Control Event" shall mean (i) the consolidation or merger of the Company with or into any other corporation or other entity (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of outstanding securities entitled to vote generally in the election of directors of the Company ("Company Voting Securities") immediately prior to such transaction beneficially own, directly or indirectly, a majority of the combined voting power of the then outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction in substantially the same proportions as their ownership of Company Voting Securities immediately prior to such merger or consolidation), or (ii) the sale of all or substantially all of the assets of the Company to any other corporation or other entity.

(e) For the purposes of this option, "Good Reason" shall mean any action on the part of the Company or a successor in interest not consented to by the Participant in writing (which action shall not have been cured within thirty (30) days following written notice from the Participant to the Company's Board of Directors and the Company's Chief Executive Officer (or the Board of Directors and Chief Executive Officer of the Company's successor in interest, if applicable) specifying that such action will give rise to a termination of employment for Good Reason) having the following effect or effects: (i) a material diminution in the Participant's responsibilities from and after the Change of Control Event; (ii) a material reduction in the Participant's base salary from and after the Change of Control Event, other than a reduction comparable to reductions generally applicable to similarly situated employees of the Company; or (iii) the Company's requiring the Participant's ongoing and regular services to be performed at a location more than fifty (50) miles from the geographic location at which the Participant was providing services before such requirement; provided, however, that the Participant must give written notice with respect to the proposed Good Reason within thirty (30) days after the action first occurs and that the Participant actually leaves employment within forty-five (45) days after the Company fails to cure the proposed Good Reason.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he/she exercises this option, is, and has been at all times since the Grant Date, an employee or officer of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he/she is an Eligible Participant and the Company has not terminated such relationship for "Cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his/her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment. If, prior

to the Final Exercise Date, the Participant is given notice by the Company of the termination of his/her employment by the Company for Cause, and the effective date of such employment termination is subsequent to the date of the delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's employment shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination of employment (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination of employment). If the Participant is party to an employment or severance agreement with the Company that contains a definition of "Cause" for termination of employment, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his/her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(f) Stockholders Agreement. As a condition to the exercise of this option, in whole or in part, the Participant, prior to such exercise of this option, shall execute and deliver or shall have executed and delivered to the Company a counterpart signature page to the Fifth Amended and Restated Stockholders Agreement dated as of May 13, 2013, as amended from time to time (the "Stockholders Agreement"), among the Company and the Stockholders (as defined therein) agreeing to become a party to the Stockholders Agreement and be bound by the terms thereof; provided that if the Participant has previously executed and delivered the Stockholders Agreement, the Participant need only reaffirm his/her obligations thereunder; and provided further that the Participant shall not be obligated to execute and deliver the Stockholders Agreement in the event that it has expired or been terminated.

4. Company Right of First Refusal.

(a) Notice of Proposed Transfer. If the Participant proposes to sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively, "transfer") any Shares acquired upon exercise of this option, then the Participant shall first give written notice of the proposed transfer (the "Transfer Notice") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "Offered Shares"), the price per share and all other material terms and conditions of the transfer.

(b) Company Right to Purchase. For 90 days following its receipt of such Transfer Notice, the Company shall have the option to purchase the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his/her receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for the Offered Shares; provided that if the terms of payment set forth in the Transfer Notice were other than cash against delivery, the Company may pay for the Offered Shares on the same terms and conditions as were set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) Shares Not Purchased By Company. If the Company does not elect to acquire the Offered Shares, the Participant may, within the 90-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 4 shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(d) Consequences of Non-Delivery. After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) Exempt Transactions. The following transactions shall be exempt from the provisions of this Section 4:

(1) any transfer of Shares to or for the benefit of any spouse, child or grandchild of the Participant, or to a trust for their benefit;

(2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and

(3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(f) Assignment of Company Right. The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 4 to one or more persons or entities.

(g) Termination. The provisions of this Section 4 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the outstanding securities entitled to vote generally in the election of directors of the Company immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) No Obligation to Recognize Invalid Transfer. The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Section 4, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

(i) Legends. The certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer of the Company securities):

> "The shares represented by this certificate are subject to a right of first refusal in favor of the Company, as provided in a certain stock option agreement with the Company."

(j) Stockholders Agreement. Notwithstanding the foregoing, in the event that and for so long as the Shares are subject to a right of first refusal in favor of the Company under the terms of the Stockholders Agreement, paragraphs (a) through (f) of this Section 4 shall be of no force or effect.

5. Agreement in Connection with Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act, (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement, and (ii) to execute any agreement necessary to effect clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering.

6. Tax Matters.

(a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

7. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

8. Delivery of Shares; Compliance with Securities Laws, Etc.

(a) General. The Company shall, upon payment of the option price for the number of Shares purchased and paid for, make prompt delivery of such Shares to the Participant, provided that if any law or regulation requires the Company to take any action with respect to such Shares before the issuance thereof, then the date of delivery of such Shares shall be extended for the period necessary to complete such action.

(b) Listing, Qualification, Etc. This option shall be subject to the requirement that if, at any time, counsel to the Company shall determine that the listing, registration or qualification of the Shares subject hereto upon any securities exchange or under any state or federal law, or the consent or approval of any governmental or regulatory body, or that the disclosure of non-public information or the satisfaction of any other condition is necessary as a condition of, or in connection with, the issuance or purchase of shares hereunder, this option may not be exercised, in whole or in part, unless such listing, registration, qualification, consent or approval, disclosure or satisfaction of such other condition shall have been effected or obtained on terms acceptable to the Board of Directors. Nothing herein shall be deemed to require the Company to apply for, effect or obtain such listing, registration, qualification, or disclosure, or to satisfy such other condition.

(c) Legends on Stock Certificates. All stock certificates representing Shares issued to the Participant upon exercise of this option shall have affixed thereto legends substantially in the following forms, in addition to any other legends required by applicable state law:

> "The shares of stock represented by this certificate have not been registered under the Securities Act of 1933 and may not be transferred, sold or otherwise disposed of in the absence of an effective registration statement with respect to the shares evidenced by this certificate, filed and made effective under the Securities Act of 1933, or an opinion of counsel satisfactory to the Company to the effect that registration under such Act is not required."

"The shares of stock represented by this certificate are subject to certain restrictions on transfer contained in an Option Agreement, a copy of which will be furnished upon request by the issuer."

9. Investment Representations.

The Participant represents, warrants and covenants as follows:

(a) Any Shares purchased upon exercise of this option shall be acquired by Participant's account for investment only, and not with a view to, or for sale in connection with, any distribution of such Shares in violation of the Securities Act, or any rule or regulation under the Securities Act.

(b) The Participant has had such opportunity as he/she has deemed adequate to obtain from representatives of the Company such information as is necessary to permit his/her to evaluate the merits and risks of his/her investment in the Company.

(c) The Participant has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in his/her investment in the Company and to make an informed investment decision with respect to such purchase.

(d) The Participant is able to bear the economic risk of holding Common Stock acquired pursuant to the exercise of this option for an indefinite period.

(e) The Participant understands that (i) the Common Stock acquired pursuant to the exercise of this option have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) such Common Stock cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists

for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register any Common Stock acquired pursuant to the exercise of this option under the Securities Act.

By making payment upon exercise of this option, the Participant shall be deemed to have reaffirmed, as of the date of such payment, the representations made in this Section 9.

10. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

TOKAI PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2007 Stock Incentive Plan.

PARTICIPANT:

_____

[_____]

Address: _____

_____

Exhibit 10.4

TOKAI PHARMACEUTICALS, INC.

Nonstatutory Stock Option Agreement
Granted Under 2007 Stock Incentive Plan

1. Grant of Option.

This agreement evidences the grant by Tokai Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on [_____] (the "Grant Date") to [_____], a director of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2007 Stock Incentive Plan, as amended (the "Plan"), a total of [_____] shares (the "Shares") of common stock, $0.001 par value per share, of the Company ("Common Stock") at an exercise price of $[_____] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [_____] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) This option shall become exercisable ("vest") as to [_____] of the shares underlying the option on [_____] and as to an additional [_____] of the original number of shares on the first day of each successive month thereafter until [_____].

(b) The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

(c) Notwithstanding anything herein to the contrary, if, on or prior to the first anniversary of the date of the consummation of a Change of Control Event (as defined below), the Participant's relationship with the Company is terminated by the Company without Cause (as defined below) or the Participant resigns as a director of the Company for Good Reason (as defined below), all of the Shares not already vested shall automatically vest and the option shall be exercisable in full upon the effective date of such termination or resignation.

(d) For the purposes of this option, a "Change of Control Event" shall mean (i) the consolidation or merger of the Company with or into any other corporation or other entity (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of outstanding securities entitled to vote generally in the election of directors of the Company ("Company Voting Securities") immediately prior to such transaction beneficially own, directly or indirectly, a majority of the combined voting power of the then outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction in substantially the same proportions as their ownership of Company Voting Securities immediately prior to such merger or consolidation), or (ii) the sale of all or substantially all of the assets of the Company to any other corporation or other entity.

(e) For the purposes of this option, "Good Reason" shall mean any action on the part of the Company or a successor in interest not consented to by the Participant in writing (which action shall not have been cured within thirty (30) days following written notice from the Participant to the Company's Board of Directors and the Company's Chief Executive Officer (or the Board of Directors and Chief Executive Officer of the Company's successor in interest, if applicable) specifying that such action will give rise to a termination for Good Reason) having the following effect or effects: (i) a material diminution in the Participant's responsibilities from and after the Change of Control Event; (ii) a material reduction in the Participant's base salary from and after the Change of Control Event, other than a reduction comparable to reductions generally applicable to similarly situated persons; or (iii) the Company's requiring the Participant's ongoing and regular services to be performed at a location more than fifty (50) miles from the geographic location at which the Participant was providing services before such requirement; provided, however, that the Participant must give written notice with respect to the proposed Good Reason within thirty (30) days after the action first occurs and that the Participant actually leaves within forty-five (45) days after the Company fails to cure the proposed Good Reason.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he exercises this option, is, and has been at all times since the Grant Date, a director of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he is an Eligible Participant and the Company has not terminated such relationship for "Cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his relationship by the Company for Cause, and the effective date of such relationship termination is subsequent to the date of

the delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's relationship shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is party to an agreement with the Company that contains a definition of "Cause" for termination, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(f) Stockholders Agreement. As a condition to the exercise of this option, in whole or in part, the Participant, prior to such exercise of this option, shall execute and deliver or shall have executed and delivered to the Company a counterpart signature page to the Fifth Amended and Restated Stockholders Agreement dated as of May 13, 2013, as amended from time to time (the "Stockholders Agreement"), among the Company and the Stockholders (as defined therein) agreeing to become a party to the Stockholders Agreement and be bound by the terms thereof; provided that if the Participant has previously executed and delivered the Stockholders Agreement, the Participant need only reaffirm his obligations thereunder; and provided further that the Participant shall not be obligated to execute and deliver the Stockholders Agreement in the event that it has expired or been terminated.

4. Company Right of First Refusal.

(a) Notice of Proposed Transfer. If the Participant proposes to sell, assign, transfer, pledge, hypothecate or otherwise dispose of, by operation of law or otherwise (collectively, "transfer") any Shares acquired upon exercise of this option, then the Participant shall first give written notice of the proposed transfer (the "Transfer Notice") to the Company. The Transfer Notice shall name the proposed transferee and state the number of such Shares the Participant proposes to transfer (the "Offered Shares"), the price per share and all other material terms and conditions of the transfer.

(b) Company Right to Purchase. For 90 days following its receipt of such Transfer Notice, the Company shall have the option to purchase the Offered Shares at the price and upon the terms set forth in the Transfer Notice. In the event the Company elects to purchase the Offered Shares, it shall give written notice of such election to the Participant within such 30-day period. Within 10 days after his receipt of such notice, the Participant shall tender to the Company at its principal offices the certificate or certificates representing the Offered Shares to be purchased by the Company, duly endorsed in blank by the Participant or with duly endorsed stock powers attached thereto, all in a form suitable for transfer of the Offered Shares to the Company. Promptly following receipt of such certificate or certificates, the Company shall deliver or mail to the Participant a check in payment of the purchase price for the Offered Shares; provided that if the terms of payment set forth in the Transfer Notice were other than cash against delivery, the Company may pay for the Offered Shares on the same terms and conditions as were set forth in the Transfer Notice; and provided further that any delay in making such payment shall not invalidate the Company's exercise of its option to purchase the Offered Shares.

(c) Shares Not Purchased By Company. If the Company does not elect to acquire the Offered Shares, the Participant may, within the 90-day period following the expiration of the option granted to the Company under subsection (b) above, transfer the Offered Shares to the proposed transferee, provided that such transfer shall not be on terms and conditions more favorable to the

transferee than those contained in the Transfer Notice. Notwithstanding any of the above, all Offered Shares transferred pursuant to this Section 4 shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(d) Consequences of Non-Delivery. After the time at which the Offered Shares are required to be delivered to the Company for transfer to the Company pursuant to subsection (b) above, the Company shall not pay any dividend to the Participant on account of such Offered Shares or permit the Participant to exercise any of the privileges or rights of a stockholder with respect to such Offered Shares, but shall, insofar as permitted by law, treat the Company as the owner of such Offered Shares.

(e) Exempt Transactions. The following transactions shall be exempt from the provisions of this Section 4:

(1) any transfer of Shares to or for the benefit of any spouse, child or grandchild of the Participant, or to a trust for their benefit;

(2) any transfer pursuant to an effective registration statement filed by the Company under the Securities Act of 1933, as amended (the "Securities Act"); and

(3) the sale of all or substantially all of the outstanding shares of capital stock of the Company (including pursuant to a merger or consolidation);

provided, however, that in the case of a transfer pursuant to clause (1) above, such Shares shall remain subject to the right of first refusal set forth in this Section 4 and such transferee shall, as a condition to such transfer, deliver to the Company a written instrument confirming that such transferee shall be bound by all of the terms and conditions of this Section 4.

(f) Assignment of Company Right. The Company may assign its rights to purchase Offered Shares in any particular transaction under this Section 4 to one or more persons or entities.

(g) Termination. The provisions of this Section 4 shall terminate upon the earlier of the following events:

(1) the closing of the sale of shares of Common Stock in an underwritten public offering pursuant to an effective registration statement filed by the Company under the Securities Act; or

(2) the sale of all or substantially all of the outstanding shares of capital stock, assets or business of the Company, by merger, consolidation, sale of assets or otherwise (other than a merger or consolidation in which all or substantially all of the individuals and entities who were beneficial owners of the outstanding securities entitled to vote generally in the election of directors of the Company immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the outstanding securities entitled to vote generally in the election of directors of the resulting, surviving or acquiring corporation in such transaction).

(h) No Obligation to Recognize Invalid Transfer. The Company shall not be required (1) to transfer on its books any of the Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Section 4, or (2) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

(i) Legends. The certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer of the Company securities):

> "The shares represented by this certificate are subject to a right of first refusal in favor of the Company, as provided in a certain stock option agreement with the Company."

(j) Stockholders Agreement. Notwithstanding the foregoing, in the event that and for so long as the Shares are subject to a right of first refusal in favor of the Company under the terms of the Stockholders Agreement, paragraphs (a) through (f) of this Section 4 shall be of no force or effect.

5. Agreement in Connection with Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act, (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement, and (ii) to execute any agreement necessary to effect clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering.

6. Tax Matters.

(a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

7. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

8. Delivery of Shares; Compliance with Securities Laws, Etc.

(a) General. The Company shall, upon payment of the option price for the number of Shares purchased and paid for, make prompt delivery of such Shares to the Participant, provided that if any law or regulation requires the Company to take any action with respect to such Shares before the issuance thereof, then the date of delivery of such Shares shall be extended for the period necessary to complete such action.

(b) Listing, Qualification, Etc. This option shall be subject to the requirement that if, at any time, counsel to the Company shall determine that the listing, registration or qualification of the Shares subject hereto upon any securities exchange or under any state or federal law, or the consent or approval of any governmental or regulatory body, or that the disclosure of non-public information or the

satisfaction of any other condition is necessary as a condition of, or in connection with, the issuance or purchase of shares hereunder, this option may not be exercised, in whole or in part, unless such listing, registration, qualification, consent or approval, disclosure or satisfaction of such other condition shall have been effected or obtained on terms acceptable to the Board of Directors. Nothing herein shall be deemed to require the Company to apply for, effect or obtain such listing, registration, qualification, or disclosure, or to satisfy such other condition.

(c) Legends on Stock Certificates. All stock certificates representing Shares issued to the Participant upon exercise of this option shall have affixed thereto legends substantially in the following forms, in addition to any other legends required by applicable state law:

> "The shares of stock represented by this certificate have not been registered under the Securities Act of 1933 and may not be transferred, sold or otherwise disposed of in the absence of an effective registration statement with respect to the shares evidenced by this certificate, filed and made effective under the Securities Act of 1933, or an opinion of counsel satisfactory to the Company to the effect that registration under such Act is not required."
>
> "The shares of stock represented by this certificate are subject to certain restrictions on transfer contained in an Option Agreement, a copy of which will be furnished upon request by the issuer."

9. Investment Representations.

The Participant represents, warrants and covenants as follows:

(a) Any Shares purchased upon exercise of this option shall be acquired by Participant's account for investment only, and not with a view to, or for sale in connection with, any distribution of such Shares in violation of the Securities Act, or any rule or regulation under the Securities Act.

(b) The Participant has had such opportunity as he has deemed adequate to obtain from representatives of the Company such information as is necessary to permit him to evaluate the merits and risks of his investment in the Company.

(c) The Participant has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in his investment in the Company and to make an informed investment decision with respect to such purchase.

(d) The Participant is able to bear the economic risk of holding Common Stock acquired pursuant to the exercise of this option for an indefinite period.

(e) The Participant understands that (i) the Common Stock acquired pursuant to the exercise of this option have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) such Common Stock cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the

Company has no obligation or current intention to register any Common Stock acquired pursuant to the exercise of this option under the Securities Act.

By making payment upon exercise of this option, the Participant shall be deemed to have reaffirmed, as of the date of such payment, the representations made in this Section 9.

10. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

TOKAI PHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2007 Stock Incentive Plan.

PARTICIPANT:

_____

[_____]

Address: _____

_____

Exhibit 10.8

July 16, 2014

Jodie Pope Morrison
99 Mount Vernon Avenue
Melrose, MA 02176

Dear Jodie:

On behalf of Tokai Pharmaceuticals, Inc. (the "Company"), set forth below are the terms of your continued employment with the Company.

1. Employment. You will continue to be employed and to serve on a full-time basis as the Company's President and Chief Executive Officer ("CEO"). In addition, we anticipate that you will remain a member of the Company's Board of Directors (the "Board") for so long as you serve as CEO. As President and CEO of the Company, you will be responsible for performing those duties and responsibilities as are consistent with your position, as well as such other duties as may from time to time be assigned to you by the Board. You shall report to the Board, and you agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the lawful rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

2. Base Salary. Your base salary will be at the rate of $29,166.67 per monthly pay period (which if annualized equals $350,000), less all applicable taxes and withholdings, to be paid in installments in accordance with the Company's regular payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company.

3. Discretionary Bonus. Following the end of each calendar year and subject to the approval of the Board, you will be eligible for a retention and performance bonus of up to 25% of your annualized base salary. The bonus, if any, you receive for a calendar year will be based on both your individual performance and the Company's performance that year, as determined by the Company in its sole discretion. In any event, you must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company.

4. Benefits. You may continue to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion.

5. Business Expenses. The Company will reimburse you for all reasonable and documented business expenses submitted in accordance with Company policy.

6. Vacation. You will be eligible for a maximum of five (5) weeks of paid vacation per calendar year, to be taken at times that will not unreasonably interfere with the Company's business. Pursuant to Company policy, vacation time cannot be carried over from year to year.

7. Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement. As a condition of your continued employment pursuant to the terms hereof, you hereby reaffirm your obligations set forth in the Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement, dated November 13, 2006 (the "Non-Competition Agreement"), which Non-Competition Agreement remains in full force and effect.

8. No Conflict. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this offer letter.

9. At-Will Employment. This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chairman of the Board that expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein.

10. Termination Without Cause or for Good Reason.

    a. *Severance Benefits*. In the event the Company terminates your employment without "Cause" (as defined below) or you terminate your employment for "Good Reason" (as defined below), and provided that within 60 days following your last day of employment (or such lesser

period as is then required by the Severance Agreement) you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"), the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your then current base salary. As used herein, the "Severance Period" shall commence on the Company's first payroll date following the eighth (8th) day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment will not begin before the first business day of that subsequent year), and shall continue for twelve (12) months; provided, however, that the Severance Period shall immediately cease on the date on which you commence employment with or begin providing services to another person, employer, or entity for, on average, at least twenty (20) hours per week, at a level of remuneration commensurate with that last paid by the Company (or an hourly equivalent rate) and you are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay hereunder will be subject to all applicable taxes and withholdings and will be payable in accordance with the Company's then-current payroll practices over the course of the Severance Period, subject to the terms and conditions set forth in paragraph 11 below.

b. *Cause*. For purposes of this paragraph, the term "Cause" means: a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence in connection with the performance of your duties or services to the Company, (ii) breached your Non-Competition Agreement, or (iii) violated Company policies or procedures in a manner that has materially injured, or is reasonably likely to materially injure, the Company's business or reputation.

c. *Good Reason*. For purposes of this paragraph, the term "Good Reason" means: (i) a material adverse change in your duties, responsibilities, title or reporting relationship, (ii) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (iii) the relocation of the Company following a Change in Control, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (i) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (ii) provide the Company with at least 30 days to cure, and (iii) if not cured, resign for Good Reason within 30 days following expiration of the cure period.

11. Section 409A.

a. *Six Month Delay*. For purposes of this letter, a termination of employment means a "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code "). If and to the extent any portion of any payment, compensation or other benefit provided to the you in connection with your separation from service (as defined in Section 409A of Code) is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures, by which determination you hereby agree that you are bound, such portion of the payment, compensation or other benefit will be paid within ten (10) days following the earlier of (i) the day that is six (6) months plus one (1) day after the date of separation from service (as determined under Section 409A) or (ii) the date of your death (as applicable, the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to you during the period between the date of separation from service and the New Payment Date will be paid to you in a lump sum in the first payroll period beginning after such New Payment Date, and any remaining payments will be paid on their original schedule.

b. *General 409A Principles*. For purposes of this letter, each amount to be paid or benefit to be provided will be construed as a separate identified payment for purposes of Section 409A, and any payments that are due within the "short term deferral period" as defined in Section 409A or are paid in a manner covered by Treas. Reg. Section 1.409A l(b)(9)(iii) will not be treated as deferred compensation unless applicable law requires otherwise. Neither the Company nor you will have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A. This letter is intended to comply with the provisions of Section 409A and the letter will, to the extent practicable, be construed in accordance therewith. Terms defined in this letter will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A. In any event, the Company makes no representations or warranty and will have no liability to you or any other person if any provisions of or payments under this letter are determined to constitute deferred compensation subject to Code Section 409A but not to satisfy the conditions of that section.

12. Entire Agreement. This letter, together with the Non-Competition Agreement, constitutes the entire agreement between the parties, and amends, restates and supersedes all prior understandings in their entirety, whether written or oral, relating to the terms of your employment, including, without limitation, your offer letter dated June 26, 2013.

If this letter correctly sets forth the terms under which you will continue to be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me.

Sincerely,

By: /s/ Seth L. Harrison
Seth L. Harrison, MD
Chairman of the Board

The foregoing correctly sets forth the terms of my continued at-will employment with Tokai Pharmaceuticals, Inc. I am not relying on any representations other than those set forth above.

/s/ Jodie Pope Morrison
Jodie Pope Morrison

7/16/2014
Date

Exhibit 10.9

September 7, 2011

Martin D. Williams
10 Linnaean St
Cambridge, MA 02138

Dear Martin:

It is my pleasure to extend to you this offer of employment with Tokai Pharmaceuticals, Inc. (the "Company"). On behalf of the Company, I set forth below the terms of your employment:

1. Employment. You will be employed to serve on a full-time basis as the Company's President and Chief Executive Officer ("CEO"), effective on a date to be mutually agreed upon, but no later than September 22, 2011. In addition, we anticipate that you will become and remain a member of the Company's Board of Directors (the "Board"). As President and CEO of the Company, you will be responsible for performing those duties and responsibilities as are consistent with your position, as well as such other duties as may from time to time be assigned to you by the Board. You shall report to the Board, and you agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. The parties acknowledge that you currently serve on the boards of directors of Paloma Pharmaceuticals, Inc. ("Paloma") and Yuma Therapeutics Corporation ("Yuma") and agree that you may continue to do so, provided that such service does not cause you to violate your covenants of non-competition and confidentiality or otherwise materially interfere with the performance of your duties to the Company. In the event you cease to serve on the board of directors of Paloma and/or Yuma and wish to serve on the board of directors of another company, you shall notify the Company and obtain the written consent of the Board to do so, which consent shall not be unreasonably withheld; provided, however, that in no event will you be permitted to serve on the boards of directors of more than two companies at one time, nor will you be permitted to serve on the board of directors of a company if such service would cause you to violate your covenants of non-competition and confidentiality or otherwise materially interfere with the performance of your duties to the Company. You agree to abide by the lawful rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

2. Base Salary. Your base salary will be at the rate of $29,166.67 per monthly pay period (which if annualized equals $350,000), less all applicable taxes and withholdings, to be paid in installments in accordance with the Company's regular payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company.

3. Signing Bonus. You shall receive as a signing bonus a one-time, lump sum payment of $50,000, less all applicable taxes and withholdings, on the first regular payroll date following your commencement of employment.

4. Discretionary Bonus. Following the end of each calendar year and subject to the approval of the Board, you will be eligible for a retention and performance bonus of up to 20% of your annualized base salary. The bonus, if any, you receive for a calendar year will be based on both your individual performance and the Company's performance that year, as determined by the Company in its sole discretion. In any event, you must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus would be pro-rated for the 2011 calendar year.

5. Stock Options. Subject to approval by the Board, the Company will grant to you a stock option (the "Stock Option") to purchase 3,993,203 shares of common stock of the Company (subject to appropriate adjustment for stock splits, stock dividends, combinations, recapitalizations and similar transactions affecting the common stock of the Company after the date hereof) under the Company's 2007 Stock Incentive Plan, at an exercise price equal to the fair market value per share of the common stock of the Company on the date of grant, as determined by the Board. The Stock Option will vest over four years, with 25% of the shares subject to the Stock Option vesting on the first anniversary of the commencement of your employment, subject to your continuing employment with the Company, and the remaining shares vesting monthly thereafter over the subsequent 36 months, in equal amounts, subject to your continuing employment with the Company.

   The terms of the Stock Option will be set forth in an option agreement consistent with the 2007 Stock Incentive Plan (the "Option Agreement"). The Option Agreement will provide that the vesting of the Stock Option will be subject to acceleration in full upon termination of your employment without Cause or by you for Good Reason (as such terms are defined below) following a Change in Control of the Company (as defined in the Option Agreement). In addition, in recognition that the number of shares of common stock issuable upon exercise of the Stock Option was calculated assuming the closing of all tranches of the Company's Series D-3 preferred stock financing, the Option Agreement will provide that, in the event of a Change in Control of the Company prior to the sale by the Company, from and after September 7, 2011 and in one or more transactions, of shares of its preferred stock for an aggregate purchase price of at least $23,000,000, the number of shares of common stock issuable upon exercise of the Stock Option will automatically be reduced (but not increased), effective immediately prior to such Change in Control, to the number of shares of common stock representing 3.5% of the sum of the total number of shares of common stock then outstanding and the total number of shares of common stock then issuable upon conversion of preferred stock then outstanding and upon exercise of stock options and warrants then outstanding (the "Fully Diluted Outstanding Shares").

6. Additional Bonus Upon Change in Control. In the event of a Change in Control of the Company during the term of your employment with the Company hereunder that results in an Upfront Payment that exceeds $500,000,000, the Company shall make an additional bonus payment to you, payable in shares of common stock or cash (such payment in cash or stock being determined by the Company in its sole discretion) as follows: for each additional $250,000,000 of Upfront Payment payable to the securityholders of the Company in excess of $500,000,000, you shall receive (i) in the case of a bonus payment payable in shares of common stock, a number of shares of common stock equal to 0.3333% of the Fully Diluted Outstanding Shares or (ii) in the case of a bonus payment payable in cash, a cash amount equal to the total per share payment that you would have received upon the closing of the Change in Control of the Company (including any amounts deposited into escrow but excluding any contingent or other future payments) if the Company had issued to you immediately prior to the closing of the Change in Control of the Company 0.3333% of the Fully Diluted Outstanding Shares; provided that if the incremental amount of Upfront Payment is less than $250,000,000, the 0.3333% used in the calculation of the bonus shall be reduced to the percentage (rounded downward to four decimal places) determined by multiplying 0.3333% by a fraction, the numerator of which is the incremental amount of the Upfront Payment and the denominator of which is $250,000,000. For illustrative purposes, if the Upfront Payment from a Change in Control of the Company were (i) $700,000,000, you would receive an additional bonus hereunder calculated with respect to 0.2666% of the Fully Diluted Outstanding Shares [0.3333 x 200,000,000/250,000,000], (ii) $800,000,000, you would receive an additional bonus hereunder calculated with respect to 0.4% of the Fully Diluted Outstanding Shares [0.3333 + 0.3333 x 50,000,000/250,000,000] and (iii) $1,000,000,000, you would receive an additional bonus hereunder calculated with respect to 0.6666% of the Fully Diluted Outstanding Shares [0.3333 + 0.3333]. Payment with respect to this additional bonus will be made within 30 days after the closing of the Change in Control. This bonus applies only to the first Change in Control to occur after the date of this offer letter.

7. Benefits. You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion.

8. Business Expenses. The Company will reimburse you for all reasonable and documented business expenses submitted in accordance with Company policy.

9. Vacation. You will be eligible for a maximum of four (4) weeks of paid vacation per calendar year, to be taken at times that will not unreasonably interfere with the Company's business. Pursuant to Company policy, vacation time cannot be carried over from year to year.

10. Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement. As a condition of your employment, you will be required to execute the enclosed

Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement (the "Non-Competition Agreement").

11. No Conflict. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this offer letter. You and the Company acknowledge that you have shared with the Company your nondisclosure, noncompetition and assignment agreement with Dicerna Pharmaceuticals, Inc., which, based upon the information you have provided, neither party believes to bar or limit your employment with the Company.

12. Proof of Legal Right to Work. You agree to provide to the Company, within three (3) days of your date of hire, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

13. At-Will Employment. This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at- will" nature of your employment may only be changed by a written agreement signed by you and the Chairman of the Board that expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein. This letter supersedes all prior understandings, whether written or oral, relating to the terms of your employment.

14. Termination Without Cause or for Good Reason.

    a. *Severance Benefits.* In the event the Company terminates your employment without "Cause" (as defined below) or you terminate your employment for "Good Reason" (as defined below), and provided that within 60 days following your last day of employment (or such lesser period as is then required by the Severance Agreement) you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"), the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your then current base salary. In addition, pursuant to paragraph 5, in the event your employment is terminated by the Company without Cause or by you for Good Reason following a Change in Control of the Company, and provided you abide by the Severance

Conditions, the Stock Option will accelerate in full in accordance with the terms set forth in the Option Agreement. As used herein, the "Severance Period" shall commence on the Company's first payroll date following the eighth (8th) day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment will not begin before the first business day of that subsequent year), and shall continue for such number of full months that you were employed by the Company prior to your termination, up to a maximum of twelve (12) months; provided, however, that in the event a Change in Control occurs prior to your twelve-month anniversary with the Company and you are subsequently terminated by the Company without Cause or you terminate your employment for Good Reason, the Severance Period shall automatically be for twelve (12) months. Notwithstanding the foregoing, the Severance Period shall immediately cease on the date on which you commence employment with or begin providing services to another person, employer, or entity for, on average, at least twenty (20) hours per week, at a level of remuneration commensurate with that last paid by the Company (or an hourly equivalent rate) and you are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay hereunder will be subject to all applicable taxes and withholdings and will be payable in accordance with the Company's then-current payroll practices over the course of the Severance Period, subject to the terms and conditions set forth in paragraph 14 below.

b. *Cause*. For purposes of this paragraph, the term "Cause" means: a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or b) a good faith finding by the Company that you have (i) engaged in dishonesty willful misconduct or gross negligence in connection with the performance of your duties or services to the Company or, if applicable, Diotima, (ii) breached your Non-Competition Agreement, or (iii) violated Company policies or procedures in a manner that has materially injured, or is reasonably likely to materially injure, the Company's business or reputation.

c. *Good Reason*. For purposes of this paragraph, the term "Good Reason" means: (i) a material adverse change in your duties, responsibilities, title or reporting relationship, (ii) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (iii) the relocation of the Company following a Change in Control, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (i) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (ii) provide the Company with at least 30 days to cure, and (iii) if not cured, resign for Good Reason within 30 days following expiration of the cure period.

15. Section 409A.

a. *Six Month Delay*. For purposes of this letter, a termination of employment means a "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code "). If and to the extent any portion of any payment, compensation or other benefit provided to the you in connection with your separation from service (as defined in Section 409A of Code) is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures, by which determination you hereby agree that your are bound, such portion of the payment, compensation or other benefit will be paid within ten (10) days following the earlier of (i) the day that is six (6) months plus one (1) day after the date of separation from service (as determined under Section 409A) or (ii) the date of your death (as applicable, the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to you during the period between the date of separation from service and the New Payment Date will be paid to you in a lump sum in the first payroll period beginning after such New Payment Date, and any remaining payments will be paid on their original schedule.

b. *General 409A Principles.* For purposes of this letter, each amount to be paid or benefit to be provided will be construed as a separate identified payment for purposes of Section 409A, and any payments that are due within the "short term deferral period" as defined in Section 409A or are paid in a manner covered by Treas. Reg. Section 1.409A l(b)(9)(iii) will not be treated as deferred compensation unless applicable law requires otherwise. Neither the Company nor you will have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A. This letter is intended to comply with the provisions of Section 409A and the letter will, to the extent practicable, be construed in accordance therewith. Terms defined in this letter will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A. In any event, the Company makes no representations or warranty and will have no liability to you or any other person if any provisions of or payments under this letter are determined to constitute deferred compensation subject to Code Section 409A but not to satisfy the conditions of that section.

If this letter correctly sets forth the terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me, along with a signed original of the Non-Competition Agreement. If you do not accept our offer within seven (7) days following receipt of this offer of employment, the offer will be deemed withdrawn.

Sincerely,

By: /s/ Seth L. Harrison
Seth L. Harrison, MD
Chairman of the Board

The foregoing correctly sets forth the terms of my at-will employment with Tokai Pharmaceuticals, Inc. I am not relying on any representations other than those set forth above.

/s/ Martin Williams
Martin Williams

September 7, 2011
Date

Exhibit 10.10

VIA HAND DELIVERY
March 27, 2013 (as amended April 3, 2013)

Martin D. Williams
10 Linnaean Street
Cambridge, MA 02138

Dear Martin:

In connection with the termination of your employment with Tokai Pharmaceuticals, Inc. (the "Company") on March 27, 2013, and pursuant to the terms of your September 7, 2011 Offer Letter with the Company, you are eligible to receive the severance benefits described in paragraph 2 below if you sign and return this letter agreement to me by April 4, 2013. By signing and returning this letter agreement, you will be entering into a binding agreement with the Company and will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 3. Therefore, you are advised to consult with an attorney before signing this letter agreement and you have been given at least seven (7) days to do so.

If you choose not to sign and return this letter agreement by April 4, 2013, you shall not receive any severance benefits from the Company. You will, however, receive payment for your final wages and any unused vacation time accrued through the Termination Date (as defined below). You may also, if eligible, elect to continue receiving group medical insurance pursuant to the "COBRA" law. Please consult the COBRA materials to be provided by the Company under separate cover for details regarding these benefits.

The following numbered paragraphs set forth the terms and conditions that will apply if you timely sign and return this letter agreement.

- **Termination Date and Resignations**—Your effective date of termination from the Company will be March 27, 2013 (the "Termination Date"). You agree to resign, as of the Termination Date, from your positions as an officer and director of the Company and of Diotima, Inc. ("Diotima"), an affiliate of the Company, and to sign and return to the Company and Diotima all letters and documents that the Company and/or Diotima may reasonably require in order to secure your resignation. As of the Termination Date, all salary payments from the Company will cease and any benefits you had as of the Termination Date under Company-provided benefit plans, programs, or practices will terminate, except as required by federal or state law.
- **Description of Severance Benefits**- If you timely sign and return this letter agreement and abide by all of its conditions, the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your base salary rate as of your Termination Date. As used herein, the "Severance Period" shall commence on the Company's first payroll date following the eighth (8th) day after you execute this letter agreement, and shall continue for up to twelve (12) months; provided, however, that in the event you commence employment with or begin providing services to another person, employer, or entity for, on average, at least twenty (20) hours per week, at a level

of remuneration commensurate with that last paid by the Company (or an hourly equivalent rate), the Company shall have no further severance pay obligation and the Severance Period shall immediately cease on the date on which you commence any such employment or begin providing any such services. You are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay during the Severance Period will be paid in installments in accordance with the Company's normal payroll practices, but in no event shall payment begin earlier than the date on which you execute this letter agreement.

- **Release**—In consideration of the payment of the severance benefits, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, Diotima, their respective affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C., § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act., Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Wage Act, Mass. Gen, Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 111, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102 and Mass. Gen. Laws ch. 214, § 1C, the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Maternity Leave Act, Mass. Gen. Laws ch. 149, § 105D, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to your September 7, 2011 Offer Letter); all claims to equity in the Company and its affiliates other than your vested equity interest in the Company as of the Termination Date; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this letter agreement prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair

employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding).

- **Continuing Obligations**—You acknowledge your obligation to keep confidential and not to use or disclose any and all non-public information concerning the Company and Diotima that you acquired during the course of your employment with the Company, including, but not limited to, any non-public information concerning the Company's and/or Diotima's business affairs, business prospects, and financial condition, except to the extent disclosure may be required by order of a court of competent jurisdiction, in which event any such disclosure must be subject to all applicable judicial protection available for like material and you must provide reasonable advance notice to the Company and/or Diotima. You further acknowledge and reaffirm your obligations set forth in the Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement you executed for the benefit of the Company, which remain in full force and effect.

- **Non-Disparagement**—You understand and agree that you will not, in public or private, make any false, disparaging, derogatory or defamatory statements to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the Company's or Diotima's business affairs, business prospects, or financial condition. The Company will, in turn, instruct those individuals to whom it makes privy the terms of this letter agreement to refrain from making any false, disparaging or derogatory statements about you.

- **Continued Assistance**—You agree that after the Termination Date you will provide all reasonable cooperation to the Company in assisting with the transition of your job duties.

- **Cooperation**—To the extent permitted by law, you agree to reasonably cooperate with the Company and/or Diotima in the defense or prosecution of any claims or actions which may be brought in the future against or on behalf of the Company and/or Diotima, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Your reasonable cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare its claims or defenses, to prepare for trial or discovery or an administrative hearing or a mediation or arbitration and to act as a witness when requested by the Company and/or Diotima at reasonable times designated by the Company and/or Diotima. For your cooperation, the Company agrees to reimburse you for reasonably necessary and documented travel, food, and lodging expenses. You agree that you will notify the Company or, if applicable, Diotima promptly in the event that you are served with a subpoena or in the event that you are asked to provide a third party with information concerning any actual or potential complaint or claim against the Company and/or Diotima.

- **Return of Company Property**—You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, pagers, etc.), Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those that you developed or helped to develop during your employment. You further confirm that you have cancelled all accounts for your benefit,

if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or pager accounts, and computer accounts.

- **Business Expenses and Final Compensation**—You acknowledge that you have been reimbursed by the Company for all business expenses you incurred in conjunction with the performance of your employment and submitted to the Company as of the Termination Date. The Company will also reimburse you, in accordance with the terms and conditions of its expense reimbursement policy and practice, for all reasonable business expenses you incurred during and in conjunction with your employment but did not submit as of the Termination Date, provided you submit such expenses by close of business on April 4, 2013. You acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages (including overtime), bonuses, and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.

- **Amendment and Waiver**—This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

- **Validity**—Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.

- **Confidentiality**—To the extent permitted by law, you understand and agree that as a condition for payment to you of the severance benefits herein described, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company.

- **Nature of Agreement**—You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

- **Acknowledgments and Voluntary Assent**—You acknowledge that you have been given at least seven (7) days to consider this letter agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement. You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

- **Applicable Law**—This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws

provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.

- **Entire Agreement**—This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your severance benefits and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements, and commitments in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede your obligations set forth in paragraph 4 above. For the avoidance of doubt, your September 7, 2011 Offer Letter is terminated as of March 27, 2013 and is of no further force or effect.

- **Tax Acknowledgement**- In connection with the severance benefits provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such severance benefits under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the severance benefits set forth in paragraph 2 of this letter agreement.

If you have any questions about the matters covered in this letter agreement, please call me.

Very truly yours,

By: /s/ Seth L. Harrison
Seth L. Harrison, MD
Chairman of the Board

I hereby agree to the terms and conditions set forth alive. I intend that this letter agreement become a binding agreement between me and the Company.

/s/ Martin D. Williams
Martin D. Williams

4/4/13
Date

To be returned by April 4, 2013

Exhibit 10.11

July 19, 2012

Adrian Senderowicz, MD
200 Blue Spruce Drive
Kennett Square, PA 19348

Dear Adrian:

It is my pleasure to extend to you this offer of employment with Tokai Pharmaceuticals, Inc. (the "Company"). On behalf of the Company, I set forth below the terms of your employment:

1. **Employment.** You will be employed to serve on a full-time basis as the Company's Vice President, Medical Development and Chief Medical Officer ("CMO"), effective August 6, 2012. As Vice President, Medical Development and CMO, you will be responsible for performing those duties customary of someone in your position, plus such other duties as may from time to time be assigned to you by the Company. You shall report to the Chief Executive Officer or his/her designee, and shall work out of the Company's Massachusetts office. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. You agree to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company, in each case as provided to you.

2. **Base Salary.** Your base salary will be at the rate of $22,916.67 per monthly pay period (which if annualized equals $275,000), less all applicable taxes and withholdings, to be paid in installments in accordance with the Company's regular payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company.

3. **Discretionary Bonus.** Following the end of each calendar year and subject to the approval of the Board of Directors of the Company (the "Board"), you will be eligible for a retention and performance bonus of up to 20% of your annualized base salary. The bonus, if any, you receive for a calendar year will be based on both your individual performance and the Company's performance that year, as determined by the Company in its sole discretion. In any event, you must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any bonus award, as it also serves as an incentive to remain employed by the Company. Any bonus would be pro-rated for the 2012 calendar year.

4. **Relocation.** In order to assist with your relocation to Massachusetts, the Company will reimburse you up to $50,000 for all reasonable relocation expenses incurred by you

prior to September 1, 2013, unless otherwise agreed with the CEO, including costs incurred by you in maintaining a temporary residence in the Greater Boston Area, following your submission of documentation evidencing such expenses. If, within 12 months following your first day of employment, you resign or the Company terminates your employment for Cause (as defined below), you will be obligated to repay to the Company , within thirty (30) days following your separation, a pro rata portion (based on the number of days you were employed) of the relocation expenses for which you were reimbursed.

5. **Stock Options.** Subject to approval by the Board, the Company will grant to you a stock option (the "Stock Option") to purchase 928,659 shares of common stock of the Company (which represents one percent (1%) of the fully diluted capital of the company) (subject to appropriate adjustment for stock splits, stock dividends, combinations, recapitalizations and similar transactions affecting the common stock of the Company after the date hereof) under the Company's 2007 Stock Incentive Plan (the "Option Plan"), at an exercise price equal to the fair market value per share of the common stock of the Company on the date of grant, as determined by the Board. 12.5% of the shares subject to the Stock Option shall become exercisable on the six- month anniversary of the commencement of your employment, subject to your continuing employment with the Company, and an additional 1/48th of the shares subject to the Stock Option shall become exercisable on the first day of each successive month thereafter, subject to your continuing employment with the Company. The terms of the Stock Option will be set forth in an option agreement consistent with the 2007 Stock Incentive Plan.

6. **Benefits.** You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion.

7. **Vacation.** You will be eligible for a maximum of four (4) weeks of paid vacation per calendar year to be taken at such tunes as may be approved in advance by the Company. The number of vacation days for which you are eligible shall accrue at the rate of 1.67 days per month that you are employed during such calendar year. Pursuant to Company policy, vacation time cannot be carried over from year to year.

8. **Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement.** As a condition of your employment, you will be required to execute the enclosed Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement (the "Non-Competition Agreement").

9. **No Conflict.** You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this offer letter.

10. **Proof of Legal Right to Work.** You agree to provide to the Company, within three (3) days of your date of hire, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

11. **At-Will Employment.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the President and Chief Executive Officer of the Company that expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein. This letter supersedes all prior understandings, whether written or oral, relating to the terms of your employment.

12. **Termination Without Cause.** In the event the Company terminates your employment without "Cause" (as defined below), the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your then current base salary (the "Severance Pay"). The Severance Pay is contingent upon your executing and allowing to become effective (within 60 days following your termination or such shorter period as the Company may specify) a severance and release of claims agreement provided by the Company (the "Severance Agreement"). As used herein, the "Severance Period" is the period beginning on the effective date of the Severance Agreement and ending on the earlier of (x) six (6) months following the effective date of the Severance Agreement, or (y) the date on which you commence employment with, or commence working as a consultant or independent contractor for, another employer or entity. You are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any Severance Pay hereunder will be subject to all applicable taxes and withholdings and will be payable in installments in accordance with the Company's then-current payroll practices over the course of the Severance Period, subject to the terms and conditions set forth in paragraph 13 below. As used herein, the term "Cause" means; (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence in connection with the performance of your duties or services to the Company; (ii) breached your Non-Competition Agreement; (iii) violated a Company policy or procedure, including without limitation a policy prohibiting harassment and discrimination or concerning drugs and alcohol; and/or (iv) failed to

satisfactorily perform your assigned duties after notice and a period of fifteen (15) days to cure.

13. **Section 409A.**

a. *Six Month Delay*. For purposes of this letter, a termination of employment means a "separation from service" as defined in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code "). If and to the extent any portion of any payment, compensation or other benefit provided to the you in connection with your separation from service (as defined in Section 409A of Code) is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are a specified employee as defmed in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures, by which determination you hereby agree that your are bound, such portion of the payment, compensation or other benefit will be paid within ten (10) days following the earlier of (i) the day that is six (6) months plus one (1) day after the date of separation from service (as determined under Section 409A) or (ii) the date of your death (as applicable, the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to you during the period between the date of separation from service and the New Payment Date will be paid to you in a lump sum in the first payroll period beginning after such New Payment Date, and any remaining payments will be paid on their original schedule.

b. *General 409A Principles*. For purposes of this letter, each amount to be paid or benefit to be provided will be construed as a separate identified payment for purposes of Section 409A, and any payments that are due within the "short term deferral period" as defined in Section 409A or are paid in a manner covered by Treas. Reg. Section 1.409A l(b)(9)(iii) will not be treated as deferred compensation unless applicable law requires otherwise. Neither the Company nor you will have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A. This letter is intended to comply with the provisions of Section 409A and the letter will, to the extent practicable, be construed in accordance therewith. Terms defined in this letter will have the meanings given such terras under Section 409A if and to the extent required to comply with Section 409A. In any event, the Company makes no representations or warranty and will have no liability to you or any other person if any provisions of or payments under this letter are determined to constitute deferred compensation subject to Code Section 409A but not to satisfy the conditions of that section.

If this letter correctly sets forth the terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me, along with a signed copy of the Non-Competition Agreement. If you do not accept this offer by July 24, 2012, the offer will be deemed withdrawn. This offer is contingent on satisfactory reference checks and approval by the Board.

Sincerely,

By: /s/ Martin Williams
Martin Williams
President and Chief Executive Officer

The foregoing correctly sets forth the terms of my at-will employment with Tokai Pharmaceuticals, Inc. I am not relying on any representations other than those set forth above.

/s/ Adrian Senderowicz
Adrian Senderowicz, MD

7/19/2012
Date

VIA HAND DELIVERY

March 27, 2013 (as amended April 2, 2013)

Adrian Senderowicz, MD

Dear Adrian:

In connection with the termination of your employment with Tokai Pharmaceuticals, Inc. (the "Company") on March 27, 2013, and pursuant to the terms of your July 19, 2012 Offer Letter with the Company, you are eligible to receive the severance benefits described in paragraph 2 below if you sign and return this letter agreement to me by April 4, 2013. By signing and returning this letter agreement, you will be entering into a binding agreement with the Company and will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 3. Therefore, you are advised to consult with an attorney before signing this letter agreement and you have been given at least seven (7) days to do so.

If you choose not to sign and return this letter agreement by April 4, 2013, you shall not receive any severance benefits from the Company. You did, however, receive payment for your final wages and any unused vacation time accrued through the Termination Date (as defined below). You may also, if eligible, elect to continue receiving group medical insurance pursuant to the "COBRA" law. Please consult the COBRA materials to be provided by the Company under separate cover for details regarding these benefits. In addition, in accordance with your incentive stock option agreement, you will have 90 days after the Termination Date to exercise your stock option to purchase the 154,776 shares that had vested as of the Termination Date (the "Vested Shares"). All unvested stock rights were cancelled on your Termination Date.

The following numbered paragraphs set forth the terms and conditions that will apply if you timely sign and return this letter agreement.

1. **Termination Date**—Your effective date of termination from the Company was March 27, 2013 (the "Termination Date"). As of the Termination Date, all salary payments from the Company ceased and any benefits you had as of the Termination Date under Company-provided benefit plans, programs, or practices terminated, except as required by federal or state law.

2. **Description of Severance Benefits**—If you timely sign and return this letter agreement and abide by all of its conditions, the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your base salary rate as of your Termination Date. The Severance Period is the period beginning on the effective date of this letter agreement (the "Effective Date") and ending on the earlier of (x) six (6) months following the Effective Date, or (y) the date on which you commence employment with, or commence working as a consultant or independent contractor for, another employer or entity. You are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay during the Severance Period will be paid in installments in accordance with the Company's normal payroll practices, but in

no event shall payment begin earlier than the date on which you execute this letter agreement.

3. **Release**—In consideration of the payment of the severance benefits, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Genetic Information Nondiscrimination Act of 2008. 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq. Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act., Mass. Gen. Laws ch. 151B, §1 et seq., the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq. (Massachusetts law regarding payment of wages and overtime), the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102 and Mass. Gen. Laws ch. 214, § 1C, the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Maternity Leave Act, Mass. Gen. Laws ch. 149, § 105D, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to your July 19, 2012 Offer Letter); all claims to any non-vested ownership interest in the Company, contractual or otherwise: all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this letter agreement (a) waives any right you have to exercise your stock option with respect to the Vested Shares; or (b) prevents you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding).

4. **Continuing Obligations**—You acknowledge and reaffirm your obligation to keep confidential and not to use or disclose any and all non-public information concerning the Company that you acquired during the course of your employment with the Company, including, but not limited to. any non-public information concerning the Company's business affairs, business prospects, and financial condition. You further

acknowledge and reaffirm your obligations set forth in the Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement you executed for the benefit of the Company, which remain in full force and effect.

5. **Non-Disparagement**—You understand and agree that you will not, in public or private, make any false, disparaging, derogatory or defamatory statements to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the Company's business affairs, business prospects, or financial condition.

6. **Continued Assistance**—You agree that after the Termination Date you will provide all reasonable cooperation to the Company, including but not limited to, assisting the Company in transitioning your job duties and performing any other tasks as reasonably requested by the Company.

7. **Cooperation**—To the extent permitted by law, you agree to cooperate fully with the Company in the defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against or on behalf of the Company, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Your full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare its claims or defenses, to prepare for trial or discovery or an administrative hearing or a mediation or arbitration and to act as a witness when requested by the Company at reasonable times designated by the Company. You agree that you will notify the Company promptly in the event that you are served with a subpoena or in the event that you are asked to provide a third party with information concerning any actual or potential complaint or claim against the Company.

8. **Return of Company Property**—You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, pagers, etc.), Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those that you developed or helped to develop during your employment. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or pager accounts, and computer accounts.

9. **Business Expenses and Final Compensation**—You acknowledge that you have been reimbursed by the Company for all relocation expenses and business expenses you incurred in conjunction with the performance of your employment and submitted to the Company as of the Termination Date. The Company will also reimburse you, in accordance with the terms and conditions of its expense reimbursement policy and practice, for all business expenses you incurred during and in conjunction with your employment but did not submit as of the Termination Date, provided you submit such expenses by May 3, 2013. In addition, the Company will reimburse you for any relocation expenses you incurred as of the Termination Date but did not submit for reimbursement by such date, up to a maximum of $34,531, provided you submit such expenses by May 3, 2013. You acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages (including overtime), bonuses, and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.

10. **Amendment and Waiver**—This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

11. **Validity**—Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.

12. **Confidentiality**—To the extent permitted by law, you understand and agree that as a condition for payment to you of the severance benefits herein described, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company.

13. **Nature of Agreement**—You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

14. **Acknowledgments and Voluntary Assent**—You acknowledge that you have been given at least seven (7) days to consider this letter agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement. You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

15. **Applicable Law**—This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.

16. **Entire Agreement**—This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your severance benefits and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements, and commitments in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede your obligations set forth in paragraph 4 above. For the avoidance of doubt, your July 19, 2012 Offer Letter is terminated as of March 27, 2013 and is of no further force or effect.

17. **Tax Acknowledgement**—In connection with the severance benefits provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such severance benefits under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the severance benefits set forth in paragraph 2 of this letter agreement.

If you have any questions about the matters covered in this letter agreement, please call me.

Very truly yours,

By: /s/ Seth L. Harrison
Seth L. Harrison, MD
Chairman of the Board

I hereby agree to the terms and conditions set forth above. I intend that this letter agreement become a binding agreement between me and the Company.

/s/ Adrian Senderowicz
Adrian Senderowicz, MD

4/3/2013
Date

To be returned by April 4, 2013.

Exhibit 10.14

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

MASTER LICENSE AGREEMENT

BETWEEN

UNIVERSITY OF MARYLAND, BALTIMORE

AND

TOKAI PHARMACEUTICALS, INC.

UMB Docket Nos.:
AB-93-031
AB-96-031
AB-98-014
VN-2002-019

MASTER LICENSE AGREEMENT TABLE OF CONTENTS

MASTER LICENSE AGREEMENT

This Master License Agreement ("**Agreement**") is effective as of the date of the last signature on the Signature Page ("**Effective Date**"), and is made by and between the UNIVERSITY OF MARYLAND, BALTIMORE ("**UMB**"), a constituent institution of the University System of Maryland ("**USM**") (which is a public corporation and an instrumentality of the State of Maryland), having an address at 515 West Lombard Street, Fourth Floor, Baltimore, Maryland 21201, and TOKAI PHARMACEUTICALS, INC., a Delaware corporation ("**Company**"), with its principal place of business at 1 Broadway, 14th Floor, Cambridge, MA 02142.

ARTICLE 1. BACKGROUND

1.1 Valuable inventions ("**Inventions**") generally known as "Androgen Synthesis Inhibitors," have been made by Angela Brodie, Ph.D., Jisong Li, Ph.D., Vincent Njar, Ph.D., and Yangzhi Ling ("**Inventors**").

1.2 Subject to certain rights retained by the U.S. Government in inventions resulting from federally supported work, under USM policy USM owns an interest in and to the Inventions and Patent Rights (as defined below) relating to the Inventions, which has been confirmed by the execution of assignments to UMB from the Inventors.

1.3 As a public research and education institution, UMB is interested in licensing the Patent Rights to Company, which desires to license the Patent Rights on the terms and conditions set forth in this Agreement.

ARTICLE 2. DEFINITIONS

In this Agreement, the following terms have the meanings set forth in this Article.

"BLA": A Biologies License Application submitted to FDA.

"**Business Day**": a day other than a Saturday, Sunday, federal holiday, or holiday observed by UMB.

"**Claim**": Any claim of an issued and unexpired patent or claim of a pending patent application contained in the Patent Rights which has not: lapsed; been irrevocably withdrawn or abandoned; been held permanently revoked, unenforceable or invalid by a final decision of a court or other governmental agency of competent jurisdiction; been held unappealable or unappealed within the time allowed for appeal; or been admitted by UMB to be invalid or unenforceable.

"**Clinical Trial**:" A human clinical trial of a Licensed Product that satisfies the requirements of 21 C.F.R. §312.21, or its foreign equivalent. A Clinical Trial shall be considered to have commenced when the Licensed Product has been administered to the first subject in the study. A Clinical Trial shall be considered to have been completed upon the earlier of: (a) the submission of all case report forms for qualified study subjects by the principal

investigators) to Company or its designee in accordance with the protocol and substantially all analysis thereof has been completed, or (b) when the trial is reported as closed to the Institutional Review Board(s) of record.

"**Combination Product**": A Licensed Product that contains at least one (1) Covered Component and at least one (1) Non-Covered Component.

"**Commercially Reasonable Efforts**": As defined in Section 4.2.

"**Company**": Shall be construed to mean "Tokai Pharmaceuticals, Inc. and/or any Company Affiliate, as the case may be," unless the context clearly indicates otherwise.

"**Company Affiliate**": Any Person which controls, is controlled by, or is under common control with Company. For purposes of this definition, a Person shall be regarded as in control of another Person if it directly or indirectly owns or controls more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the Person or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the Person.

"**Company Confidential Information**": Confidential Information which (a) is made or owned by one or more Company Personnel or Sublicensee Personnel, or owned by Company or Sublicensee(s); and (b) is actually disclosed prior to the Effective Date or during the Term to TEC-COM or the Inventors by Company.

"**Company Improvement**": Any Improvement which: (a) was invented solely by one or more Company Personnel; or (b) otherwise is owned by Company.

"**Company Personnel**": (a) Officers, directors, employees, and agents of Company, and (b) members of Company's Scientific Advisory Board.

"**Confidential Information**": Information (including without limitation documents, notes, drawings, models, designs, data, memoranda, tapes, records, formulae and algorithms, in hard copy form or in electronic form) which has not been made public and which is disclosed by a Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement, including without limitation information that (a) is related to and results from or arises out of use of the Inventions, the Improvements, or the Patent Rights, or (b) is reasonably necessary for the practice of the Patent Rights or for the development or commercialization of Licensed Products.

"**Covered Component**": A component of a Combination Product the manufacture, use, or sale of which is covered by a Claim of the Patent Rights.

"**Combination Product Net Revenues**": As defined in Section 5.5.2.

"**Effective Date**": The date of the last signature on the Signature Page.

"**Eligible Sublicensee**": A Sublicensee that: (a) is not in default of its material obligations under its Sublicense or under any agreement with UMB, USM, or the State of Maryland, and is current on all of its material financial obligations to UMB, USM, or the State of Maryland (including without limitation taxes); (b) is not an adverse party in any litigation, arbitration, administrative or other similar proceeding with UMB or USM; (c) has not made a general assignment for the benefit of creditors of all or substantially all of its assets; (d) has not commenced a case under or otherwise sought relief from its obligations under any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution, or liquidation law, statute, or proceeding; (e) has not by any act indicated its consent to, approval of, or acquiescence in any proceeding or the appointment of a receiver of or trustee for it or a substantial part of its property, or suffered any such receivership or trusteeship to continue undismissed for a period of sixty (60) days; and (f) is not a debtor in any case under any chapter of the U.S. Bankruptcy Code.

"**European States**": Member states of the European Patent Convention (EPC) regional patent system and designated as "EP" in the request of an international patent application filed under the Patent Cooperation Treaty (PCT).

"**Fair Market Value**": For purposes of determining the Fair Market Value of securities hereunder, the following rules shall apply:

(a) If at the time of such issuance the issuing corporation does not have a class of securities registered under the Securities Exchange Act of 1934, as amended ("Exchange Act"), Fair Market Value shall mean the price per share as determined in good faith by the Board of Directors of the issuing corporation with reference, in the case of any preferred stock, to any recent or then contemplated financing by venture capital or similar investors; and

(b) If at the time of such issuance the issuing corporation has a class of securities registered under the Exchange Act, then (i) if the securities so issued are of the same class as securities of the issuing corporation then traded on a national securities exchange, in over-the-counter trading, or similar trading system, then Fair Market Value shall be the average trading price over the twenty (20) day period preceding the date of issuance, and (ii) if the securities are not of the same class as securities of the issuing corporation then so publicly traded, then the Fair Market Value shall be the amount determined in good faith by the Board of Directors of the issuing corporation.

(c) Notwithstanding the foregoing, UMB shall have the right in good faith to dispute any valuation determined by the Board of Directors of the issuing corporation. In that event, any dispute regarding Fair Market Value of the securities shall be resolved in accordance with Section 14.3.

"**FDA**": The U.S. Food and Drug Administration, or any successor agency thereto.

"**Federal Patent Policy**": As defined in Section 3.5.1.

"**First Commercial Sale**": The initial Sale of a Licensed Product to a Third Party end user.

"**Improvement**": An invention or discovery which: (a) is directly related to the Patent Rights, but is not included within the definition of Patent Rights; (b) is or may be patentable or otherwise protected or protectable under law; and (c) either (i) cannot be practiced without infringing one or more Claims of the Patent Rights, or (ii) would itself be infringed by the practicing of the Patent Rights.

"**IND**": An Investigational New Drug Application submitted to FDA under Section 505 of the Federal Food, Drug, and Cosmetic Act, which satisfies the requirements of 21 C.F.R. §312.

"**Infringement**": As defined in Section 9.1.

"**Inventions**": As defined in Section 1.1.

"**Inventors**": As defined in Section 1.1.

"**Joint Improvement**": Any Improvement which was invented by one or more Company Personnel and by one or more UMB Personnel.

"**Licensed Field**": The use of Patent Rights in the prevention, diagnosis, treatment or control of any human or animal disease, disorder, or condition.

"**Licensed Improvement**": As defined in Section 3.6.5.

"**Licensed Product**": Any product (including without limitation any Combination Product) whose manufacture, use, Sale or import would infringe the Patent Rights, or any process whose practice would infringe the Patent Rights.

"**Licensed Territory**": Worldwide.

"**NDA**": A New Drug Application submitted to the FDA to market a new drug under Section 505 of the Federal Food, Drug, and Cosmetic Act, which satisfies the requirements of 21 C.F.R. §313.

"**Net Revenues**": The gross amounts invoiced to any Third Party by Company or Sublicensees for Sales of Licensed Products, less the following:

(a) Trade, quantity and cash discounts, chargebacks, rebates, credits and allowances actually allowed and taken;

(b) Sales or use taxes, excise taxes, surcharges and customs duties and other governmental charges included in the invoiced amount;

(c) Distribution fees and sales agent fees or commissions;

(d) Amounts invoiced to the customer for outbound transportation, shipping, handling, and insurance; and

(e) Amounts actually allowed or credited on returns or rejections of Licensed Products, retroactive price reductions or billing errors.

Combination Product Net Revenues shall be determined in accordance with Section 5.5.2. "Net Revenues" shall also include any recovery of compensatory or actual damages in an Infringement action, as set forth in Section 9.3.2. "Net Revenues" shall not include (1) any amounts which are within the definition of "Sublicense Income," or (2) any amounts in connection with Sales of Licensed Products at or below cost for purposes of clinical trials.

"**Non-Commercial Organization**": A government agency; a university or other institution of higher education; an organization of the type described in Section 501(c)(3) of the Internal Revenue Code, and exempt from taxation under Section 501(a) of the Internal Revenue Code); a nonprofit scientific or educational organization qualified under a state nonprofit organization statute; or any foreign equivalent of any of the foregoing.

"**Non-Commercial Uses**": Research, scholarly use, teaching, education, and other similar uses.

"**Non-Covered Component**": A component of a Combination Product that is an active ingredient or other functional component or product (including without limitation a delivery or similar device but excluding non-active ingredients or non-proprietary excipients, buffers or similar substances that are formulated with drug products), the manufacture, use, or sale of which is not covered by a Claim of the Patent Rights.

"**Option**": As defined in Section 3.6.4.

"**Option Term**": As defined in Section 3.6.5.

"**Optioned Improvement**": As defined in Section 3.6.3.

"**Party**": UMB or Company; "Parties" means collectively UMB and Company.

"**Patent Expenses**": All fees, charges, expenses, and costs incurred before and after the Effective Date in connection with the preparation, filing, prosecution, issuance, reissuance, reexamination, interference, and/or maintenance of patents or applications for patent or equivalent protection for the Patent Rights, including without limitation all fees and charges of outside patent counsel.

"Patent Rights": U.S. and foreign patent applications and patents listed in **Schedule A**, as it may be amended from time to time by mutual agreement of the Parties or to add Licensed Improvements pursuant to Section 3.6, together with any substitution, divisional, continuation, and continuation-in-part (to the extent a continuation-in-part contains one or more Claims directed to any of the foregoing); any Letters Patent therefor; any reissue,

renewal, confirmation, revalidation, addition, reexamination, or extension therefrom; and all foreign counterparts or equivalents of any of the foregoing.

"**Person**": A natural person, trustee, corporation, business trust, partnership, limited partnership, limited liability company, governmental authority, or any other form of legal entity.

"**Personnel**": Officers, directors, employees, and agents.

"**Phase 1 Clinical Trial**": A Clinical Trial that is intended to initially evaluate the safety and/or pharmacological effect in subjects, or that would otherwise satisfy the requirements of 21 C.F.R. §312.21(a).

"**Phase 2 Clinical Trial**": A Clinical Trial for which a primary endpoint is a preliminary determination of efficacy and/or dose ranges in patients with the disease target being studied, or that would otherwise satisfy the requirements of 21 C.F.R. §312.21(b).

"**Phase 3 Clinical Trial**": A Clinical Trial that is performed after preliminary evidence suggesting effectiveness of the drug has been obtained and that is intended to gather confirmatory data supporting effectiveness and safety, to provide an adequate basis for physician labeling, or that would otherwise satisfy the requirements of 21 C.F.R. §312.21(c).

"**Post-Termination Approved Sublicense**": A Sublicense that is approved by UMB pursuant to Section 3.3.5.

"**Pre-Approved Sublicense**": A Sublicense that is approved by UMB pursuant to Section 3.3.3.

"**Qualified Sublicense**": As defined in Section 3.3.4.

"**Sales**," "**Sell**," "**Resell**," or any correlative term: The sale, lease, transfer, or other disposition of a Licensed Product by Company or Sublicensees in return for any type of consideration.

"**Sublicense**": Any agreement pursuant to which all or some of the Patent Rights are licensed, conveyed, assigned, granted rights to, or otherwise transferred.

"**Sublicensee**": A Person (other than a Company Affiliate) to which Company or a Company Affiliate licenses, conveys, assigns, grants rights to, or otherwise transfers all or some of the Patent Rights.

"**Sublicense Income**": Consideration in the form of cash, cash equivalents, or securities received by Company in consideration for the grant to any Sublicensee of a Sublicense of some or all of the Patent Rights, including without limitation up-front fees, license signing fees, license maintenance fees, milestone payments, success fees, amounts paid for equity of Company by a Sublicensee in excess of its Fair Market Value, and any other consideration paid by or on behalf of the Sublicensee. "Sublicense Income" shall not include (a) any running royalties based on Sales of Licensed Product by any Sublicensee,

and (b) any payment or consideration received by Company in consideration for anything other than a Sublicense of some or all of the Patent Rights, including without limitation consideration for any investment in or extension of credit to Company, reimbursement for research rendered by Company or any payments earmarked for research to be performed, or consideration for a license granted under technology other than the Patent Rights.

"**TEC-COM**": The Technology Commercialization Group in UMB's Office of Research and Development, and any successor to its responsibilities.

"**Term**": As defined in Section 10.1.

"**Third Party**": Any Person other than UMB, UMB Personnel, UMB Related Organizations, Company, Company Affiliates or Company Personnel.

"**UMB Related Organizations**": University of Maryland Medical System Corporation, faculty practice organizations of UMB, the Baltimore Veterans Administration Medical Center, USM, and any constituent institutions of the University System of Maryland.

"**UMB Confidential Information**": Confidential Information which either: (1) TEC-COM receives prior to the Effective Date or during the Term from UMB Personnel; or (2) is actually disclosed prior to the Effective Date or during the Term to Company by TEC-COM or UMB Personnel.

"**UMB Improvement**": An Improvement which: (a) was invented solely by one or more UMB Personnel; or (b) otherwise is owned by UMB or a UMB Related Organization.

"**UMB Personnel**": Inventors while they are employed by UMB; and UMB employees, faculty members, students, trainees, and other individuals working under the supervision or direction of Inventors and using UMB resources and who are subject to the USM IP Policy.

"**USM IP Policy**": The University System of Maryland Policy on Intellectual Property, effective July 1, 2002, as amended, or, as applicable, the predecessor Policy on Patents, effective May 31, 1990, as amended, and any successor policy adopted by USM regarding intellectual property and applicable to the Patent Rights.

ARTICLE 3. GRANT OF LICENSE

3.1 License. UMB hereby grants to Company, and Company hereby accepts, an exclusive license under the Patent Rights to make, have made, use, Sell, offer to Sell, and import the Licensed Products and otherwise practice the Patent Rights in any manner, but only during the Term, within the Licensed Field, and in the Licensed Territory. However, the license is subject to: (a) rights of the U.S. under grants to UMB and Federal Patent Policy, and (b) the terms and conditions of this Agreement, including without limitation Section 3.2.

3.2 UMB's Reservation of Rights. Notwithstanding anything contained herein to the contrary, UMB specifically reserves for itself and UMB Related Organizations the following rights:

3.2.1 To practice under the Patent Rights and to make and use the Licensed Products on a royalty-free basis solely for Non-Commercial Uses;

3.2.2 To license, without the right to Sublicense, Non-Commercial Organizations to practice under the Patent Rights and make and use the Licensed Products on a royalty-free basis solely for their internal Non-Commercial Uses;

3.2.3 To provide UMB Confidential Information and material covered by the Patent Rights (excluding Company Confidential Information) to Non-Commercial Organizations, solely for their internal Non-Commercial Uses, if the Non-Commercial Organization agrees in writing in advance not to transfer such material to any other Person;

3.2.4 To disseminate and publish scientific findings from research related to Patent Rights and/or the Licensed Products, and to permit UMB Personnel to do the same, subject to Section 6.4 (Publication) and Article 7 (Confidentiality); and

3.2.5 To license the Patent Rights to Third Parties for applications outside the Licensed Field and/or Licensed Territory.

Nothing in this Section 3.2 shall imply any obligation on Company or any Sublicensee to supply any Licensed Product, any material covered by the Patent Rights, or any other technology or any intellectual property rights to UMB or any Non-Commercial Organization.

3.3 Sublicenses.

3.3.1 Authority to Grant. Company may grant Sublicenses to one or more Sublicensees without consent of UMB, provided that there is no uncured default or material breach of this Agreement by Company at the time of the grant. Company shall provide to UMB a true and complete copy of each fully-signed Sublicense and amendments thereto, including all exhibits, attachments and related documents reasonably promptly after executing the same.

3.3.2 Requirements of Sublicenses.

(a) Any Sublicense shall be consistent with and subject to the relevant terms and conditions of this Agreement. Any Sublicense shall require that any further Sublicense from a Sublicensee must satisfy the requirements of this Section.

(b) Any Sublicense shall expressly include provisions for the benefit of UMB substantially similar to this Section 3.3 (Sublicenses), Section 5.5 (Running Royalties on Sales of Licensed Products and Combination Products), Section 5.6 (Sublicense Income), Article 7 (Confidentiality), Article 8 (Reports, Payments, and Accounting), Section 11.4 (Patent Marking), Section 12.2 (Disclaimer of Warranties by UMB), and Article 13 (Claims, Indemnification, and Insurance).

(c) Any Sublicense shall also require that any dispute between Sublicensee and UMB which may arise upon termination of this Agreement shall be subject to dispute resolution on the terms and conditions set forth in Article 14 (Dispute Resolution) of this Agreement.

3.3.3 Pre-Approved Sublicenses.

(a) Company may, at its option, seek UMB's prior approval of a proposed Sublicense. In that event, prior to execution, Company shall notify UMB of the identity of the proposed Sublicensee and shall provide to UMB a true and complete copy of the proposed Sublicense in substantially final form. UMB shall have [**] days after receipt to notify Company in writing of its determination as to whether the Sublicense and Sublicensee are approved and the reasons for its determination. Any Sublicense that is approved by UMB pursuant to this Section shall be a "**Pre-Approved Sublicense**."

(b) UMB shall not unreasonably withhold its approval of a Sublicense and Sublicensee if: (i) the Sublicense complies with Section 3.3.2; (ii) the proposed Sublicensee is an Eligible Sublicensee at that time; (iii) the Sublicensee has sufficient financial capacity and resources to commercialize the Licensed Products within the scope of the Sublicense and to fulfill its financial obligations under the Sublicense; (iv) the Sublicensee agrees to make commercially reasonable payments (such as royalties, milestone payments or other fees) under the Sublicense in light of the then current commercial and regulatory circumstances for the Licensed Products; and (v) the Sublicensee is able to fulfill the diligence obligations required by this Agreement (as they may reasonably be adjusted in light of the then current commercial and regulatory circumstances for the Licensed Products).

(c) In the event of termination of this Agreement, upon written request of a Sublicensee within [**] days following the effective date of termination, any Patent Rights sublicensed by Company under a Pre-Approved Sublicense shall become directly licensed from UMB to the Sublicensee if as of the effective date of direct license the Sublicensee is an Eligible Sublicensee. In that event, the Sublicensee shall comply with Section 3.3.6.

3.3.4 Qualified Sublicenses.

(a) In the event of termination of this Agreement, upon written request of a Sublicensee within [**] days following the effective date of termination, any Patent Rights sublicensed by Company under a Qualified Sublicense shall become directly licensed from UMB to the Sublicensee if as of the date of the written request the Sublicensee is an Eligible Sublicensee. In that event, the Sublicensee shall comply with Section 3.3.6.

(b) "**Qualified Sublicense**" means a Sublicense that: (i) complies with Section 3.3.2; (ii) contains provisions that require payment by the Sublicensee to Company of amounts that, taken as a whole, are equal to or greater than the amounts payable by Company to UMB under Section 5.2 (License Maintenance Fees), Section 5.3 (Milestone Payments), Section 5.4 (Minimum Annual Royalty), Section 5.5 (Running Royalties on Sales of Licensed Products and Combination Products), and Section 5.6 (Sublicense Income); (iii) requires the

Sublicensee to use Commercially Reasonable Efforts to commercialize one or more Licensed Products; and (iv) requires the Sublicensee to achieve the due diligence milestones set forth on **Schedule B** (subject to reasonable adjustment based on the field of use and territory of the Sublicense).

3.3.5 Post-Termination Approved Sublicenses.

(a) In the event of termination of this Agreement, any Sublicensee of Patent Rights under a Sublicense from Company that is not a Pre-Approved Sublicense or a Qualified Sublicense may request in writing within [**] days following the effective date of termination that UMB directly license those Patent Rights to the Sublicensee. Not later than [**] days following the request, UMB shall provide written notice to Company and the Sublicensee of its determination as to whether that direct license and Sublicensee are approved and the reasons for its determination. Any direct license that is approved by UMB pursuant to this Section shall be a "**Post-Termination Approved Sublicense**."

(b) UMB shall not unreasonably withhold approval of that request, if: (i) the Sublicense complies with Section 3.3.2; (ii) as of the date of the written request the Sublicensee is an Eligible Sublicensee; (iii) the Sublicensee has sufficient financial capacity and resources to commercialize the Licensed Products within the scope of the Sublicense and to fulfill its financial obligations under the Sublicense; (iv) the Sublicensee agrees to make commercially reasonable payments (such as royalties, milestone payments or other fees) under the Sublicense in light of the then current commercial and regulatory circumstances for the Licensed Products; and (v) the Sublicensee is able to fulfill the diligence obligations required by this Agreement (as they may reasonably be adjusted in light of the then current commercial and regulatory circumstances for the Licensed Products).

(c) The Sublicensee under a Post-Termination Approved Sublicense shall comply with Section 3.3.6.

3.3.6 Confirmation of the Direct License; Insurance.

(a) With respect to a Pre-Approved Sublicense, Qualified Sublicense, or Post-Termination Approved Sublicense that is to survive, the Sublicensee shall promptly confirm in writing that:

(i) The Patent Rights are directly licensed to the Sublicensee by UMB with the same exclusivity, field of use, and territory as contained in the Sublicense;

(ii) UMB shall not have any obligations broader in scope than it has under this Agreement or any obligations of Company to the Sublicensee which are inconsistent with the Federal Patent Policy, other law, or a written USM or UMB policy;

(iii) The Sublicensee agrees to deliver to UMB all reports that would have been due to Company under its Sublicense after the date of termination of this Agreement, and to pay to UMB all payments accruing and due after the termination of this Agreement that would have been payable to Company under its Sublicense;

(iv) The Sublicensee agrees to achieve the diligence obligations required by the Sublicense;

(v) The Sublicensee agrees to be bound by terms substantially similar to those required by Section 3.3.2(b), Section 6.1, and Section 6.2, and to the reimbursement of Patent Expenses (which reimbursement will be on a pro rata basis, if more than one Sublicensee receives a direct license following termination of this Agreement); and

(vi) The Sublicensee agrees that any provision of its Sublicense which is inconsistent with this Agreement shall not be effective as to the relationship between UMB and the Sublicense.

(b) With respect to a Pre-Approved Sublicense, Qualified Sublicense, or Post-Termination Approved Sublicense that is to survive, the Sublicensee shall promptly deliver to UMB a certificate evidencing the insurance coverage required by this Agreement. The certificate shall evidence that UMB has been listed as an additional insured, and that the insurance was effective no later than the effective date of the termination.

3.3.7 Non-Survival of Other Sublicenses. In the event of termination of this Agreement, no Patent Rights sublicensed by Company shall become directly licensed from UMB other than as specifically set forth in this Section.

3.3.8 Third Party Beneficiaries. Each Sublicensee of a Pre-Approved Sublicense, a Qualified Sublicense, or a Post-Termination Approved Sublicense is an intended third party beneficiary of this Section, and the terms of this Section are enforceable by those Sublicensees against UMB.

3.4 No Implied Rights. This Agreement confers no license or rights by implication, estoppel, or otherwise in any technology, except as explicitly set forth in this Agreement.

3.5 Government Rights and Regulations.

3.5.1 To the extent that any Invention has been funded in whole or in part by the U.S. Government, the U.S. Government retains certain rights in the Invention under Federal law and applicable regulations, including without limitation 35 U.S.C. §200-212 (the "**Federal Patent Policy**"). This Agreement is subject in all respects to the Federal Patent Policy.

3.5.2 As a condition of the license granted hereby, Company acknowledges and agrees to comply with all aspects of the Federal Patent Policy applicable to the Patent Rights, including without limitation the obligation as set forth in the Federal Patent Policy that Licensed Products used or sold in the U.S. be manufactured substantially in the U.S (unless such obligation is waived in accordance with the Federal Patent Policy). Nothing contained in this Agreement shall obligate UMB to take any action that would conflict in any respect with its past, current or future obligations to the U.S. Government under the Federal Patent Policy.

3.5.3 Solely to the extent set forth in the Federal Patent Policy, the U.S. Government retains the right in certain circumstances to require UMB to grant to a responsible

applicant a nonexclusive, partially exclusive, or exclusive license to use the Inventions in the applicant's field of use on terms that are reasonable under the circumstances; or, if UMB fails to do so, to grant a license itself.

3.5.4 The use and disclosure of technical Confidential Information acquired pursuant to this Agreement and the exercise of Patent Rights granted by this Agreement are subject to the export, assets, and financial control regulations of the U.S., including without limitation restrictions under regulations of the U.S. that may be applicable to direct or indirect reexportation of technical Confidential Information or of equipment, products, or services directly produced by use of technical Confidential Information. Company is responsible for complying with these regulations.

3.6 Improvements.

3.6.1 UMB Improvements shall be owned by UMB. Joint Improvements shall be owned jointly by Company and UMB. Company Improvements shall be owned by Company.

3.6.2 UMB shall report promptly to Company in writing each UMB Improvement and/or Joint Improvement made by UMB during the Term which is disclosed to TEC-COM, and whether that UMB Improvement and/or Joint Improvement is subject to rights of a Third Party which sponsors research at UMB as a result of which the Improvement was discovered or invented. Company shall report promptly to UMB in writing each Joint Improvement made by Company during the Term. These reports shall be in sufficient detail to determine inventorship and to file and prosecute patent applications for Improvements. These reports shall be subject to Article 7 (Confidentiality).

3.6.3 Company and UMB shall discuss whether a patent application or applications pertaining to each UMB Improvement and/or Joint Improvement should be filed. If Company notifies UMB in writing that patent application(s) should be filed with respect to any UMB Improvement and/or Joint Improvement (each, an "**Optioned Improvement**"), then UMB shall be responsible for preparing and filing such patent applications in accordance with Sections 6.1 and 6.2 hereof and Company shall be responsible for the reasonable Patent Expenses incurred by UMB for such filings in accordance with Section 3.6.8. If Company notifies UMB in writing that it is not interested in having patent application(s) filed with respect to a particular UMB Improvement and/or Joint Improvement, or if Company fails to notify UMB of its interest within [**] days from the date on which the Improvement was disclosed by UMB, then Company shall not be responsible for Patent Expenses and shall have no further right to UMB's rights to such UMB Improvement and/or Joint Improvement.

3.6.4 Subject to rights of a Third Party which sponsors the research at UMB as a result of which the Improvement was invented or discovered, Company is hereby granted a first option to receive an exclusive license to UMB's rights in any Optioned Improvement within the Licensed Field (the "**Option**") during the Option Term; *provided*, *however*, that this Agreement is then in effect, there are at that time no uncured defaults or breaches by Company of this Agreement or any other Agreement between Company and UMB, and Company pays Patent Expenses in accordance with Section 3.6.8.

3.6.5 Company may exercise the Option by giving written notice to UMB at any time within [**] days after Company receives notice from UMB under Section 3.6.2 concerning the particular Optioned Improvement (the "**Option Term**"). Upon written notice by Company during the Option Term, the Parties shall negotiate in good faith for a period of [**] days (or such longer period as the Parties may agree) (the "**Negotiation Period**") an amendment to this Agreement adding such Optioned Improvement to the Patent Rights set forth on **Schedule A**. If an amendment is executed by the Parties, but only in that event, the Optioned Improvement ("**Licensed Improvement**") shall be deemed to constitute part of the Patent Rights. The Optioned Improvement shall not be considered part of Patent Rights unless and until added by such amendment.

3.6.6 Any amendment shall provide that the Licensed Improvement shall be subject to the terms and conditions of this Agreement, including without limitation Article 5 (Consideration). However, (a) if USM bond counsel advises that U.S. tax law relating to tax-exempt bond issues which financed the construction or renovation of UMB resources used for research related to the Licensed Improvement (including without limitation the "Safe Harbor" provisions of Internal Revenue Procedure 97-14) would be applicable to the license of the Licensed Improvement, and (b) UMB or USM reasonably determines that the royalty rate set forth in this Agreement as applied to the Licensed Improvement would not satisfy the requirements of that tax law, then the Parties shall negotiate in good faith to set a commercially reasonable royalty rate that does satisfy those requirements. If the Parties are unable to agree upon a royalty rate for the Licensed Improvement during the Negotiation Period, the Parties shall submit the issue for dispute resolution pursuant to Section 14.3.

3.6.7 If the Negotiation Period ends and the Parties have not executed an amendment, Company shall have no rights with respect to the Optioned Improvement, shall have no obligation to pay Patent Expenses related to such Optioned Improvement, and UMB may license all or a portion of its interest in the Optioned Improvement to one or more Third Parties; *provided*, *however* that for a period of [**] after the expiration of the Negotiation Period, UMB may only offer the rights to Third Parties on terms and conditions that are not more favorable than the last offer made by UMB to Company, unless those more favorable terms and conditions have first been offered in writing to Company, and either (a) Company has declined in writing to accept the offer, or (b) Company has filed to respond to the offer within [**] days after receiving the offer.

3.6.8 In consideration for the Option, Company shall be responsible for payment of all Patent Expenses with respect to Optioned Improvements. If Company fails to pay timely any undisputed invoice for the Patent Expenses, the Option with respect to the relevant Optioned Improvement shall terminate and be of no further force or effect, effective as of the date of UMB's written notice of termination. If Company notifies UMB of its intent not to exercise the Option with respect to any particular Optioned Improvement, or does not timely exercise the Option, Company shall have no obligation to pay Patent Expenses related to the Optioned Improvement which are incurred more than [**] days after UMB's receipt of the notice or the date of expiration of the applicable Option, as the case may be. UMB shall use reasonable efforts to minimize the Patent Expenses incurred during the [**] day period.

3.6.9 For purposes of this Agreement, inventorship of any Improvement shall be determined only in accordance with U.S. patent law, notwithstanding that the patent laws of other countries where patent applications are filed may follow rules of inventorship that differ from U.S. patent law. For purposes of this Agreement, an invention shall be deemed to be "made" when it is conceived.

ARTICLE 4. DILIGENCE REQUIREMENTS

4.1 R&D Plan and Business Plan.

4.1.1 Company has delivered to UMB prior to execution of this Agreement: (a) a research and development plan (the "**R&D Plan**") to be reasonably acceptable to UMB, showing the amount of money and time budgeted and planned for technical development of the Patent Rights, and (b) a business plan (the "**Business Plan**") to be reasonably acceptable to UMB, showing the proposed commercialization scheme for Licensed Products.

4.1.2 Company shall provide [**] written reports for the first [**] after the Effective Date, and [**] written reports thereafter, to UMB on progress against the R&D Plan and the Business Plan (and any commercially reasonable updates thereto by Company), including general information on the progress of research and development activities related to the Licensed Products and marketing analyses and the occurrence or satisfaction of each of the due diligence milestones set forth on **Schedule B**. Such reports shall contain information sufficient for UMB to determine whether Company is making progress with respect to Licensed Products, but Company shall not be required to disclose detailed or sensitive data or trade secrets. The reports shall be due within [**] days following the expiration of each reporting period. Any information or reports provided under this Section shall be Company Confidential Information subject to Article 7 (Confidentiality).

4.2 Licensed Products to Market. Company shall use Commercially Reasonable Efforts to bring one or more Licensed Products to market as soon as practicable in accordance with the R&D Plan and the Business Plan. "**Commercially Reasonable Efforts**" means, with respect to the commercialization of a Licensed Product, efforts that are consistent with those utilized by companies of similar size and type for products with similar commercial potential at a similar stage, taking into consideration their safety and efficacy, their cost to develop, the competitiveness of alternative products, the nature and extent of their market exclusivity, the likelihood of regulatory approval, their profitability, and all other relevant factors.

4.3 Due Diligence Milestones. Company shall timely achieve the due diligence milestones set forth on **Schedule B**.

ARTICLE 5. CONSIDERATION

The Parties acknowledge and agree that each of the payment obligations set forth in this Article 5 have been established for the convenience of the Parties after due consideration was given to alternative payment structures. Such payment obligations have been deemed by the Parties to be the most appropriate and convenient means of valuing Company's right to practice

the Patent Rights under this Agreement and to receive the benefit of UMB entering into this Agreement. In consideration of the license hereunder:

5.1 License Fee. Within [**] days after the Effective Date, Company shall pay to UMB a non-refundable license fee of Twenty Thousand Dollars (U.S. $20,000.00). The license fee is not creditable against any other fee, royalty, or payment.

5.2 License Maintenance Fees. Company shall pay license maintenance fees to UMB of Ten Thousand Dollars (U.S. $10,000.00) per annum commencing on the first anniversary of the Effective Date, and continuing on each anniversary of the Effective Date during the Term, until the year in which the First Commercial Sale occurs. The license maintenance fees are not creditable against any other fee, royalty, or payment.

5.3 Milestone Payments. Company shall pay to UMB the following milestone payments:

On submission of each IND for a Licensed Product to the U.S. FDA:	U.S. $50,000.00	Within [**] days following submission
On approval of each NDA or BLA for a Licensed Product by the U.S. FDA:	U.S. $100,000.00	Within [**] days following receipt of approval

5.4 Minimum Annual Royalty. Company shall pay UMB guaranteed minimum annual royalties of Fifty Thousand Dollars (U.S. $50,000.00) per year, beginning with the calendar year following the year in which the First Commercial Sale occurs. The minimum annual royalty for the year of First Commercial Sale shall be pro-rated according to the date of First Commercial Sale. Company shall pay the minimum annual royalty, if any, due with respect to a calendar year by the next February 1 following that year. Minimum annual royalties shall be creditable against running royalties payable under Section 5.5.

5.5 Running Royalties on Sales of Licensed Products and Combination Products.

5.5.1 Licensed Products. Subject to the terms of this Section 5.5, Company shall pay to UMB a running royalty of [**] percent ([**]%) of Net Revenues on Sales of Licensed Products (other than Combination Products) by Company or Sublicensees.

5.5.2 Combination Products.

(a) Subject to the terms of this Section 5.5, Company shall pay to UMB a running royalty of [**] percent ([**]%) of Combination Product Net Revenues (as defined below) on Sales by Company or Sublicensees of Combination Products. "**Combination Product Net Revenues**" shall be determined as follows:

(1) by multiplying the Net Revenues of the Combination Product by the fraction A/(A+B), if on a country-by-country basis, the Covered Component(s) and Non-Covered Component(s) are sold separately in finished form in such country, where A is

the average invoiced sales price of the Covered Component(s) sold separately in finished form in such country and B is the average invoiced sales price of the Non-Covered Component(s) sold separately in finished form in such country;

(2) by multiplying the Net Revenues of the Combination Product by the fraction C/(C+D), if on a country-by-country basis the Covered Component(s) are sold separately in finished form in such country, but the Non-Covered Component(s) are not sold separately in finished form in such country, where C is the average invoiced sales price of the Covered Component(s) in finished form in such country and D is the difference between the average invoiced sales price of the Combination Product and the average sales price of the Covered Component(s) in finished form in such country;

(3) by multiplying the Net Revenues of the Combination Product by the fraction 1 minus C/(C+D), if on a country-by-country basis the Non-Covered Component(s) are sold separately in finished form in such country but the Covered Component(s) are not sold separately in finished form in such country, where C is the average invoiced sales price of the Non-Covered Component(s) in finished form in such country and D is the difference between the average invoiced sales price of the Combination Product and the average invoiced sales price of the Non-Covered Component(s); or

(4) if on a country-by-country basis neither the Covered Component(s) nor the Non-Covered Components) are sold separately in finished form in a country, Combination Product Net Revenues shall be determined by the Parties in good faith based on the relative fully allocated costs of goods for each Covered Component and Non-Covered Component; *provided*, *however*, that if either Party can establish in good faith that using the relative fully allocated costs of goods would not produce a reasonable determination of Combination Product Net Revenues, the matter shall be resolved pursuant to the dispute resolution procedures set forth in Article 14.

5.5.3 Duration. Royalties under Sections 5.5.1 and 5.5.2 shall be payable on a country-by-country and Licensed Product-by-Licensed Product basis commencing with the First Commercial Sale until the later of: (a) the expiration of the last to expire of the Claims of the Patent Rights covering the manufacture, use or sale of a Licensed Product in such country (the "**Claim Expiration Date**"), or (b) ten (10) years after the First Commercial Sale of a Licensed Product in such country. However, if the Claim Expiration Date is earlier than the tenth (10th) anniversary of the First Commercial Sale in such country then, for the period commencing upon the Claim Expiration Date and ending ten (10) years after the First Commercial Sale in such country, the royalty rate set forth in Section 5.5.1 and 5.5.2 shall be reduced by [**] percent ([**]%) (i.e., to [**] percent ([**]%)).

5.5.4 Royalty Reduction. UMB and Company shall negotiate in good faith an appropriate reduction in the royalty rate if Company proves that it suffered a loss of Sales due to competition from a product whose manufacture, use or sale is covered by a UMB-owned patent which was invented by one or more of the Inventors, and is sold by a Third Party under a license from UMB.

5.5.5 Sales to Company Affiliates or Sublicensees. Company shall not be required to pay royalties on Sales of Licensed Products to a Company Affiliate or Sublicensee, and these Sales shall not be included in Net Revenues on which royalties are calculated. However, if the Company Affiliate or Sublicensee is an end user of a Licensed Product, these Sales shall be included in Net Revenues of the Licensed Product for the purpose of calculating royalties, at the average selling price charged by Company to Third Parties for the Licensed Product during that same period and in the relevant country.

5.5.6 Royalty Stacking. If Company or a Sublicensee is reasonably required to license one or more technologies of one or more Third Parties in order to make, have made, use, offer to Sell, Sell or import Licensed Products, and is required to pay a royalty therefor, then up to [**] percent ([**]%) of the royalty may be deducted from running royalties payable to UMB; *provided*, *however*, that the running royalties payable to UMB shall not be reduced by more than [**] percent ([**]%). Company shall not permit any Sublicensee to deduct from Sublicense Income due to Company more than [**] percent ([**]%) of royalties due as a result of any licenses from one or more Third Parties to that Sublicensee.

5.6 Sublicense Income.

5.6.1 Company shall pay to UMB a percentage of all Sublicense Income that is received from each Sublicensee, according to when the Sublicense is executed, as follows:

Prior to the 1st anniversary of the Effective Date: [**]%

On or after the 1st anniversary but prior to the 2nd anniversary of the Effective Date: [**]%

On or after the 2nd anniversary but prior to the 3rd anniversary of the Effective Date: [**]%

On or after the 3rd anniversary but prior to the 4th anniversary of the Effective Date: [**]%

On or after the 4th anniversary of the Effective Date: 10%

5.6.2 Any share of a milestone payment from a Sublicensee which is paid to UMB pursuant to this Section may be credited toward the milestone payments due under Section 5.3.

5.6.3 Company shall pay UMB the required share of any Sublicense Income paid in cash within [**] days of the end of each calendar quarter.

5.6.4 For any non-cash Sublicense Income paid in securities that are publicly traded or otherwise have a value that can be agreed by the Parties at that time, the Parties shall agree on an acceptable method to have UMB's share paid within [**] days of Company receiving the securities, by Company either (a) transferring and delivering to UMB the required percentage of the securities, or (b) paying in cash the Fair Market Value of such securities.

Notwithstanding the foregoing, if Company is unable to transfer, deliver, or liquidate the securities within the period without violating an applicable law, regulation, other legal requirement, or any agreement or other arrangement with any other Person (including the Sublicensee), then Company shall compensate UMB in accordance with the foregoing within [**] days after it is first able to transfer and deliver the securities without such a violation. UMB shall execute and deliver, prior to any transfer of securities, all commercially reasonable stockholder agreements and other documents applicable to the securities to be transferred to UMB.

5.6.5 As to any other form of Sublicense Income that cannot be valued as contemplated by this Section 5.6, the Parties shall negotiate in good faith to arrive at a mutually agreeable solution under which UMB shall receive its required share.

5.7 Payments For Net Revenues in Foreign Countries.

5.7.1 Royalties are payable from the country in which they are earned and are subject to foreign exchange regulations then prevailing in the country. Royalty payments must be paid to UMB in U.S. Dollars by check(s) drawn to the order of UMB or by electronic funds transfers to an account designated by UMB. To the extent Sales are made in a foreign country, those royalties shall be determined first in the currency of the country in which the royalties are earned, and then converted to their equivalent in U.S. Dollars. The buying rates of exchange for converting the currencies involved into the currency of the U.S. quoted by the Morgan Guaranty Trust Company of New York, New York (or any successor), averaged on the last business day of each of six (6) consecutive calendar months constituting the period in which the royalties were earned, shall be used to determine any conversion. Company shall bear any loss of exchange or value or pay any expenses incurred in the transfer or conversion to U.S. dollars.

5.7.2 If any applicable law or regulation (including without limitation currency exchange regulations) prevents or limits royalty payments with respect to Net Revenues in any country, Company shall render to UMB annual reports of Sales of Licensed Products in that country. All monies due and owing UMB as provided in the annual reports shall, at UMB's option: (a) be deposited promptly in a local bank in that country in an account to be designated by UMB in writing; or (b) be paid promptly to UMB or deposited in its account, as directed in writing by UMB in any other country where the payment or deposit is lawful.

ARTICLE 6. PATENT PROSECUTION AND PUBLICATIONS

6.1 Patent Prosecution.

6.1.1 UMB is solely responsible for preparing, filing, prosecuting (including without limitation defense of the applications in an interference proceeding), and maintaining the Patent Rights.

6.1.2 UMB shall prepare and file patent applications for the Patent Rights in the U.S., and in other countries as set forth in Section 6.2.

6.1.3 UMB is solely responsible for selection of patent counsel and for matters regarding the scope and content of U.S. and foreign patent applications and other filings. UMB shall not seek to substantially narrow the scope of or irrevocably abandon a pending application or an issued patent without obtaining Company's written consent.

6.1.4 Each Party shall consult with the other Party as to the filing, prosecution and maintenance of the Patent Rights reasonably prior to any deadline or action with the U.S. Patent and Trademark Office or any foreign patent office, and shall furnish the other Party with copies of all relevant documents reasonably in advance of the consultation. Each Party will wherever commercially and legally reasonable incorporate any comments requested by the other Party, and will provide reasonable justification if it determines not to incorporate such comments. Each Party shall cooperate with the other Party in connection with the prosecution, filing, and maintenance of any Patent Rights. Each Party shall advise the other Party reasonably promptly as to material developments with respect to the Patent Rights.

6.1.5 Neither Party shall be liable for any loss, as a whole or in part, of a patent or patent term extension granted by the U.S. Patent and Trademark Office (or any foreign patent office) on a patent included in the Patent Rights, including without limitation if the loss results from acts or omissions of outside patent counsel retained by a Party.

6.1.6 At UMB's or Company's option, Company shall be responsible for defense of any issued patent regarding the Patent Rights in an interference proceeding, at Company's sole expense.

6.2 Foreign Patent Prosecution.

6.2.1 UMB shall prepare and file patent applications for Patent Rights in Japan, Australia, Canada, the European States, and in those additional countries which are specified by Company in accordance with this Section. No later than [**] days before the applicable national phase filing deadline Company shall specify in writing to UMB the additional foreign countries in which patent applications for Patent Rights are to be filed and prosecuted.

6.2.2 UMB may elect to file and prosecute patent applications, at its own expense, in any foreign country not specified under Section 6.2.1, or as to which Company has declined or failed to pay Patent Expenses. If UMB so elects, as to any such country Company shall have: no right to give input into patenting strategy or decisions; no license rights with respect to Patent Rights; and no Option rights with respect to Improvements.

6.2.3 Upon at least [**] days prior written notice to UMB, Company may elect to discontinue payment of Patent Expenses in any country, provided however that Company shall consult with UMB regarding the election to discontinue payment of Patent Expenses with respect to any particular Patent Right in the U.S., Japan, Australia, Canada, U.K., France, Germany and Spain but in no event shall Company, without the consent of UMB, elect to discontinue payment of Patent Expenses with respect to all Patent Rights in the U.S., Japan, Australia, Canada, U.K., France, Germany or Spain. Company shall be responsible for reasonable Patent Expenses incurred during the [**] day period with respect to the country or countries where Company is

discontinuing payments. At the end of the [**] day period, Company's rights in Patent Rights shall terminate with respect to the country or countries, and Company shall execute documents as reasonably may be requested by UMB to confirm termination of Company's rights.

6.3 Patent Expenses. Company shall be solely responsible for all Patent Expenses incurred before the Effective Date (to the extent not reimbursed to UMB by a Third Party) and during the Term. Company shall pay each undisputed invoice for Patent Expenses in full within [**] days after the date of invoice. Company's failure to pay any undisputed invoice on time shall result in a loss of input into patenting decisions until the failure is cured, together with accrued interest and late fees, if any.

6.4 Publication. UMB (through TEC-COM) shall request UMB Personnel not to publish or otherwise publicly disclose the results of research relating to the Patent Rights within the Licensed Field, unless any materials containing those results are first submitted to TEC-COM for review, comment, and consideration of appropriate patent action. UMB shall request that UMB Personnel submit any materials to TEC-COM for review at least [**] days prior to the date of the planned submission for written publication or planned public disclosure. UMB shall forward such material to Company. Company shall advise TEC-COM within [**] days after receipt of the materials whether patent applications should be filed in connection with obtaining or maintaining Patent Rights related to the materials. TEC-COM shall request UMB Personnel to delay written publication or public disclosure up to a maximum of [**] days after the date Company receives the materials to enable TEC-COM to file, at Company's expense, any patent applications recommended by Company.

ARTICLE 7. CONFIDENTIALITY.

7.1 General Restrictions on Use and Disclosure.

7.1.1 Each Party may disclose to the other certain Confidential Information. Confidential Information may be used or disclosed by the Receiving Party only in accordance with the provisions of this Article. The Receiving Party shall use that level of care to prevent the use or disclosure of the Disclosing Party's Confidential Information as it exercises in protecting its own Confidential Information.

7.1.2 Each Party may disclose or use Confidential Information if: (a) with respect to Company as the Receiving Party, the disclosure or use is reasonably necessary to exercise the license granted hereunder; or (b) with respect to UMB as the Receiving Party, the use is reasonably necessary to determine compliance with the terms of this Agreement, or (c) the disclosure or use is reasonably necessary to fulfill or comply with requirements of governmental authorities having jurisdiction, including without limitation the Securities and Exchange Commission, National Institutes of Health, FDA and U.S. Patent and Trademark Office.

7.1.3 The Receiving Party shall not disclose or use the Confidential Information for a period of [**] years after receipt, other than as expressly set forth in this Agreement.

7.1.4 Any Confidential Information that would identify human research subjects or patients shall be maintained confidentially in accordance with applicable law.

7.1.5 Any permitted disclosure or use of Confidential Information shall be made only to those individuals who have a need to know and who are subject to written confidentiality restrictions consistent with those set forth in this Article.

7.2 Exceptions. These obligations of non-disclosure and nonuse do not apply to the extent to which the Receiving Party can demonstrate by reliable written evidence that:

7.2.1 The Confidential Information was or becomes generally available to the public (other than through a breach of this Agreement, a confidential disclosure agreement, any other agreement, or applicable law, and not due to any unauthorized act by the Receiving Party);

7.2.2 The Confidential Information was already in the possession of the Receiving Party at the time of the disclosure (other than pursuant to a confidential disclosure agreement between the Parties and not due to any unauthorized act by the Receiving Party); and

7.2.3 The Confidential Information was developed by the Receiving Party independent of and with no reliance upon the Disclosing Party's Confidential Information.

In addition, the Receiving Party may disclose Confidential Information to the extent necessary to comply with applicable laws or regulations, or with a court or administrative order, provided that the Disclosing Party receives prior written notice of such disclosure, to the extent reasonably possible, and that the Receiving Party takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, to the extent possible, to minimize the extent of such disclosure.

7.3 Markings and Legends. All Confidential Information shall be clearly marked as confidential by the Disclosing Party. If the Confidential Information is not in written or tangible form when disclosed, it shall be indicated as confidential upon disclosure and then summarized in writing and so marked as confidential within [**] days after disclosure to the Receiving Party.

7.4 UMB Standards and Practices. UMB is an educational institution with standards and practices for protection of Confidential Information which differ from Company's standards and practices. UMB shall only be required to use reasonable efforts to protect the confidentiality of Company Confidential Information in a manner consistent with the standards and practices used by UMB to protect its own Confidential Information. Provided that those efforts are made, Company agrees not to seek to hold UMB or UMB Personnel liable in the event of disclosure or use of Company Confidential Information.

7.5 Maryland Access to Public Records Law. The records of UMB are subject to the Maryland Access to Public Records Law(Title 10, Subtitle 6, Part III, State Government Article, Annotated Code of Maryland) (the "**Act**"). This Agreement and its Schedules and Exhibits (whether or not made part of this Agreement) and reports to UMB pursuant to Article 8 are public records of UMB. Company takes the position that any Company Confidential Information provided to UMB under this Agreement is confidential financial, commercial, or trade secret information, not subject to disclosure as provided in Section 10-617(d) of the Act. Unless UMB determines on the advice of counsel that Company's position is not reasonable,

UMB agrees to assert that position in response to any request for public records applicable to Company Confidential Information, and to promptly notify Company upon receipt of a request so that the Company may seek to preserve the confidentiality of Confidential Information.

ARTICLE 8. REPORTS, PAYMENTS, AND ACCOUNTING

8.1 Audits. During the term of this Agreement and for [**] years after its expiration or termination, Company shall keep (and shall require each Sublicensee to keep) complete, true, and accurate records containing all the particulars that may be necessary to determine royalties, fees, Patent Expenses, or other amounts payable to UMB. The records shall be subject to inspection at any time during regular business hours upon reasonable notice (but not more than [**]) by an independent auditor appointed by UMB for this purpose and reasonably acceptable to Company. The auditor shall report to UMB only the amount of royalties, fees, Patent Expenses, or other amounts payable under this Agreement. This audit shall be at UMB's expense; *provided*, *however*, if the audit shows an underpayment of [**] percent ([**]%) or more for any period, the audit expense shall be borne by Company.

8.2 Reports. Within [**] days after the close of each calendar quarter, Company shall deliver to UMB a true and accurate report, giving particulars of the business conducted by Company and Sublicensees, if any, in the preceding period that are pertinent to any accounting for royalties, fees, Patent Expenses, or other payments payable under this Agreement. These reports shall be certified as correct by an authorized officer of Company and shall include at least the following for the period:

8.2.1 Number of Licensed Products (including Combination Products) sold by Company and Sublicensees;

8.2.2 Net Revenues (including the deductions as provided in the definition of Net Revenues) for Licensed Products (including Combination Products) received by Company and Sublicensees and the aggregate Sublicense Income received by Company; and

8.2.3 Data used to calculate Combination Product Net Revenues for Sales of Combination Products.

8.2.4 Names and addresses of all Company Affiliates practicing the Patent Rights, and names and addresses of all Sublicensees.

8.3 Payment with Report. With each report submitted in accordance with Section 8.2, Company must pay to UMB the royalties, fees, or other payments due and payable under this Agreement for the period covered by the report. If no royalties, fees or other payments are due, Company shall so report.

8.4 Due Diligence Milestones. Company shall report in writing to UMB no later than [**] days following the occurrence or satisfaction of each of the due diligence milestones set forth on **Schedule B**. Company shall make milestone payments due upon achievement of the items set forth in Section 5.3.

8.5 Interest on Late Payments. Interest is due on any payment to UMB required under this Agreement that is more than [**] days late, and on any underpayment of royalties or other amounts payable under this Agreement. The interest rate is [**]% simple interest per month accruing from the due date.

8.6 Taxation. UMB is a unit of the government of the State of Maryland, and therefore is exempt from taxation. Company shall assert to all applicable governmental authorities that UMB is exempt from tax by virtue of its governmental status. If Company nevertheless is required to withhold tax on royalties or other payments due to UMB under this Agreement, it shall pay promptly any tax to the appropriate governmental authority. In that event, it shall furnish UMB with proof of payment of the tax together with official or other appropriate evidence issued by the competent governmental authority sufficient to enable UMB to support a claim for tax exemption, credit, or refund with respect to any sum so withheld. Company shall cooperate with UMB if UMB elects to seek, at its own expense, administrative or judicial determination of tax exemption, credit, or refund.

ARTICLE 9. INFRINGEMENT

9.1 Notification. Each Party shall promptly notify the other if it has knowledge of or reasonable grounds to suspect any infringement of any Claim of the Patent Rights, or of any misuse, misappropriation, theft, or breach of confidence related to the Patent Rights (collectively, an "**Infringement**").

9.2 Company's Right to Sue Infringers; Defense of Third Party Claims.

9.2.1 Company shall have the first right, but not the obligation, to bring suit for any Infringement in its own name, at its own expense, and on its own behalf. If required by law, UMB shall permit any action under this Section to be brought in its name including being named as a party-plaintiff; *provided*, *however*:

(a) It is necessary in the reasonable opinion of Company's counsel and the Office of the Attorney General of Maryland to achieve standing or otherwise avoid dismissal of the suit;

(b) UMB is not the first named party in the action (to the extent this can be controlled by the Company and, in the reasonable opinion of Company's counsel, will not affect the ability to bring suit); and

(c) The pleadings and any public statements about the action state that Company is pursuing the action and that Company has the right to join UMB as a party (only to the extent, in the reasonable opinion of Company's counsel, such statements in the pleadings or in public will not affect the ability to bring suit).

9.2.2 If a declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights is brought against Company or raised by way of counterclaim or affirmative defense in an infringement suit brought by Company under Section 9.2.1. Company

shall have the first right, but not the obligation, to defend the suit in its own name, at its own expense, and on its own behalf.

9.3 Litigation Expenses; Recoveries.

9.3.1 In any action under Section 9.2 Company shall be responsible for all litigation expenses, including without limitation costs, fees, expert witness fees, attorney fees, and disbursements. Up to [**]%) of the expenses may be credited against the running royalties payable on Sales in the country in which the suit is filed. Any amount which exceeds the amount of running royalties payable on Sales in that country in any year may be carried over as a credit on the same basis in succeeding years.

9.3.2 Any recovery by Company of compensatory or actual damages (including without limitation damages awarded to compensate for lost profits or lost sales due to infringing sales, price erosion due to infringing sales, diminution of value of Licensed Products, or lost sales of unpatented related products) shall be treated as Net Revenues, and Company shall pay royalties thereon to UMB.

9.3.3 Any recovery by Company of punitive, special, incidental, consequential, indirect, or other non-compensatory damages (including without limitation treble damages for willful infringement under Section 284 of the Patent Act, or attorney's fees under Section 285 thereof), first shall be applied to reimburse UMB for credits against running royalties under Section 9.3.1, and then to reimburse Company for its unreimbursed litigation expenses. Any remaining amount from this recovery shall be shared equally by Company and UMB.

9.4 UMB's Rights to Sue or Intervene.

9.4.1 If Company fails to bring suit under Section 9.2.1 by any required filing deadline (but not later than [**] months after receiving notice or otherwise having knowledge of Infringement), UMB shall have the right, but not the obligation, to initiate a suit. If Company fails to timely notify UMB of its intent to respond in opposition to a legal action under Section 9.2.2 within [**] days after Company's receipt of notice of the filing of the action, or if Company notifies UMB that it does not intend to oppose the action, UMB shall have the right, but not the obligation, to respond to the action at its own expense. In addition, UMB shall have a continuing right to intervene in any action described in Section 9.2.1 or 9.2.2.

9.4.2 Notwithstanding anything herein to the contrary, if UMB files suit, responds to a legal action, or otherwise intervenes pursuant to Section 9.4, UMB shall be responsible for its own litigation expenses and shall be entitled to all recoveries which it obtains for itself in connection therewith.

9.5 Conduct of Suit.

9.5.1 Company shall diligently pursue any suit or action under Section 9.2.1 or 9.2.2. Company shall keep UMB reasonably apprised of all developments in the suit. Company shall not prosecute, defend, settle, or otherwise compromise any suit in a manner that materially

adversely affects the scope, validity, or enforceability of the Patent Rights without UMB's prior written consent, which consent shall not be unreasonably withheld or delayed.

9.5.2 If the Parties so agree, they may institute suit jointly. In that event, they will prosecute the suit in both their names; bear the out-of-pocket litigation expenses equally; share any recovery or settlement equally; and negotiate in good faith regarding how they will exercise control over the action.

9.5.3 Each Party shall cooperate fully with the other Party in connection with any action under this Article. Each Party shall provide prompt access to all necessary documents and shall render reasonable assistance in response to requests by the other Party.

9.5.4 Any Party which commences a suit and then wants to abandon it, shall give timely notice to the other Party. The other Party may continue prosecution of the suit, in which event the Parties shall negotiate in good faith regarding the sharing of expenses and any recovery in the suit.

9.5.5 UMB shall not be liable for any losses incurred as a result of an action for infringement brought against Company as a result of Company's actions or omissions, including without limitation its exercise of any right granted under this Agreement.

ARTICLE 10. TERM AND TERMINATION

10.1 Term and Expiration. This Agreement shall commence as of the Effective Date. Unless sooner terminated in accordance with this Article, this Agreement shall expire on a country-by-country basis as of the later of: (a) the date of expiration of the last to expire of the Claims of the Patent Rights in such country, or (b) ten (10) years after the First Commercial Sale of a Licensed Product in that country (the "**Term**").

10.2 Termination by UMB.

10.2.1 Failure To Pay. In the event of a default or failure by Company to pay UMB any sum due and payable under this Agreement, UMB may terminate this Agreement and the license(s) granted under this Agreement, if the default or failure is not cured within [**] days of receiving written notice thereof from UMB.

10.2.2 Diligence Default. In the event of any default or material breach of Section 4.3 (Due Diligence Milestones), UMB may terminate this Agreement and the licenses granted under this Agreement if the default or breach is not cured within [**] days of receiving written notice thereof from UMB. The withholding by a regulatory agency of marketing or other approval in spite of Company's Commercially Reasonable Efforts to obtain the approval shall not constitute a default or material breach of Section 4.3 (Due Diligence Milestones).

10.2.3 Other Default or Material Breach. In the event of any default or material breach of this Agreement by Company (other than under another subsection of this Section 10.2), UMB may terminate this Agreement and the license(s) granted under this Agreement, if the default or breach is not cured within [**] days of written notice thereof; *provided*, *however*, that

if any default or breach cannot be cured by the exercise of due diligence within [**] days, then the time for cure shall be extended for the time reasonably necessary to effect the cure (the extension not to exceed [**] days), provided that Company promptly commences to cure within said period and at all times thereafter proceeds diligently to cure the default or breach.

10.2.4 Bankruptcy. UMB may terminate this Agreement and the license granted hereunder if Company: (a) makes a general assignment for the benefit of creditors; (b) commences a case under or otherwise seeks to take advantage of any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution, or liquidation law, statute, or proceeding; (c) by any act indicates its consent to, approval of, or acquiescence in any proceeding or the appointment of a receiver of or trustee for it or a substantial part of its property, or suffers any receivership, trusteeship, or proceeding to continue undismissed for a period of thirty (30) days; or (d) becomes a debtor in any case under any chapter of the U.S. Bankruptcy Code.

10.3 Termination by Company. If Company determines at any time that a license under the Patent Rights in any particular country shall no longer be advantageous to Company's commercial success, then Company may terminate this Agreement as to that country. In that event, Company shall provide UMB with thirty (30) days advance written notice of termination, and shall pay to UMB all payments due through the effective date of the termination with respect to that country, including without limitation royalties, fees, and Patent Expenses.

10.4 Survival. Expiration or termination of this Agreement does not relieve either Party of any obligation which arises before expiration or termination. Articles 5, 7, 8, 10, 13, and 14 shall survive expiration or termination, and shall expire in accordance with their terms, if any. Other Sections of this Agreement shall survive and be effective after expiration or termination where that intent is clear from the content of those Sections.

10.5 Effect of Termination. Upon expiration or termination of this Agreement in whole or in part for any reason:

10.5.1 On or before the effective date of expiration or termination, Company shall pay to UMB all amounts due hereunder, including without limitation royalties, fees, and Patent Expenses;

10.5.2 Company shall be obligated to pay Patent Expenses incurred during a [**] day period following the effective date of termination or expiration, provided that UMB shall use reasonable efforts to minimize the Patent Expenses incurred during that period;

10.5.3 Company shall return all UMB Confidential Information to UMB, together with all copies and other forms of reproduction, except that a single archive copy may be kept in Company's legal files subject to the terms of this Agreement;

10.5.4 UMB shall return all Company Confidential Information in the actual possession of TEC-COM to Company, together with all copies and other forms of reproduction, except that a single archive copy may be kept in UMB's legal files subject to the terms of this Agreement;

10.5.5 Each Party shall execute and deliver any agreements, instruments, and documents as are reasonably necessary or appropriate to carry out the terms and conditions of this Section; and

10.5.6 UMB agrees that any Patent Rights sublicensed by Company to a Sublicensee shall become directly licensed from UMB to the Sublicensee in accordance with Section 3.4.

ARTICLE 11. MISCELLANEOUS AGREEMENTS

11.1 Non-Solicitation of UMB Personnel.

11.1.1 Company shall not knowingly employ or compensate, directly or indirectly, any Person working on matters related to the Patent Rights (including but not limited to UMB Personnel) or involved in negotiating this Agreement on behalf of UMB, while the Person is employed by UMB or for [**] years thereafter, unless UMB provides Company with prior written consent of the UMB President to the employment or compensation by Company. "**Compensation**" includes but is not limited to: stock option or stock purchase agreements, consulting agreements, any other form of agreement, and cash payments. "**Employment**" includes both uncompensated and compensated service to Company. The Maryland Public Ethics Law (Title 15, State Government Article, Annotated Code of Maryland) may apply to a decision by the UMB President in regard to the matter.

11.1.2 This Section 11.1 is not intended to prevent or allow an Inventor to own stock of Company received by Inventor as a distribution of licensing revenues under the USM IP Policy. As a Company shareholder, an Inventor may receive dividends and enjoy other benefits of stock ownership, subject to any terms and conditions UMB may require in order to satisfy conflict of interest concerns or the Maryland Public Ethics Law. This provision is not intended to prevent Company from placing any reasonable restrictions upon Inventor's stock that may be necessary to satisfy federal or state laws or regulations applicable to Company or to development or commercialization of Licensed Products.

11.2 Clinical Trials. If Company conducts clinical trials of a Licensed Product, it shall reasonably consider using UMB, the University of Maryland Medical System Corporation, or other UMB Related Organizations as a site for clinical trials, subject to agreement on terms and conditions, including compensation, to be negotiated in good faith. Policies of UMB and/or the University System of Maryland may prevent or limit participation of UMB Personnel in the clinical trials.

11.3 Use of Names. Neither Party shall use the name of the other or any of its Personnel, or any adaptation thereof, in any advertising, promotional, or sales literature without prior written consent obtained from the other Party. Either Party may publicize the fact that the Parties have entered into this Agreement.

11.4 Patent Marking. Company shall cause "Patent Pending," the Patent Rights patent number, or other patent markings to appear on all Licensed Products, their labels or their

packaging to the extent required by and in accordance with the law in each country where Licensed Products are sold or offered for sale.

11.5 Inspection. Company shall allow UMB to inspect, at any time during regular business hours and upon reasonable notice, all Company correspondence to and from the FDA and any other applicable U.S. regulatory agency, and any foreign equivalent related to Licensed Products.

ARTICLE 12. REPRESENTATIONS AND WARRANTIES

12.1 By UMB. UMB hereby represents that to the actual knowledge of TEC-COM, as of the Effective Date:

12.1.1 As confirmed by assignments from UMB Personnel who are known by TEC-COM to be inventors of the Inventions, UMB has full right, title, and interest in and to the Patent Rights, subject to any rights of the U.S. under grants to UMB and Federal Patent Policy;

12.1.2 The Patent Rights are not the subject matter of any currently pending litigation involving UMB, and TEC-COM has no actual knowledge of any related litigation contemplated either by UMB or any Third Party;

12.1.3 No Person disputes ownership of Patent Rights as described in this Agreement;

12.1.4 The execution, delivery and performance of this Agreement and the transactions contemplated hereby have been duly approved; this Agreement has been properly executed by authorized officers of UMB; and this Agreement is the valid and binding obligation of UMB and is enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, reorganization, insolvency, and similar laws affecting the rights of creditors generally, general principles of equity, and Maryland law with regard to actions in contract against the State of Maryland;

12.1.5 The execution, delivery and performance of this Agreement do not violate any agreement to which UMB is a party, or any order, judgment, or decree applicable to UMB; and

12.1.6 No consent, approval, or authorization of, or designation, declaration, or filing with any governmental authority or other Person, is required on the part of UMB in connection with the execution, delivery, or performance of this Agreement.

12.2 Disclaimer of Warranties by UMB.

12.2.1 UMB EXPRESSLY DISCLAIMS ALL IMPLIED OR EXPRESS WARRANTIES, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR PATENT VALIDITY, WITH RESPECT TO PATENT RIGHTS, UMB

CONFIDENTIAL INFORMATION, OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT.

12.2.2 UMB DOES NOT WARRANT THE VALIDITY OF THE PATENT RIGHTS OR THE RELIABILITY OR ACCURACY OF UMB CONFIDENTIAL INFORMATION AND MAKES NO REPRESENTATIONS WHATSOEVER WITH REGARD TO THE SCOPE OF THE PATENT RIGHTS, OR THAT PATENT RIGHTS MAY BE EXPLOITED BY COMPANY OR ITS SUBLICENSEES WITHOUT INFRINGING OTHER PATENTS.

12.3 By Company. Company hereby represents and warrants to UMB as of the Effective Date that:

12.3.1 Company is a corporation duly organized, validly existing, and in good standing under the laws of the State of Delaware, and Company has all requisite corporate power and authority to own, operate, and lease its properties, to carry on its business as now being conducted and as contemplated by this Agreement, to enter into this Agreement, and to carry out the transactions contemplated hereby;

12.3.2 Company's directors have duly approved the execution, delivery and performance of this Agreement and the transactions contemplated hereby; this Agreement has been properly executed by the duly-authorized officers of Company; and this Agreement is the valid and binding obligation of Company and is enforceable in accordance with its terms, except as the enforceability may be limited by applicable bankruptcy, reorganization, insolvency, and similar laws affecting the rights of creditors generally, and general principles of equity;

12.3.3 The execution, delivery and performance of this Agreement do not violate the terms of Company's organizational documents, any agreement to which Company is a party, or any order, judgment, or decree applicable to Company;

12.3.4 No consent, approval, or authorization of or designation, declaration, or filing with any governmental authority or other Person is required on the part of Company in connection with the execution, delivery or performance of this Agreement, except as specifically set forth herein;

12.3.5 Company is not a party to any agreement or instrument or subject to any charter or other corporate restriction or any judgment, order, writ, injunction, or, to Company's knowledge, any rule or regulation which materially and adversely affects the operations, prospects, properties, assets, or condition (financial or otherwise) of Company;

12.3.6 No suit, action, litigation, administrative proceeding, arbitration proceeding, governmental proceeding, investigation, inquiry, or other proceeding is pending or, to the best of Company's knowledge, threatened against Company which would materially and adversely affect the operations, prospects, properties, assets, or condition (financial or otherwise) of Company;

12.3.7 To the best of Company's knowledge, Company has fully complied with all federal, state, and local laws, rules, regulations, and administrative directives which apply to or materially affect the conduct and operation of its business; and

12.3.8 Company qualifies as a small entity that meets the size standards set forth in 37 C.F.R. §1.27 to be eligible for reduced patent fees, and Company shall promptly provide written notice to UMB if it has knowledge that Company no longer qualifies as a small entity.

ARTICLE 13. CLAIMS, INDEMNIFICATION, AND INSURANCE

13.1 Maryland Tort Claims Act. UMB and UMB Personnel acting within the scope of their employment are subject to the Maryland Tort Claims Act (Title 12, Subtitle 1, State Government Article, Annotated Code of Maryland) which permits claims in tort against the State of Maryland under certain circumstances and subject to limits provided by law.

13.2 Sovereign Immunity. Nothing in this Agreement shall be interpreted as: (a) a denial to either Party of any remedy or defense available to it under the laws of the State of Maryland or Federal law; (b) the consent of the State of Maryland or its agencies and agents to be sued; or (c) a waiver of sovereign immunity or any other governmental immunity of the State of Maryland and UMB beyond the extent of any waiver provided by law.

13.3 Company's Insurance.

13.3.1 Company shall maintain during the Term comprehensive liability insurance coverage in the following minimum amounts per policy period:

(a) Comprehensive general liability (including product liability): $[**] per claim and $[**] aggregate;

(b) Property damage: $[**] per claim; $ [**] aggregate.

13.3.2 Company warrants that its liability insurance covers contractually assumed liabilities referred to in Section 13.4, and agrees to maintain the coverage throughout the Term. A certificate evidencing the required insurance coverage shall be delivered to UMB: (a) on or before execution of this Agreement; (b) each time there is a material change in Company's insurance coverage; and (c) each time Company's insurance coverage is renewed. Company agrees to require its insurance carrier(s) to notify UMB within [**] days prior to cancellation of Company's insurance coverage. If Company's liability insurance is written on a claims-made basis (rather than on an occurrence basis), Company shall purchase extending reported coverage or otherwise provide insurance satisfying its obligations hereunder for a period of not less than [**] years following termination or expiration of this Agreement.

13.4 Indemnification by Company.

13.4.1 Company agrees to defend, indemnify, and hold harmless the State of Maryland, University System of Maryland, UMB, UMB Related Organizations, their Personnel and regents, students, and trainees (each individually a "**Licensor Party**" and all, collectively

"**Licensor Parties**") against any and all claims, costs or liabilities, including attorney's fees, expert witness fees, and court costs at trial and appellate levels, for any loss, damage, personal injury, or loss of life:

(a) Caused by the action or omission under this Agreement of Company, Sublicensees, or their Personnel or any Third Party acting on behalf of or under authorization from Company or a Sublicensee;

(b) Arising out of use of the Patent Rights by Company, Sublicensees, or their Personnel or by any Third Party acting on behalf of or under authorization from Company or a Sublicensee; or

(c) Arising out of use by a Licensor Party of products, processes, or protocols developed by Company, Sublicensees, or their Personnel, or by any Third Party acting on behalf of or under authorization from Company or a Sublicensee using Patent Rights, provided the use was consistent with any protocols or supervision provided directly to a Licensor Party by Company or a Sublicensee.

13.4.2 The agreement to defend, indemnify and hold harmless a Licensor Party is conditioned upon: (a) a Licensor Party promptly notifying Company in writing after Licensor Party receives notice of any claim; and (b) the Licensor Party cooperating with Company in the defense of the claim.

13.4.3 The agreement to defend, indemnify and hold harmless a Licensor Party shall not apply to the extent that any claim, cost, or liability was proximately caused by the negligent act or willful misconduct of the Licensor Party.

ARTICLE 14. DISPUTE RESOLUTION

14.1 Negotiation. If a dispute between the Parties related to this Agreement arises, either Party, by notice to the other Party, may have the dispute referred to the Parties' respective officers designated below, or their successors, for attempted resolution by good faith negotiations within [**] days after the notice is received. The designated officers are as follows:

For Company: President and CEO

For UMB: Vice President, Research and Development

14.2 Mediation. In the event the designated officers are not able to resolve the dispute within this [**] day period, or any agreed extension, they shall confer in good faith with respect to the possibility of resolving the matter through mediation with a mutually acceptable Third Party or a national mediation organization. If the Parties agree to attempt to resolve the matter through mediation, they shall participate in any mediation sessions in good faith in an effort to resolve the dispute in an informal and inexpensive manner. All expenses of the mediator shall be shared equally by the Parties.

14.3 Disputes Regarding Valuation. Any dispute regarding valuation under this Agreement (including without limitation Sections 3.6.3 or 5.6) which is not timely resolved through the dispute resolution procedures of this Article 14 shall be submitted to a national independent certified public accounting firm or other independent expert in valuation, to be appointed by mutually agreement of UMB and Company. The costs and expenses of the valuation consultant shall be shared equally by UMB and Company.

14.4 Statute of Limitations: Admissibility of Evidence. Any applicable statute of limitations shall be tolled during the pendency of a dispute resolution procedure initiated under this Agreement. Evidence of anything said or any admission made in the course of any dispute resolution procedure shall not be admissible in evidence in any civil action between the parties. In addition, no document prepared for the purpose of, or in the course of, or pursuant to, the dispute resolution procedure, or copy thereof, shall be admissible in evidence in any civil action between the parties. However, the admissibility of evidence shall not be limited if all parties who participated in the dispute resolution procedure consent to disclosure of the evidence.

ARTICLE 15. NOTICES AND INVOICES

15.1 Notices. Notices under this Agreement shall be in writing and shall be delivered personally as proven by a signed receipt, sent by a reputable, national overnight delivery service, charges prepaid, or sent by certified mail return receipt requested. Notices shall be addressed to a Party at the address specified below, or at such other place or places as shall from time to time be specified in a notice similarly given. All notices shall be effective upon receipt.

If to UMB:

Director, Technology Commercialization
Office of Research and Development
University of Maryland, Baltimore
515 West Lombard Street, Suite 400
Baltimore, Maryland 21201 -1602

Copy to:

University Counsel
University of Maryland, Baltimore
520 West Lombard Street
East Hall, Suite 200
Baltimore, Maryland 21201-1627

If to Company:

Tokai Pharmaceuticals, Inc.
1 Broadway, 14th Floor
Cambridge, MA 02142
Attn: President and CEO

Copy to:

Marcia H. Anderegg
Edwards Angell Palmer & Dodge LLP
111 Huntington Avenue at Prudential Center
Boston, Massachusetts 02199-7613

15.2 Invoices. Invoices to Company under this Agreement may be sent to the following address or at such other place or places as shall from time to time be specified in a notice similarly given:

Tokai Pharmaceuticals, Inc.
1 Broadway, 14th Floor

Cambridge, MA 02142
Attn: Finance Department

15.3 Changes of Address. Each Party shall at all times keep the other Party informed of its current address. Each Party shall promptly notify the other Party of any change specifying such changed address for the delivery of notices or invoices.

ARTICLE 16. ASSIGNMENT

16.1 General. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors, and permitted assigns. Any reference in this Agreement to a Party shall be deemed to include that Party's successors and permitted assigns. Any purported assignment in violation of this Section shall be null and void.

16.2 Assignment by Company.

16.2.1 Company may not assign its rights and obligations under this Agreement without the prior written consent of UMB, which consent shall not be unreasonably withheld or delayed.

16.2.2 Notwithstanding the foregoing, Company may, without consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of the assets of the portion of Company's business to which this Agreement relates, or Company's merger, consolidation, or change in control or similar transaction; *provided*, *however*, that the purported assignee as of the date of assignment: (a) is not in default of its material obligations under any agreement with UMB, USM, or the State of Maryland, and is current on all of its material financial obligations to UMB, USM, or the State of Maryland (including without limitation taxes); and (b) is not an adverse party in any litigation, arbitration, administrative or other similar proceeding with UMB or USM.

16.2.3 Company shall give UMB written notice identifying the prospective assignee at least [**] Business Days prior to the closing of the transaction. Any permitted assignee shall assume in writing all accrued and prospective obligations of Company under this Agreement. No assignment shall relieve Company of responsibility for the performance of any accrued obligation under this Agreement, including without limitation Section 13.3 (Company's Insurance) and Section 13.4 (Indemnification by Company).

16.2.4 Any permitted assignee shall meet with representatives of UMB within [**] days of the closing of the transaction to discuss the assignee's plans for the future development, commercialization, and/or Sales of Licensed Products. If the assignee determines that it does not wish to continue the development, commercialization, and/or Sales of Licensed Products, then the assignee shall immediately give notice terminating this Agreement under Section 10.3.

16.3 Assignment by UMB. UMB may assign this Agreement to a successor-in-interest, but UMB may not otherwise assign or transfer this Agreement without the prior written consent of Company, which shall not be unreasonably withheld or delayed.

ARTICLE 17. MISCELLANEOUS

17.1 Governing Law. This Agreement is made and construed in accordance with the laws of the State of Maryland without regard to choice of law issues, except as set forth in Section 3.6.9.

17.2 Jurisdiction. Each Party consents to the jurisdiction and venue of the courts of Baltimore City or Baltimore County, Maryland and the U.S. District Court for the District of Maryland in Baltimore, Maryland in any action or judicial proceeding brought to enforce, construe or interpret this Agreement.

17.3 WAIVER OF TRIAL BY JURY. UMB AND COMPANY WAIVE THEIR RIGHTS TO TRIAL BY JURY IN ANY LITIGATION BETWEEN THEM RELATING TO THIS AGREEMENT.

17.4 Entire Agreement. This Agreement, together with any Schedules specifically referenced and attached, embodies the entire understanding between Company and UMB. Other than a Confidential Disclosure Agreement dated May 27, 2005, there are no contracts, understandings, conditions, warranties or representations, oral or written, express or implied, with reference to the subject matter of this Agreement that are not merged in this Agreement. No oral statements or prior written material not specifically incorporated herein shall be of any force and effect. The Parties specifically acknowledge that in entering into and executing this Agreement, the Parties relied solely upon the representations and agreements contained in this Agreement and no others. All prior representations or agreements, whether written or oral, not expressly incorporated herein are superseded.

17.5 Severability. A ruling by any court that one or more of the provisions contained in this Agreement is invalid, illegal, or unenforceable shall not in any respect affect any other provision of this Agreement. Thereafter, this Agreement shall be construed as if the invalid, illegal, or unenforceable provision had been amended to the extent necessary to be enforceable within the jurisdiction of the court making the ruling.

17.6 Force Majeure. Neither Party is liable for failure or delay in performing any of its obligations under this Agreement if the failure or delay is required in order to comply with any governmental regulation, request or order, or necessitated by other circumstances beyond the reasonable control of the Party so failing or delaying, including but not limited to Acts of God, war (declared or undeclared), insurrection, terrorism, fire, flood, accident, labor strikes, work stoppage or slowdown (whether or not the labor event is within the reasonable control of the Parties), or inability to obtain raw materials, supplies, power or equipment necessary to enable a Party to perform its obligations. Each Party shall: (a) promptly notify the other Party in writing of an event of force majeure, the expected duration of the event and its anticipated effect on the ability of the Party to perform its obligations; and (b) make reasonable efforts to remedy the effects of the event of force majeure.

17.7 Amendments; Waivers. This Agreement, including Schedules, may not be amended, nor may any right or remedy of either Party be waived, unless the amendment or waiver is in writing and signed by a duly authorized representative of each Party.

17.8 Waivers; Cumulative Remedies. A failure or delay by a Party in exercising any of its rights or remedies under this Agreement does not constitute a waiver of the rights or remedies, nor does any single or partial exercise of any right or remedy preclude any other or further exercise thereof or the exercise of any other right or remedy. The rights and remedies of the Parties provided in this Agreement are cumulative and not exclusive of any rights or remedies provided by law.

17.9 Relationship Between the Parties. UMB and Company are not (and nothing in this Agreement may be construed to constitute them as) partners, joint venturers, agents, representatives or employees of the other. Neither Party has any responsibility nor liability for the actions of the other Party except as specifically provided in this Agreement. Neither Party has any right or authority to bind or obligate the other Party in any manner or make any representation or warranty on behalf of the other Party.

17.10 Expenses. Except as otherwise specifically set forth herein, all costs and expenses incurred in connection with this Agreement shall be paid by the Party which incurs the cost or expense, and the other Party has no liability for the cost or expense.

17.11 No Third Party Beneficiaries. This Agreement is not intended to create, and does not create, enforceable legal rights as a third party beneficiary or through any other legal theory on the part of any UMB Personnel, or any other Person, except as otherwise provided by Section 3.3 (Sublicenses) and Section 13.4 (Indemnification by Company).

17.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original, and all of which shall together constitute one agreement. In proving this Agreement, it shall only be necessary to produce or account for the counterpart signed by the Party against whom the proof is being presented.

17.13 Interpretation. Each Party to this Agreement participated in the drafting of this Agreement. Each Party was represented by counsel, or had the opportunity to be represented by counsel. Therefore, no Party shall be deemed to be the "draftsman," and ambiguities shall not be construed against any particular Party. The section and subsection headings of this Agreement have been included for convenience only, are not part of this Agreement, and shall not be taken as an interpretation thereof. Whenever used herein, the singular includes the plural and the plural includes the singular. The use of any gender, tense, or conjugation includes all genders, tenses, and conjugations. The words "including," "inclusive," or words of similar import shall be construed to mean "including without limitation," unless the context clearly indicates otherwise. References to "writing" or "written" include printing, typing, lithography, and other means of reproduction in a visible form. References to agreements and other contractual instruments include all subsequent amendments thereto or changes therein entered into in accordance with their respective terms and not prohibited by this Agreement.

17.14 Further Assurances. The Parties shall execute and deliver and cause to be executed and delivered further agreements, instruments and documents and shall take further actions as may reasonably be required or appropriate to carry out the terms and conditions of this Agreement.

{SIGNATURES ON FOLLOWING PAGE}

SIGNATURE PAGE TO
MASTER LICENSE AGREEMENT

The Parties have caused this Agreement to be executed by their duly authorized representatives on the dates indicated below.

WITNESS:

/s/ illegible

UNIVERSITY OF MARYLAND, BALTIMORE.

By: /s/ David J. Ramsay (SEAL)
David J. Ramsay, D.M., D. Phil.
President

Date: 5/19/06

ATTEST:

/s/ illegible

TOKAI PHARMACEUTICALS, INC.

By: /s/ Joseph A. Yanchik (SEAL)
Joseph A. Yanchik III
Chief Executive Officer

Date: May 15, 2006

SCHEDULE A
PATENT RIGHTS

[**]

SCHEDULE B
DUE DILIGENCE MILESTONES

1) *Within [**] months after the Effective Date:* Submission to UMB of supporting data and a detailed timeline for *in vivo* validation and the completion of toxicology testing leading to an IND application to the FDA or a similar application to a foreign equivalent of the FDA.

2) *Within [**] months after the Effective Date*: Filing of an IND application with the FDA or a similar application to a foreign equivalent of the FDA for a Phase 1 Clinical Trial related to a Licensed Product.

3) *Within [**] months after IND approval by the FDA or a foreign equivalent of the FDA*: Commencement of the first Phase 1 Clinical Trial of a Licensed Product.

4) *Within [**] months after the completion of all Phase 1 Clinical Trials of a Licensed Product*: Commencement of First Phase 2 Clinical Trial of a Licensed Product.

5) *Within [**] months after completion of all Phase 2 Clinical Trials of a Licensed Product*: Commencement of First Phase 3 Clinical Trial of a Licensed Product.

6) *Within [**] months after completion of all Phase 3 Clinical Trials of a Licensed Product*: Filing of an NDA or a BLA with the FDA for a Licensed Product or a similar application to a foreign equivalent of the FDA.

7) *Within [**] months after approval by the FDA or foreign equivalent of the FDA*: First Commercial Sale of a Licensed Product.

FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment ("**First Amendment**") is effective as of the date of the last signature on the signature page between the UNIVERSITY OF MARYLAND, BALTIMORE ("**UMB**"), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, and TOKAI PHARMACEUTICALS, INC., a Delaware corporation ("**Company**"). Company and UMB are referred to collectively as the "**Parties**" and each as a "**Party**."

BACKGROUND

UMB and Company have entered into the Master License Agreement effective as of May 19, 2006 ("MLA"), under which Company received an exclusive worldwide license to practice the Patent Rights. (Any capitalized term which is not otherwise defined in this First Amendment shall have the meaning set forth in the MLA.)

A valuable invention generally known as "Novel Prodrugs of C-17-Heteroaryl Steroidal CYP17 Inhibitors/Antiandrogens: Synthesis, In Vitro Biological Activities, Pharmacokinetics, and Antitumor Activity" (*UMB ref: VN-2008-030*) has been made by Dr. Vincent Njar, Dr. Angela Brodie, and Dr. Lalji Gediya, which constitutes an Improvement pursuant to the MLA.

Company has duly exercised its Option to receive an exclusive license to the Improvement, pursuant to Section 3.6 of the MLA. The Parties have negotiated in good faith to enter into this First Amendment to add the Improvement to the Patent Rights under the MLA, such that the invention will henceforth constitute a Licensed Improvement.

The Parties agree to amend the MLA as set forth herein.

NOW THEREFORE, the Parties agree as follows:

1. Article 2 (Definitions) of the MLA is amended by deleting the definition of "TEC-COM." Any reference in the MLA to "TEC-COM" shall hereafter be amended to be a reference to "CVIP." Article 2 is further amended by adding the following definitions:

"**CVIP**": The Commercial Ventures and Intellectual Property Group in UMB's Office of Research and Development, and any successor to its responsibilities.

"**Initial Licensed Product**": Any product (including without limitation any Combination Product) whose manufacture, use, Sale or import would infringe, or any process whose practice would infringe, the Initial Patent Rights.

"**Initial Patent Rights**": The Patent Rights set forth in Part A of **Schedule A**.

"**Oral Prodrug Licensed Product**": An orally administered prodrug formulation (including without limitation any Combination Product) whose manufacture, use, Sale or import would infringe, or any process whose practice would infringe, the Oral Prodrug Patent Rights.

"**Oral Prodrug Patent Rights**": The Patent Rights set forth in Part B of **Schedule A**.

"**Patent Expenses**": All fees, charges, expenses, and costs incurred before and after the Effective Date in connection with the preparation, filing, prosecution, issuance, reissuance, reexamination, interference, and/or maintenance of patents or applications for patent or equivalent protection for the Patent Rights, including without limitation all fees and charges of outside patent counsel. Patent Expenses shall be considered to be incurred when the fee, charge, expense, or cost is actually incurred (rather than when it is invoiced). For example, charges of outside patent counsel are considered to be incurred as of the date on which the professional services are rendered.

"**Patent Rights**": (a) U.S. and foreign patents and patent applications listed in **Schedule A**, as it may be amended from time to time by mutual agreement of the Parties or to add Licensed Improvements pursuant to Section 3.6; (b) all patents and patent applications related to clause (a), whether filed before or after the Effective Date, which claim priority under 35 U.S.C. §119 or the benefit of the filing date under 35 U.S.C. §120 or §371 (but only to the extent of subject matter in a patent or patent application for which priority or benefit is claimed); (c) any substitution, divisional, continuation, and continuation-in-part (but only to the extent a Claim in the continuation-in-part is directed to subject matter contained in a patent or patent application described in clause (a) or (b)); (d) any patent issuing from any patent or patent application described in clause (a), (b), or (c); (e) any reissue, renewal, reexamination, or extension of any patent or patent application described in clause (a), (b), (c), or (d); and (f) any foreign counterpart or equivalent of any patent or patent application described in clause (a), (b),(c), (d), or (e).

2. Schedule A (Patent Rights) of the MLA is hereby deleted in its entirety, and replaced with **Schedule A** attached hereto.

3. Schedule B (Diligence Milestones) of the MLA is hereby deleted in its entirety, and replaced with **Schedule B** attached hereto.

4. Section 4.1 (R&D Plan and Business Plan) is hereby amended by adding the following:

4.1.3 Company shall promptly notify UMB of any substantial change in the R&D Plan or Business Plan if such change will materially alter or affect the timely achievement of any milestone set forth on **Schedule B**. Any amendment of the R&D Plan or Business Plan that will materially alter or affect the timely achievement of any milestone shall require the consent and approval of UMB, which shall not be unreasonably withheld, delayed or conditioned. The Parties shall negotiate in good faith and amend any provision of this Agreement to the extent reasonably necessary to conform to any approved modification of the R&D Plan or Business Plan, including without limitation the milestones set forth on Schedule B and the milestone payments set forth in Section 5.3.

5. Section 5.3 (Milestone Payments) is hereby deleted in its entirety, and replaced with the following:

5.3 Milestone Payments. Company shall pay to UMB the following milestone payments:

On submission of each IND for a Licensed Product to the U.S. FDA:	U.S. $50,000.00	Within [**] days following submission
On approval of each NDA or BLA for a Licensed Product by the U.S. FDA:	U.S. $100,000.00	Within [**] days following receipt of approval
Upon issuance of the first patent citing U.S. Provisional Patent Application No. 61/039,133 as priority	U.S. $40,000.00	Within [**] days following issuance

6. Section 10.2.2 (Diligence Default) is hereby deleted in its entirety, and replaced with the following:

10.2.2 Diligence Default. In the event of any default or material breach of Section 4.3 (Due Diligence Milestones) due to Company failing to timely achieve a milestone set forth on **Schedule B**, as such milestones may from time to time be amended as contemplated by Section 4.1.3 hereof and then in effect, and the failure is not cured within [**] days of written notice thereof, UMB may terminate the license granted under this Agreement to the category of Patent Rights to which such milestone relates as shown on **Schedule B** (i.e. Initial Patent Rights or Oral Prodrug Patent Rights). However, if that failure cannot be cured by the exercise of due diligence within [**] days of written notice, then the time for cure shall be extended for the time reasonably necessary to effect the cure (the extension not to exceed an additional [**] days), provided that Company promptly commences to cure within said period and at all times thereafter proceeds diligently to cure the failure. The termination of the license granted hereunder for any category of Patent Rights to which such milestone relates as

shown on **Schedule B** shall not affect the license granted hereunder for any other Patent Rights related to the milestones shown on such **Schedule B**. The withholding by a regulatory agency of marketing or other approval in spite of Company's Commercially Reasonable Efforts to obtain the approval shall not constitute a default or material breach of Section 4.3 (Due Diligence Milestones).

7. Section 15.1 (Notices) of the MLA is hereby amended by deleting the address for UMB, and replacing it with the following:

If to UMB:

Commercial Ventures & Intellectual Property
Office of Research and Development
University of Maryland, Baltimore
620 West Lexington Street, 4th Floor
Baltimore, Maryland 21201
Attn: Executive Director

Copy to:

University Counsel
University of Maryland, Baltimore
220 Arch Street, Room 03-111
Baltimore, Maryland 21201

8. In consideration of the license to the Oral Prodrug Patent Rights granted under this First Amendment, Company agrees to pay a one-time, non-refundable license fee of Ten Thousand Dollars ($10,000) to UMB on or before execution of this First Amendment.

9. Company shall be responsible for payment of all Patent Expenses regarding the Oral Prodrug Patent Rights incurred before the effective date of this First Amendment (to the extent not reimbursed to UMB by a Third Party) and during the Term, in accordance with Section 6.3 of the MLA.

10. Except as specifically modified in this First Amendment, all terms and conditions of the MLA (including without limitation the royalty rate and other payment obligations of Company) shall remain in full force and effect.

{Signatures on following page}

IN WITNESS WHEREOF, each Party has caused this First Amendment to be executed under seal by its duly authorized representative.

WITNESS:

/s/ illegible

UNIVERSITY OF MARYLAND, BALTIMORE

By: /s/ David J. Ramsay (SEAL)
David J. Ramsay; D.M., D. Phil.
President

Date: March 3, 2009

WITNESS/ATTEST:

/s/ illegible

TOKAI PHARMACEUTICALS, INC.

By: /s/ Scott Chappel
(SEAL)

Title: CSO

Date: 2/19/09

SCHEDULE A
PATENT RIGHTS

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of three pages were omitted. [**]

SCHEDULE B
DUE DILIGENCE MILESTONES

INITIAL LICENSED PRODUCTS

1) *Within [**] months after the Effective Date*: Submission to UMB of supporting data and a detailed timeline for in vivo validation and the completion of toxicology testing leading to an IND application to the FDA or a similar application to a foreign equivalent of the FDA related to an Initial Licensed Product.

2) *Within [**] months after the Effective Date*: Filing of an IND application with the FDA or a similar application to a foreign equivalent of the FDA for a Phase 1 Clinical Trial related to an Initial Licensed Product.

3) *Within [**] months after IND approval by the FDA or a foreign equivalent of the FDA*: Commencement of the first Phase 1 Clinical Trial of an Initial Licensed Product.

4) *Within [**] months after the completion of all Phase 1 Clinical Trials of an Initial Licensed Product*: Commencement of First Phase 2 Clinical Trial of an Initial Licensed Product.

5) *Within [**] months after completion of all Phase 2 Clinical Trials of an Initial Licensed Product*: Commencement of First Phase 3 Clinical Trial of an Initial Licensed Product.

6) *Within [**] months after completion of all Phase 3 Clinical Trials of an Initial Licensed Product*: Filing of an NDA or a BLA with the FDA for an Initial Licensed Product or a similar application to a foreign equivalent of the FDA.

7) *Within [**] months after approval by the FDA or foreign equivalent of the FDA*: First Commercial Sale of an Initial Licensed Product.

ORAL PRODRUG LICENSED PRODUCTS

1) *Within [**] months following the execution of this First Amendment*: Submission to UMB of (a) an R&D Plan reasonably acceptable to UMB, showing the amount of money and time budgeted and planned for technical development of the Oral Prodrug Patent Rights, and (b) a Business Plan reasonably acceptable to UMB, showing the proposed commercialization scheme for Oral Prodrug Licensed Products.

2) *Within [**] months after the submission of the R&D Plan and Business Plan*: Submission to UMB of supporting data and a detailed timeline for in vivo validation and the completion of toxicology testing leading to an IND application to the FDA or a similar application to a foreign equivalent of the FDA related to an Oral Prodrug Licensed Product.

3) *Within [**] months after the submission of the R&D Plan and Business Plan*: Filing of an IND application with the FDA or a similar application to a foreign equivalent of the FDA for a Phase 1 Clinical Trial related to an Oral Prodrug Licensed Product.

4) *Within [**] months after IND approval by the FDA or a foreign equivalent of the FDA*: Commencement of the first Phase 1 Clinical Trial of an Oral Prodrug Licensed Product.

5) *Within [**] months after the completion of all Phase 1 Clinical Trials of an Oral Prodrug Licensed Product*: Commencement of First Phase 2 Clinical Trial of an Oral Prodrug Licensed Product.

6) *Within [**] months after completion of all Phase 2 Clinical Trials of an Oral Prodrug Licensed Product*: Commencement of First Phase 3 Clinical Trial of an Oral Prodrug Licensed Product.

7) *Within [**] months after completion of all Phase 3 Clinical Trials of an Oral Prodrug Licensed Product*: Filing of an NDA or a BLA with the FDA for an Oral Prodrug Licensed Product or a similar application to a foreign equivalent of the FDA.

8) *Within [**] months after approval by the FDA or foreign equivalent of the FDA*: First Commercial Sale of an Oral Prodrug Licensed Product.

SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment to License Agreement ("**Second Amendment**") is effective as of the date of the last signature on the signature page between the UNIVERSITY OF MARYLAND, BALTIMORE ("**UMB**"), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, and TOKAI PHARMACEUTICALS, INC., a Delaware corporation ("**Company**"). Company and UMB are referred to collectively as the "**Parties**" and each as a "**Party**."

BACKGROUND

UMB and Company entered into a Master License Agreement, effective as of May 9, 2006 ("**MLA**") and first amended March 3, 2009, under which Company received an exclusive worldwide license to practice the Patent Rights. (Any capitalized term which is not otherwise defined in this Second Amendment shall have the meaning set forth in the MLA.)

A valuable invention generally known as "CYP17 Inhibitor VN/124-1 Inhibits Growth of Androgen Independent Prostate Cancer Cells via Induction of the Endoplasmic Reticulum Stress Response" (*UMB ref: VN-2008-067*) has been made by Dr. Vincent Njar, Dr. Angela Brodie, and Dr. Robert Bruno, which x constitutes an Improvement pursuant to the MLA.

Company has duly exercised its Option to receive a license to the Improvement, pursuant to Section 3.6 of the MLA. The Parties have negotiated in good faith to enter into this Second Amendment to add the Improvement to the Patent Rights under the MLA, such that the invention will henceforth constitute a Licensed Improvement on the terms and conditions set forth in this Second Amendment.

Since entering into the MLA, UMB has been solely responsible for preparing, filing, prosecuting, and maintaining the Patent Rights. Company has requested the right to assume responsibility for patent prosecution upon execution of this Second Amendment.

The Parties agree to amend the MLA as set forth herein.

NOW THEREFORE, the Parties agree as follows:

1. Article 2 (Definitions) of the MLA is hereby amended by deleting the definition of "CVIP." Any reference in the MLA to "CVIP" shall hereafter be amended to be a reference to "OTT." Article 2 (Definitions) of the MLA is further amended by adding the following definitions:

"**ER Stress Response Licensed Product**": Any product (including without limitation any Combination Product) whose manufacture, use, Sale or import would infringe, or any process whose practice would infringe, the ER Stress Response Patent Rights.

"**ER Stress Response Patent Rights**": The Patent Rights set forth in Part C of **Schedule A**.

"**OTT**": The Office of Technology Transfer in UMB's Office of Research and Development, and any successor to its responsibilities.

2. Schedule A (Patent Rights) of the MLA is hereby amended by adding the following:

[**]

3. Section 6.1 of the MLA is hereby deleted in its entirety, and replaced with the following:

6.1 Patent Prosecution Responsibility and General Issues.

6.1.1 On and after the date of execution of this Second Amendment, Company shall assume sole responsibility for preparing, filing, prosecuting, and maintaining the Patent Rights (including without limitation defense of the Patent Rights in an interference proceeding).

6.1.2 UMB and Company shall not be liable for any loss, in whole or in part, of a patent term extension granted by the U.S. Patent and Trademark Office on a patent issuing under Patent Rights, even if such loss resulted from the acts or omissions of UMB, UMB Personnel working under their direction or supervision, Company, Company Personnel, or Company's patent counsel.

6.1.3 Following execution of this Second Amendment, the Patent Rights will be prepared, prosecuted, filed, and maintained by Company's current independent patent counsel. However, Company shall change patent counsel if reasonably requested by UMB. Company's choice of outside patent counsel is subject to UMB's prior approval, which approval must not be unreasonably withheld. Outside patent counsel will be ultimately responsible to Company. Company authorizes UMB to communicate directly with Company's outside patent counsel.

6.1.4 Company shall (and shall instruct outside patent counsel to) (i) advise UMB promptly as to all material developments with respect to the Patent Rights, and (ii) promptly provide copies of all communications received and filed in connection with prosecution of Patent Rights.

6.1.5 Company shall promptly notify UMB, and Company shall instruct outside patent counsel to promptly notify UMB, before taking any substantive actions in prosecuting the Claims. UMB may provide comments and suggestions with respect to any substantive actions to be taken by Company, and comment on the type and scope of Claims and the nature of supporting disclosures. Company shall reasonably consider all comments and suggestions and shall take all prosecution actions reasonably recommended by UMB.

6.1.6 Company shall not do any of the following with respect to the Patent Rights, except upon prior approval of UMB: materially modify or limit the scope of patent coverage; modify the identification of inventors; or finally abandon any patent or patent application.

6.1.7 If UMB and Company do not agree on actions relating to the scope of patent coverage for any of the Patent Rights reasonably recommended to Company by UMB under Section 6.1.5, then UMB may terminate immediately Company's right to prosecute the patent application(s) involved, and in such case UMB may continue prosecution using its own independent counsel. Before UMB terminates the Company's right to prosecute the patent application(s) involved, UMB shall reasonably consider any comments provided by Company regarding prosecution of the Claims.

6.1.8 All information exchanged between the parties or between Company's outside patent counsel and UMB regarding preparation, filing, prosecution, or maintenance of the Patent Rights shall be deemed Confidential Information. In addition, the parties acknowledge and agree that, with regard to such preparation, filing, prosecution, and maintenance of the Patent Rights, the interests of the parties as licensor and licensee are to obtain the strongest and broadest patent protection possible. The parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights, including without limitation privilege under the common interest doctrine and similar or related doctrines. "

4. Section 6.2 of the MLA is hereby deleted in its entirety, and replaced with the following:

6.2 Foreign Patent Prosecution.

6.2.1 If Company gives at least [**] days prior written notice to UMB, Company may elect to discontinue support for Patent Expenses with respect to any particular Patent Right, but UMB's written consent shall be required prior to discontinuing support for Patent Expenses in the United States, Japan, Australia, Canada, United Kingdom, France, Germany or Spain. Company shall be responsible for reasonable Patent Expenses incurred in that [**] day period with respect to the county or countries where the Company is ceasing support. From and after UMB's receipt of Company's notice, Company's rights in Patent Rights will terminate with respect to the country or countries where

Company is ceasing support, and Company shall execute such documents as reasonably may be requested by UMB to confirm termination of Company's rights.

6.2.2 UMB may elect to file and prosecute patent applications, solely at its own expense, in foreign countries where Company has declined or failed to pay Patent Expenses for such patent applications. If UMB so elects, in those countries, Company will have no input into patenting decisions, no license rights with respect to those Patent Rights, and no Option rights with respect to related Improvements.

5. Section 6.3 of the MLA is hereby deleted in its entirety, and replaced with the following:

6.3 Patent Expenses.

6.3.1 Company shall be solely responsible for all Patent Expenses. Company shall reimburse UMB for Patent Expenses which were incurred prior to the execution of this Second Amendment, resulted from instructions given by Company prior to that date, or otherwise were incurred by UMB as agreed between the Parties or pursuant to the terms of this Agreement. Company shall pay each undisputed invoice for Patent Expenses in full within [**] days after the date of invoice.

6.3.2 If this Agreement is terminated for any reason other than expiration, Company will have no obligation to pay Patent Expenses related to Patent Rights incurred by UMB for patent filing and prosecution activities occurring more than [**] days after Company's notice of termination, and no obligation to pursue prosecution of patent applications related to Patent Rights and pay related Patent Expenses for more than [**] days following notice of termination. UMB will act in good faith to minimize the Patent Expenses incurred between receipt of notice of termination and the end of the [**] day period.

6. In consideration of the license granted under this Second Amendment, Company agrees to pay a one-time, non-refundable license fee of Ten Thousand Dollars ($10,000) to UMB on or before execution of this Second Amendment.

7. Except as specifically modified in this Second Amendment, all terms and conditions of the MLA (including without limitation the royalty rate and other payment obligations of Company) shall remain in full force and effect.

IN WITNESS WHEREOF, each Party has caused this Second Amendment to be executed under seal by its duly authorized representative.

WITNESS: **UNIVERSITY OF MARYLAND, BALTIMORE**

/s/ Dorothy C. [illegible]

By: /s/ Jay A. Perman (SEAL)
Jay A. Perman, M.D.
Title: President
Date: 4/10/12

ATTEST:

TOKAI PHARMACEUTICALS, INC.

/s/ Holly [illegible]

By: /s/ Martin D. Williams (SEAL)

Name: Martin D. Williams
Title: CEO
Date: April 9, 2012

THIRD AMENDMENT TO LICENSE AGREEMENT

This Third Amendment to License Agreement ("**Third Amendment**") is effective as of the date of the last signature on the signature page hereto and is between the UNIVERSITY OF MARYLAND, BALTIMORE ("**UMB**"), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, and TOKAI PHARMACEUTICALS, INC., a Delaware corporation ("**Company**"). Company and UMB are referred to collectively as the "**Parties**" and each as a "**Party**."

BACKGROUND

UMB and Company entered into a Master License Agreement, effective as of May 9, 2006, as amended ("**MLA**"), under which Company received an exclusive worldwide license to practice the Patent Rights. (Any capitalized term which is not otherwise defined in this Third Amendment shall have the meaning set forth in the MLA.)

A valuable invention generally known as "Androgen Receptor Down-regulating Agents for the Treatment of All Forms of Prostate Cancer" (*UMB ref: VN-2013-061*) (the "**ARDA Invention**") has been made by Vincent Njar, Puranik Purushottamachar, Lalji K. Gediya, Abhijit M. Godbole (*all employees of UMB and formerly of Thomas Jefferson University*), Andrew K. Kwegyir-Afful (*an employee of UMB*), and Tadas S. Vasaitis (*an employee of University of Maryland, Eastern Shore*), which constitutes an Improvement pursuant to the MLA.

UMB, Thomas Jefferson University, and the University of Maryland, Eastern Shore each own an undivided joint interest in the ARDA Invention. UMB has been granted the exclusive right to negotiate, execute, and administer any license agreement related to the ARDA Invention on behalf of the co-owning institutions, pursuant to an Inter-Institutional Agreement dated as of June 30, 2013 (the "**IIA**"), a fully-executed copy of which is attached to this Third Amendment as **Exhibit A**.

Company has duly exercised its Option to receive a license to the Improvement, pursuant to Section 3.6 of the MLA. The Parties have negotiated in good faith to enter into this Third Amendment to add exclusive rights of all co-owners of the Improvement to the Patent Rights under the MLA, such that the ARDA Invention will henceforth constitute a Licensed Improvement on the terms and conditions set forth in this Third Amendment.

Company desires to retain its license rights with respect to the Oral Prodrug Patent Rights. However, Company has requested, and UMB has agreed, to delete the requirement of achieving diligence milestones with respect to Oral Prodrug Licensed Products, because development of an oral prodrug will likely not be required for clinical development and commercialization of a Licensed Product.

The Parties agree to amend the MLA as set forth herein.

NOW THEREFORE, the Parties agree as follows:

1. Article 2 (Definitions) of the MLA is hereby amended by adding the following definitions:

"**ARDA Licensed Product**": Any product (including without limitation any Combination Product) whose manufacture, use. Sale or import would infringe, or any process whose practice would infringe, the ARDA Patent Rights.

"**ARDA Patent Rights**": The Patent Rights set forth in Part D of **Schedule A**.

2. A new Section 4.4 is added to the MLA as follows:

4.4 ARDA Licensed Products. Notwithstanding anything herein to the contrary:

4.4.1 Within [**] years from the effective date of this Third Amendment, Company shall submit to UMB (a) an R&D Plan reasonably acceptable to UMB, showing the amount of money and time budgeted and planned for technical development of the ARDA Patent Rights, and (b) a Business Plan reasonably acceptable to UMB, showing the proposed commercialization scheme for ARDA Licensed Products. Alternatively, Company may elect to terminate the license granted hereunder with respect to the ARDA Patent Rights.

4.4.2 If Company submits the R&D Plan and Business Plan contemplated in Section 4.4.1, upon approval by UMB, the Parties shall negotiate in good faith appropriate amendments to Schedule B (Diligence Milestones) to add diligence milestones for development and commercialization of ARDA Licensed Products.

4.4.3 If Company submits the R&D Plan and Business Plan contemplated in Section 4.4.1, thereafter Company shall provide prompt written notice to UMB if and when: (a) Company elects to discontinue efforts under the R&D Plan and the Business Plan with respect to ARDA Patent Rights and ARDA Licensed Products: or (b) Company determines that it is not technically or commercially feasible to develop and/or commercialize ARDA Licensed Products.

4.4.4 Upon receipt of the notice contemplated in Section 4.4.3, UMB may, within [**] days after receipt, either: (a) convert the license granted hereunder with respect to ARDA Patent Rights to a nonexclusive license; or (b) terminate the license granted hereunder with respect to ARDA Patent Rights; *provided*, *however*, if the notice contemplated in Section 4.4.3 states that the Company has determined that it is not technically or commercially feasible to develop and/or commercialize ARDA Licensed Products, then UMB may only

convert the license granted hereunder with respect to ARDA Patent Rights to a non-exclusive license.

3. Schedule A (Patent Rights) of the MLA is hereby amended by adding the following:

[**]

4. Schedule B (Diligence Milestones) of the MLA is hereby amended by deleting in its entirety the section related to the Oral Prodrug Licensed Products.

5. UMB hereby represents that, as of the effective date of this Third Amendment, the IIA has been executed by duly authorized representatives of each of the parties thereto and that the IIA is in full force and effect in accordance with its terms.

6. In consideration of the license granted under this Third Amendment, Company agrees to pay a one-time, non-refundable license fee of Ten Thousand Dollars ($10,000) to UMB within [**] business days of the execution of this Third Amendment by both parties.

7. Except as specifically modified in this Third Amendment, all terms and conditions of the MLA (including without limitation the royalty rate and other payment obligations of Company) shall remain in full force and effect.

IN WITNESS WHEREOF, each Party has caused this Third Amendment to be executed under seal by its duly authorized representative.

WITNESS:

/s/ Dorothy C. [illegible]

UNIVERSITY OF MARYLAND, BALTIMORE

By: /s/ Jay A. Perman (SEAL)
Jay A. Perman, M.D.
Title: President
Date: 10/28/13

WITNESS/ATTEST:

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie Morrison (SEAL)
Name: Jodie Morrison
Title: Chief Executive Officer
Date: 10/23/13

INTER-INSTITUTIONAL AGREEMENT

BETWEEN

UNIVERSITY OF MARYLAND, BALTIMORE

AND

UNIVERSITY OF MARYLAND, EASTERN SHORE

AND

THOMAS JEFFERSON UNIVERSITY

UMB Docket No.:	TJU Docket No:
VN-2013-061	NJA_VIN.007

INTER-INSTITUTIONAL AGREEMENT

This Inter-Institutional Agreement ("**Agreement**") is effective as June 30, 2013 ("**Effective Date**") by and between the UNIVERSITY OF MARYLAND, BALTIMORE ("**UMB**"); the UNIVERSITY OF MARYLAND, EASTERN SHORE ("**UMES**") (by the University of Maryland, College Park, Office of Technology Commercialization); and THOMAS JEFFERSON UNIVERSITY ("**TJU**"), a Pennsylvania non-profit organization. UMB and UMES are both constituent institutions of the University System of Maryland ("**USM**"), which is a public corporation and an instrumentality of the State of Maryland.

BACKGROUND

B-l. A valuable invention generally known as "*Androgen Receptor Down-regulating Agents for the Treatment of All Forms of Prostate Cancer*" (the "**Joint Invention**") has been made by Vincent Njar, Puranik Purushottamachar, Lalji K. Gediya, Abhijit M. Godbole (*all employees of UMB and formerly of TJU*), Andrew K. Kwegyir-Afful (*an employee of UMB*), and Tadas S. Vasaitis (*an employee of UMES*).

B-2. UMB, TJU, and UMES have separate agreements with their respective inventors or have intellectual property policies pursuant to which (a) their respective inventors assigned (or are required to assign) all right, title, and interest in the Joint Invention to their institution, and (b) their respective inventors agreed (or are required) to cooperate with and assist their respective institution in preparing, filing, prosecuting, and maintaining patent applications and patents relating to the Joint Invention.

B-3. The Joint Invention was made with government support under National Institutes of Health Grants CA117991 and CA129379.

B-4. UMB and Tokai Pharmaceuticals, Inc. ("**Tokai**") have entered into a Master License Agreement, effective as of May 9, 2006, as amended (the "**Tokai MLA**"), pursuant to which Tokai was granted an exclusive license to six (6) other technologies which are solely owned by UMB (the "**UMB Technologies**").

B-5. The Tokai MLA granted to Tokai an option to license any "Improvements" to the UMB Technologies. The Joint Invention constitutes such an "Improvement," and Tokai has exercised its option to license the Joint Invention. UMB has negotiated with Tokai an amendment to the Tokai MLA for such license.

ARTICLE 1. DEFINITIONS

In this Agreement, the following terms have the meanings set forth in this Article.

"**Administrative Fee**": [REDACTED]

"**Confidential Information**": Information (including without limitation documents, notes, drawings, models, designs, data, results, memoranda, tapes, records, hardware, software, formulae and algorithms, in hard copy form or in electronic form) which is not generally available to the public and which is disclosed by a party to the other party in connection with this Agreement, including without limitation information that: (a) is related to and results from or arises out of use of the Joint Invention or the Patent Rights, or (b) is reasonably necessary for the practice of the Patent Rights or for the development or commercialization of Licensed Products.

"**Federal IP Policy**": U.S. law and regulations applicable to intellectual property funded in whole or in part by the U.S. Government pursuant to which the U.S. Government retains certain rights, including without limitation 35 U.S.C. §200 *et seq*., 15 U.S.C. §3710a, and 37 C.F.R. Part 401.

"**Gross Income**": All cash and non-cash consideration actually received from or in connection with the Tokai MLA that is allocable to the Joint Invention. If any payment under the Tokai MLA is not separately allocated to the Joint Invention, it is agreed that such payment will be allocated [REDACTED] Invention.

"**Infringe**," "**infringement**," or any correlative term: Any infringement (whether direct, indirect, contributory or otherwise) of the intellectual property rights of UMB, TJU, or UMES (including without limitation under the doctrines of claim construction or differentiation, literal overlap or equivalents); or any misuse, misappropriation, theft, or breach of confidence related to the Joint Invention and/or the Patent Rights.

"**Inventor**": Each of the personnel of UMB, TJU, and UMES who invented the Joint Invention, as identified in Section B-l.

"**Licensed Product**": Any product, service, or process, the making, use, offer for sale, sale, importation, or providing of which uses the Joint Invention or any technology disclosed in the Patent Rights.

"**Net Revenues**": Gross Income less (a) unreimbursed Patent Expenses, and (b) the Administrative Fee.

"**OTT**": The Office of Technology Transfer group in UMB's Office of Research and Development, and any successor to its responsibilities.

"**Patent Expenses**": All fees, charges, expenses, and costs incurred before and after the Effective Date with respect to the Joint Invention in connection with the preparation, filing, prosecution, issuance, reissuance, reexamination, interference, enforcement, and/or maintenance of patents or patent applications relating to the Patent Rights, including without limitation all fees and charges of outside patent counsel or patent agent. Patent Expenses shall be considered to be incurred when the fee, charge, expense, or cost is actually incurred (rather than when it is invoiced). For example, charges of outside patent counsel are considered to be incurred as of the date on which the professional services are rendered.

"**Patent Rights**": (a) U.S. and foreign patents and patent applications listed in Schedule A, as it may be amended from time to time by mutual agreement of the parties; (b) all patents and patent applications related to clause (a), whether filed before or after the Effective Date, which claim priority under 35 U.S.C. §119 or the benefit of the filing date under 35 U.S.C. §120 or §371 (but only to the extent of subject matter in a patent or patent application for which priority or benefit is claimed); (c) any substitution, divisional, continuation, and continuation-in-part (but only to the extent a claim in the continuation-in-part is directed to subject matter contained in a patent or patent application described in clause (a) or (b)); (d) any patent issuing from any patent or patent application described in clause (a), (b), or (c); (e) any reissue, renewal, reexamination, or extension of any patent or patent application described in clause (a), (b), (c), or (d); and (f) any foreign counterpart or equivalent of any patent or patent application described in clause (a), (b), (c), (d), or (e).

ARTICLE 2. OWNERSHIP; RESERVED RIGHTS; CONFIDENTIAL INFORMATION

2.1 Ownership.

2.1.1 Subject to certain rights retained by the U.S. Government in inventions resulting from federally supported work pursuant to Federal IP Policy, UMB, TJU, and UMES each own an undivided joint interest in and to the Joint Invention and Patent Rights.

2.1.2 During the Term: (a) TJU and UMES shall forbear granting to any third party (other than to UMB) any right, title, or interest in, to or under the Joint Invention and Patent Rights, and (b) TJU and UMES grant to UMB the sole responsibility for administering and commercializing the Joint Invention and Patent Rights.

2.2 Reservation of Rights. The following rights are specifically reserved with respect to the Joint Invention and the Patent Rights by each of the parties:

2.2.1 To use the Joint Invention, practice under the Patent Rights, and to make and use Licensed Products on a non-exclusive, royalty-free basis for research, scholarly use, teaching, education, patient care incidental to the foregoing, and other similar uses, including without limitation sponsored research and collaborations ("**Non-Commercial Uses**");

2.2.2 To license government agencies, universities or other educational institutions, organizations of the type described in §501(c)(3) of the Internal Revenue Code, scientific or educational organizations qualified under a state nonprofit organization statute (or foreign equivalents of the foregoing) ("**Non-Commercial Organizations**") use the Joint Invention, practice under the Patent Rights, and to make and use Licensed Products on a non-exclusive, royalty-free basis solely for Non-Commercial Uses; and to provide material and information (excluding Company's Confidential Information) to Non-Commercial Organizations solely for Non-Commercial Uses; and

2.2.3 To disseminate and publish scientific findings from research related to the Joint Invention, Patent Rights, and/or Licensed Products, and to permit its respective personnel to do the same, subject to **Schedule B** (Confidentiality).

2.3 Reporting. Each party is responsible for making all reports required to be made by it by the Federal Government or other sponsors research related to the Joint Invention.

2.4 Confidentiality. The parties agree to abide by the terms and conditions of **Schedule B** regarding Confidential Information.

ARTICLE 3. PATENT PROSECUTION

3.1 Prosecution.

3.1.1 In the event that the Joint Invention is licensed to Tokai pursuant to the Tokai MLA and the Tokai MLA is in effect, UMB shall have the sole discretion to make decisions with respect to patent applications and patent preparation, filing, prosecution, and maintenance, subject to the conditions set forth in this Agreement. UMB may retain legal counsel of its choosing.

3.1.2 It is understood that Tokai has been granted the right to control patent prosecution, pursuant to the terms of the Tokai MLA. UMB will promptly advise UMES and TJU if it receives information from Tokai or its outside patent counsel of material developments with respect to the Patent Rights regarding the Joint Invention. If UMB receives any communications in connection with prosecution of Patent Rights regarding the Joint Invention, UMB will promptly provide copies of the same to UMES and TJU.

3.1.3 If UMB has an opportunity to provide comments and suggestions with respect to any substantive actions to be taken by Tokai with respect to the Patent Rights regarding the Joint Invention, or to comment on the type and scope of claims and the nature of supporting disclosures, it will solicit comments and suggestions from TJU and UMES. UMB will forward any such comments and suggestions which UMB receives from TJU and/or UMES.

3.1.4(a) In the event that the Tokai MLA is no longer in effect or that the Joint Invention is no longer licensed to Tokai pursuant to the Tokai MLA, UMB shall have the sole discretion to make decisions with respect to patent applications and patent preparation, filing, prosecution, and maintenance, subject to the conditions set forth in this Section 3.1.4.

(b) If Section 3.1.4(a) is applicable, UMB shall consult with, incorporate reasonable input from, and keep UMES and TJU informed as to the preparation, filing, prosecution, and maintenance of all applicable patent applications and patents. UMB shall send UMES and TJU copies of formal correspondence with the U.S. Patent and Trademark Office and with any foreign patent office concerning the preparation, filing, prosecution, and maintenance of all applicable patent applications and patents.

(c) If UMB desires to discontinue prosecution of any patent application or maintenance of any patent within any country, it shall first give written notice of its intent to UMES and TJU at least sixty (60) days prior to the next applicable deadline. UMES and/or TJU may assume responsibility for paying Patent Expenses in that country by providing written notice to UMB at least thirty (30) days prior to the next applicable deadline. In that event, UMES and/or TJU, as the case may be, shall thereafter be responsible at its sole expense

in that country for patent prosecution or maintenance of those Patent Rights. Any party who is not responsible for paying Patent Expenses in that country thereby relinquishes rights to revenues resulting from those Patent Rights within such country.

3.2 Patent Expenses.

3.2.1 Under the Tokai MLA, Tokai is responsible to pay Patent Expenses. If any Patent Expenses are not otherwise reimbursed or reimbursable under the Tokai MLA, each party shall be responsible for a portion of Patent Expenses in proportion to the number of Inventors of the Joint Invention from each party's institution, as follows: [REDACTED]

3.2.2 UMB may advance Patent Expenses, and may invoice TJU and UMES for its share. TJU and UMES shall reimburse UMB within thirty (30) days of receipt of invoice therefor. UMB shall maintain adequate records showing all Patent Expenses incurred. These records shall be made available to TJU and UMES for inspection on reasonable notice.

3.3 Consultation and Notice. UMB shall consult with and keep TJU and UMES informed as to the preparation, filing, prosecution, and maintenance of all applicable patent applications and patents. UMB shall send TJU and UMES copies of formal correspondence with the U.S. Patent and Trademark Office and with any foreign patent office concerning the preparation, filing, prosecution, and maintenance of all applicable patent applications and patents.

ARTICLE 4. LICENSING OF THE JOINT INVENTION

4.1 Licensing.

4.1.1 UMB shall have the sole right, on behalf of the parties, to grant a license to the Joint Invention to Tokai, as an amendment to the Tokai MLA, on terms and conditions to be negotiated by UMB.

4.1.2 UMB shall be responsible for assuring compliance by Tokai in accordance with the terms of the Tokai MLA, for otherwise enforcing the Tokai MLA, and for protecting the rights of the parties pursuant to and in accordance with this Agreement. UMB shall consult with and keep TJU and UMES reasonably promptly informed with respect to all material matters during administration of the Tokai MLA as it relates to the Joint Invention.

ARTICLE 5. LICENSING REVENUE

5.1 UMB shall use reasonable efforts to collect all material amounts due under the Tokai MLA with respect to the Joint Invention. UMB shall calculate: (a) the amount of Gross Income; (b) the amount of each party's unreimbursed Patent Expenses, (c) the Administrative Fee, and (d) Net Revenues. UMB shall provide a written report of its calculations to TJU and UMES periodically, but no less often than annually. TJU and UMES shall review those calculations and shall notify UMB of any discrepancies within fifteen (15) days after receipt of that report.

5.2 After the parties approve the calculations in accordance with Section 5.1. UMB shall disburse as follows:

5.2.1 First, to each party in an amount necessary to reimburse any outstanding Patent Expenses;

5.2.2 Second, to UMB the Administrative Fee, if applicable; and

5.2.3 Then, remaining Net Revenues shall be disbursed as follows:

(a) If the Net Revenues are specifically allocable to the Joint Invention, remaining Net Revenues shall be disbursed [REDACTED]; or

(b) If the Net Revenues are not specifically allocable to the Joint Invention, remaining Net Revenues shall be disbursed [REDACTED]; or

provided, *however*, if the Tokai MLA is further amended such that there are a different total number of licensed technologies, then the parties will negotiate reasonably and in good faith a different sharing of Net Revenues than that set forth in this Section 5.2.3.

5.3 UMB shall pay to TJU and UMES its share of Net Revenues concurrently with the distributions it makes to its own Inventors, but in any case no later than June 30 for the preceding calendar year.

5.4 Each party shall be responsible for distributing a portion of its respective share of Net Revenues to its Inventor(s), as required.

5.5 During the term of this Agreement and for [**] years after its expiration or termination, UMB shall keep (and shall require Tokai to keep) complete, true, and accurate records containing all the particulars that may be necessary to determine Net Revenues, the Administrative Fee, Patent Expenses, or other amounts payable under this Agreement. The records shall be subject to inspection at any time during regular business hours upon reasonable notice by an independent auditor appointed by TJU or UMES for this purpose and reasonably acceptable to UMB. The auditor shall report only the amount of Net Revenues, Administrative Fees, Patent Expenses, or other amounts payable under this Agreement. This audit shall be at TJU's or UMES' expense; *provided*, *however*, if the audit shows an underpayment often percent (10%) or more, the audit expense shall be payable by UMB.

ARTICLE 6. INFRINGEMENT

6.1 Management of Proceedings.

6.1.1 If a party has knowledge of or reasonable grounds to suspect any infringement of the Patent Rights, it shall promptly provide notice to the other parties. If required by the Tokai MLA, UMB shall be responsible to provide notice of infringement to Tokai.

6.1.2 Pursuant to the Tokai MLA, Tokai in its own name, at its own expense, and on its own behalf may bring suit for any infringement, or defend a suit alleging invalidity or non-infringement of the Patent Rights. In that event, UMB shall use reasonable efforts to ensure that Tokai manages the proceedings related to the infringement according to the terms of the Tokai MLA. If a suit is filed or defended by Tokai, each party may join in the suit at its own expense, but otherwise the parties shall take no action with respect to the infringement.

6.1.3 If (a) Tokai fails to take actions regarding the infringement required by the Tokai MLA, or (c) Tokai provides notice to UMB that Tokai has decided not to take any action, the parties shall by mutual agreement determine which party will be primarily responsible for attempting to terminate the infringement. If the parties are unable to agree in a timely manner, UMB shall be primarily responsible. The designated party shall use reasonable efforts, in cooperation with the other party and to the extent permitted by the Tokai MLA, to terminate the infringement without litigation.

6.1.4 If the infringement is not eliminated within [**] days after notice to the infringer, and if Tokai will not be instituting suit or managing the proceedings (as set forth in Section 6.1.3), each party shall have the right after consulting with the other parties to: (a) commence suit on its own account; (b) join with the other parties and/or Tokai in that suit; or (c) refuse to participate in that suit.

6.1.5 Each party agrees to cooperate in any infringement proceeding instituted under this Agreement. An infringement proceeding (including any settlement) shall be controlled by the party bringing the suit; *provided*, *however*, that UMB shall control the suit if brought jointly, unless UMB joins only as a nominal plaintiff. Each party shall request its Inventor(s) and other relevant personnel to cooperate with and to assist to the extent reasonably required in connection with any infringement proceeding.

6.2 Expenses and Recoveries.

6.2.1 If the parties join in any suit for infringement solely regarding the Joint Invention: (a) [REDACTED] (including without limitation counsel fees, expert witness fees, and discovery costs); and (b) all recoveries received [REDACTED].

6.2.2 If the parties join in any suit for infringement which regards the Joint Invention in addition to any other technology(ies) (including without limitation the UMB Technologies), the parties shall negotiate reasonably and in good faith a different sharing of expenses and recoveries.

6.2.3 Any party bringing a suit on its own account shall be solely responsible for all litigation expenses incurred in connection with that action, and shall be entitled to retain all recoveries as a result of that action.

ARTICLE 7. TERM AND TERMINATION

7.1 Term. Unless sooner terminated in accordance with this Article 7, this Agreement will continue in full force and effect until the later of: (a) the date of expiration of the last to

expire of the claims of the Patent Rights; (b) ten (10) years after the Effective Date); or (c) the expiration or termination of the Tokai MLA if they extend beyond clause (a) and (b) (the "**Term**").

7.2 Unilateral Termination. Either party may terminate this Agreement by giving ninety (90) days notice to the other party.

7.3 Termination Upon Default. If a party defaults in the performance of any material obligation under this Agreement, and the default has not been remedied to the other parties' reasonable satisfaction within sixty (60) days after the date of written notice of that default, the non-defaulting parties may by written notice to the defaulting party terminate this Agreement effective immediately.

7.4 Effect of Termination.

7.4.1 Termination or expiration of this Agreement does not relieve any party of any obligation which arises before expiration or termination, including without limitation any obligation to distribute Net Revenues, to reimburse Patent Expenses, and to cooperate and share expenses for pursuit of infringement. Any provision of this Agreement which contemplates performance or observance subsequent to any termination or expiration of this Agreement shall survive any termination or expiration of this Agreement and continue in full force and effect.

7.4.2 Termination or expiration shall not affect the Tokai MLA. The applicable provisions of this Agreement shall continue to be applied with respect to the Tokai MLA, notwithstanding the termination or expiration of this Agreement.

7.4.3 In addition, upon any termination or expiration:

(a) Each party shall continue to own an undivided joint interest in the Joint Invention and the related Patent Rights.

(b) Each party shall make available to the other party copies of all relevant documents called for under the Agreement applicable to the Joint Invention, to the extent that copies have not been furnished previously.

ARTICLE 8. DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITY

8.1 DISCLAIMER OF WARRANTIES. THE JOINT INVENTION, PATENT RIGHTS, LICENSED PRODUCTS, AND UMB CONFIDENTIAL INFORMATION ARE "AS IS." EACH PARTY DISCLAIMS ALL EXPRESS OR IMPLIED REPRESENTATIONS OR WARRANTIES REGARDING THE JOINT INVENTION, PATENT RIGHTS, PATENT APPLICATIONS, LICENSED PRODUCTS, OR CONFIDENTIAL INFORMATION, INCLUDING WITHOUT LIMITATION: SCOPE, VALIDITY OR ENFORCEABILITY; WHETHER A PATENT APPLICATION WILL BE APPROVED OR THAT A PATENT WILL ISSUE; RELIABILITY, COMPLETENESS, OR ACCURACY OF CONFIDENTIAL INFORMATION; INFRINGEMENT OR NON-INFRINGEMENT; THE PERFORMANCE OF LICENSED PRODUCTS, INCLUDING WITHOUT LIMITATION AS TO THEIR SAFETY, EFFECTIVENESS. OR COMMERCIAL VIABILITY; AND THE WARRANTIES OF

MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF DEALING, OR USAGE OF TRADE.

8.2 Limitation of Liability. In no event will any party's liability of any kind include any special, indirect, incidental, consequential or punitive losses or damages, even if the party has been advised of the possibility of such damages.

8.3 No Joint Liability. The liability of the parties under this Agreement shall be several, and not joint and several. The parties agree that nothing in this Agreement shall be construed as implying joint liability in any case and that each party will be solely responsible for its own acts or omissions. If an action is brought by an outside party against two or more parties to this Agreement, the parties agree that no party to this Agreement will be liable for an amount greater than its proportional contribution to any finding of negligence upon which such action is based.

ARTICLE 9. NOTICES

9.1 Notices. Notices under this Agreement shall be in writing and shall be delivered personally as proven by a signed receipt, sent by a reputable, national overnight delivery service, charges prepaid, or sent by certified mail return receipt requested. Notices shall be addressed to a party at the address specified below, or at those other place or places as shall from time to time be specified in a notice similarly given. All notices shall be effective upon receipt.

If to UMB:
Assistant Vice President, OTT Office of Research and Development
University of Maryland, Baltimore
620 West Lexington Street, 4th Floor
Baltimore, Maryland 21201-1508

Copy to:

University Counsel
University of Maryland, Baltimore
220 Arch Street, Room 03-111
Baltimore, Maryland 21201-1531

If to TJU:
Office of Technology Transfer and Business Development
Thomas Jefferson University
1020 Locust Street, Suite M34
Philadelphia, PA 19107
Attn: Executive Director

Copy to:

Office of University Counsel
Thomas Jefferson University
1020 Walnut Street
Philadelphia, PA 19107

If to UMES:
c/o University of Maryland Office of Technology Commercialization
0133 Cole Student Activities Bldg.
College Park, MD 20742-1001
Attn: Executive Director

Copy to:

Office of Legal Affairs
University of Maryland
2101 Main Administration Bldg.
College Park, MD 20742

9.2 Changes of Address. Each party shall reasonably promptly notify the other party of any change specifying that changed address for the delivery of notices or invoices.

ARTICLE 10. ASSIGNMENT

10.1 General. This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors, and pennitted assigns. Any reference in this Agreement to a party shall be construed to include that party's successors and permitted assigns. Any purported assignment in violation of this Section shall be null and void.

10.2 Permitted Assignment. Either party may assign this Agreement to a successor-in-interest, but may not otherwise assign or transfer this Agreement without the prior written consent of the other parties, which shall not be unreasonably withheld or delayed. Each party

may also assign this Agreement to its Inventor(s), in the event of an assignment to the Inventor(s) of the Joint Invention pursuant to Federal IP Policy.

ARTICLE 11. MISCELLANEOUS

11.1 Governing Law. This Agreement is made and shall be construed in accordance with the laws of the State of Maryland without regard to the principles of conflicts of laws.

11.2 Jurisdiction. Each party consents to the jurisdiction of the Circuit Court of Baltimore City or Anne Arundel County, Maryland for any suit relating to this Agreement, and agrees to file any such suit in one of those courts.

11.3 No Limitation of State Defenses. No provision of this Agreement shall constitute or be construed as a limitation, abrogation, or waiver of any defense or limitation of liability available to the State of Maryland or its units (including without limitation USM, UMB, and UMES), officials, or employees under Maryland or Federal law, including without limitation the defense of sovereign immunity or any other governmental immunity.

11.4 Waiver of Trial by Jury. THE PARTIES WAIVE THEIR RIGHTS TO TRIAL BY JURY IN ANY LITIGATION BETWEEN THEM RELATING TO THIS AGREEMENT.

11.5 Entire Agreement. This Agreement embodies the entire understanding between the parties with respect to the subject matter of this Agreement. There are no contracts, understandings, conditions, warranties or representations, oral or written, express or implied, with reference to the subject matter of this Agreement that are not merged in this Agreement.

11.6 Relationship Between the Parties. UMB, TJU, and UMES are not (and nothing in this Agreement may be construed to constitute them as) partners, joint venturers, agents, representatives, or employees of the other. No party has any responsibility or liability for the actions of the other party except as specifically provided in this Agreement.

11.7 Further Assurances. The parties shall execute and deliver and cause to be executed and delivered further agreements, instruments and documents and shall take further actions as may reasonably be required or appropriate to carry out the terms and conditions of this Agreement.

11.8 Use of Names; Publicity. None of the parties shall use the name, seal, logo, trademark, or service mark of the other or any of its personnel, or any adaptation thereof, in any advertising, promotional, or sales literature without prior written consent obtained from the other parties. Either party may publicize the fact that the parties have entered into this Agreement. However, press releases or other public releases of information shall be coordinated between the parties prior to release.

11.9 No Implied Rights. Nothing in the Agreement shall be construed to imply any license rights or other commitments with respect to any future research, or any intellectual property rights, or any technology, other than for the express terms set forth in the Agreement relative to the Joint Invention and Patent Rights.

11.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original, and all of which shall together constitute one agreement.

[SIGNATURES ON FOLLOWING PAGE]

SIGNATURE PAGE TO
INTER-INSTITUTIONAL AGREEMENT

The parties have caused this Agreement to be executed by their duly authorized representatives, to be effective as of the date of the last signature below.

WITNESS:

UNIVERSITY OF MARYLAND, BALTIMORE

By: /s/ Philip J. Robilotto (SEAL)
Philip J. Robilotto
Title: AVP/OTT
Date: 3-October-2013

WITNESS:

THOMAS JEFFERSON UNIVERSITY

By: /s/ Theodore F. Tarasdin (SEAL)

/s/ illegible 10/18/13

Name: Theodore F. Tarasdin
Title: VPR
Date: 10/18/13

WITNESS:

UNIVERSITY OF MARYLAND, EASTERN SHORE

By: University of Maryland, College Park Office of Technology Commercialization

/s/ Felicia Metz

By: /s/ Gayatri Varma (SEAL)
Name: Gayatri Varma, Ph.D
Title: Executive Director
Date: September 24, 2013

SCHEDULE A
PATENT RIGHTS

[**]

SCHEDULE B
STANDARD CONFIDENTIALITY PROVISIONS

1. General Restrictions on Use and Disclosure.

1.1 A party ("**Provider**") may disclose Confidential Information to the other party ("**Recipient**"). For a period of [**] years following the disclosure, Recipient shall hold the Confidential Information in confidence, and may disclose or use the Confidential Information only as permitted by this Agreement. Recipient shall not use Provider's Confidential Information for any other purpose without the prior written consent of Provider, UMB, TJU, and UMES each shall have the right to use the Confidential Information for its own Non-Commercial Uses. Notwithstanding the foregoing, each party is permitted to disclose the Confidential Information to the extent reasonably necessary to market the Joint Invention and to fulfill its obligations under this Agreement, provided that any disclosure is made subject to confidentiality restrictions consistent with those in this Agreement.

1.2 Recipient shall use the level of care to prevent the unauthorized use or disclosure of Provider's Confidential Information that Recipient exercises in preventing the unauthorized use or disclosure of its own Confidential Information. Recipient may disclose Provider's Confidential Information only to its personnel who have a need to know or require access to the Confidential Information for the purposes permitted by this Agreement. Any Confidential Information that would identify human research subjects or patients shall be maintained confidentially in accordance with applicable law.

1.3 UMB, TJU, and UMES are educational institutions with practices for protection of Confidential Information which differ from industry standards and practices. Each party shall only be required to use reasonable efforts to protect the confidentiality of the other party's Confidential Information in a manner consistent with the practices used by that party to protect its own Confidential Information.

2. Permitted Use and Disclosure.

2.1 The confidentiality obligations created by this Agreement shall not apply if and to the extent that: (a) the information is generally available to the public (other than through Recipient's breach of this Agreement, any other agreement, or applicable law, or any unauthorized act by the Recipient); (b) the information was already in the possession of Recipient at the time of the disclosure (other than pursuant to a confidential disclosure agreement or any unauthorized act by Recipient); (c) the information is or was developed by Recipient independent of and with no reliance upon information of Provider or any other information furnished to Recipient by Provider under obligation of confidentiality; (d) the disclosure or use is reasonably necessary to fulfill or comply with requirements of governmental authorities having jurisdiction, including without limitation the U.S. Securities and Exchange Commission, National Institutes of Health, Food and Drug Administration, and U.S. Patent and Trademark Office, and foreign equivalents of the foregoing; or (e) disclosure is required by law.

2.2 In the event of disclosure pursuant to clauses (d) or (e) of Section 2.1, Recipient shall use reasonable efforts to give Provider prior written notice of disclosure. Recipient, consistent with its counsel's advice, shall take reasonable and lawful actions to obtain confidential treatment for disclosed information of the Provider and to minimize the extent of the disclosure, or allow Provider the opportunity to take those actions.

2.3 Nothing in this Agreement contained shall preclude a party from disclosing to Tokai those aspects of the Joint Invention necessary to evaluate and/or practice the Patent Rights in a limited role as licensee. Any disclosure to Tokai of Confidential Information shall be contingent upon execution by Tokai of a non-disclosure agreement substantially on the terms set forth in this Schedule B. In the event of a dispute as to the applicability of this Section 2, the burden of proof shall be upon Recipient to demonstrate permissibility of disclosure or use.

3. Markings and Legends. Provider shall use reasonable efforts to mark all Confidential Information disclosed to Recipient as "Confidential." If the Confidential Information is not in written or tangible form and marked "Confidential" when disclosed, Provider shall use reasonable efforts to summarize the information in writing, marked as "Confidential", and to provide the summary to Recipient within [**] days after disclosure of the Confidential Information to Recipient. To the extent Recipient has actual knowledge that information is Confidential Information, failure to meet the marking requirements shall not affect Recipient's confidentiality obligations under this Agreement.

4. Public Information Act. This Agreement and Confidential Information provided to UMB or UMES under this Agreement is a public record when in the possession of UMB or UMES. It may be subject to inspection pursuant to the Public Information Act (§10-611 *et seq*., State Government Article, Annotated Code of Maryland) (the "**Public Information Act**"). If TJU asserts that any Confidential Information provided under this Agreement is a trade secret, confidential financial information, confidential unpublished scientific information, or confidential commercial information, which is exempt from disclosure under the Public Information Act, then UMB and/or UMES shall assert in response to any request for inspection of TJU's Confidential Information that inspection should be denied pursuant to § 10-617(d) of the Public Information Act, unless UMB and/or UMES determines on the advice of its counsel that TJU's position is not reasonable.

5. Government and Sponsor Rights. Confidential Information may have been developed under a grant or contract or in collaboration with the U.S. Government, state governments, research sponsors, or other entities. They may have rights in Confidential Information and may have the right to license or use Confidential Information, Patent Rights, and/or Licensed Products. Upon written request, each party shall provide the other party with further information about any sponsor's or collaborator's rights, subject to confidentiality obligations.

6. Export Control Laws. To the best of its knowledge, Discloser shall notify Recipient, prior to disclosing any Confidential Information, whether the information being disclosed is subject to any restrictions or controls imposed by the Arms Export Control Act; the Export Administration Act of 1979; the International Traffic in Arms Regulations; the Export Administration Regulations; or any other rules or regulations pertaining to restrictions on use or

disclosure of goods, information, or technology, of any applicable governmental agency (collectively, the "**Export Control Laws**"). Recipient shall use reasonable efforts to prevent Confidential Information and any direct product thereof from being used for any purpose prohibited by the Export Control Laws, and to cause uses of that Confidential Information to comply with the Export Control Laws.

7. Return or Destruction of Confidential Information. Upon expiration or termination of this Agreement for any reason, Recipient shall either return or destroy Discloser's Confidential Information, together with all copies and other forms of reproduction, and shall provide written notice to Discloser of same. However, Recipient may retain one copy of Discloser's Confidential Information in the event of any question or dispute concerning Recipient's obligations under this Agreement. If and to the extent any regulatory agency requests access to a party's files after the return of such Confidential Information to the Provider, the party responding to the request may either refer that agency to the Provider, or the Provider shall grant limited access again to such materials to allow compliance with the request.

Exhibit 10.15

tōkai pharmaceuticals

January 30, 2014

John McBride
89 West Main Street
Westborough, MA 01581

Dear John:

It is my pleasure to extend to you this offer of employment with Tokai Pharmaceuticals, Inc. (the "Company"). On behalf of the Company, I set forth below the terms of your employment:

1. **Employment.** You will be employed to serve on a full-time basis as Chief Operating Officer, effective February 3, 2014. As Chief Operating Officer, you will be responsible for the daily operations of the Company plus any other duties as may from time to time be assigned to you by the Company. You shall report to the Chief Executive Officer or his/her designee, and you agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. Notwithstanding the foregoing, you may continue to serve on the Board of Directors of Intezyne, Inc. provided that doing so does not interfere with you fulfilling your responsibilities as Chief Operating Officer of Tokai. You agree to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

2. **Base Salary.** Your base salary will be at the rate of $12,500 per semi-monthly pay period (which if annualized equals $300,000 dollar amount), less all applicable taxes and withholdings, to be paid in installments in accordance with the Company's regular payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company. In addition, the Company agrees to compensate you for the employer paid portion of the current family medical and dental plans offered to employees as long as you are not participating in the plans.

3. **Discretionary Bonus.** Following the end of each calendar year and subject to the approval of the Company's Board of Directors (the "Board"), you will be eligible for a retention and performance bonus of up to 20% of your annualized base salary, based on your performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion. In any event, you must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any such bonus award, as it also serves as an incentive to remain employed by the Company.

4. **Equity.** Subject to approval by the Board, you will receive an option to purchase, 2,190,107 shares of the Company's Common Stock at an exercise price per share equal to the fair market value of one share of the Common Stock as determined by the Board in its sole discretion (the "Option"). The Option would be granted pursuant and subject to the terms of a stock option agreement to be entered into with the Company and under the Company's Stock Incentive Plan.

   The Option would vest over a four year period, with the first twelve and a half percent (12.5%) of the Option vesting upon the date that is five (5) months after the first day of the first month following the month in which your employment hereunder commences and the balance of the Option vesting in 42 equal monthly installments on the first day of each month thereafter, subject to your continued employment with the Company through each vesting date.

   Notwithstanding the foregoing, in the event that a Change in Control of the Company occurs or a definitive agreement that results in a Change of Control of the Company is entered into prior to August 3, 2014, then immediately prior to the Change in Control of the Company, the Option with respect to 50% of the underlying shares originally covered by the Option (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar events affecting the Common Stock) will terminate and be of no further force or effect, and the balance of the Option shall continue in force or effect as if it had originally been granted for a number of shares equal to 50% of the underlying shares originally covered by the Option (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar events affecting the Common Stock).

   You may also be eligible for other grants of stock or stock options as determined by and in the sole discretion of the Board. Nothing in this section shall affect your status as an employee at will, as set for below.

5. **Benefits.** You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion.

6. **Business Expenses:** The Company will reimburse you for all submitted reasonable and documented business expenses in accordance with Company policy.

7. **Vacation.** You will be eligible for a maximum of four weeks of paid vacation per calendar year to be taken at such times as may be approved in advance by the Company. The number of vacation days for which you are eligible shall accrue at the rate of 1.67 days per month that you are employed during such calendar year. Pursuant to Company policy, vacation time cannot be carried over from year to year.

8. **Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement.** You will be required to execute the attached Confidentiality, Inventions, Non-

Competition and Non- Solicitation Agreement (the "Non-Competition Agreement") as a condition of employment.

9. **No Conflict.** You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this offer letter.

10. **Proof of Legal Right to Work.** You agree to provide to the Company, within three (3) days of your date of hire, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

11. **At-Will Employment.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer of the Company, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein. This letter supersedes all prior understandings, whether written or oral, relating to the terms of your employment.

12. **Termination Without Cause**

a. Severance. In the event the Company terminates your employment without "Cause" (as defined below), then, subject to the terms and conditions set forth in Exhibit A, and provided that you have been employed by the Company for at least three (3) months, and provided further that you execute and return to the Company a severance and release of claims agreement provided by and satisfactory to the Company (the "Severance Agreement") and such Severance Agreement becomes binding and enforceable within 60 calendar days after your termination of employment, the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your then current base salary in accordance with the Company's then current payroll practices. As used herein, the "Severance Period" shall commence on the Company's first payroll period after your Severance Agreement becomes binding (the "Effective Date"), and shall continue until the earlier of (x) the six-month anniversary of the Effective Date, and (y) the date on which you commence employment with or begin providing services to another person, employer, or entity, provided that if

the foregoing 60 day period would end in a calendar year subsequent to the year in which your employment ends, payments will not be made before the first payroll period of the subsequent year. You are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay hereunder will be subject to all applicable taxes and withholdings. You shall not be entitled to any severance pay if your employment is terminated by the Company for Cause, or if you resign your employment with the Company for any reason.

b. Cause. For purposes of this Section 12, the term "Cause" means: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence,(ii) breached or threatened to breach the Non-Competition Agreement, (iii) violated Company policies or procedures, and/or (iv) failed to perform your assigned duties to the Company's satisfaction, following notice of such failure by the Company and a period of fifteen (15) days to cure.

13. **Entire Agreement**. This letter, together with the Non-Competition Agreement and the option agreement evidencing the Option, constitute the entire agreement between you and the Company pertaining to their subject matter, and supersede all previous written or oral representations, agreements and understandings between you and the Company related to the subject matter of this letter and those agreements. Accordingly, upon the Effective Date, the Consulting Agreement dated April 3, 2013 between Alliance Life Science Advisors, Inc. and the Company shall terminate and be of no further force or effect except as provided therein, and your obligations under the Non-Competition Agreement shall apply to Confidential Information, the Materials and Service-related IP (each as defined in the Consulting Agreement) as if the effective date of this letter and the Non-Competition Agreement were April 3, 2013.

If this letter correctly sets forth the terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me, along with a signed copy of the Non-Competition Agreement. If you do not accept this offer by "10 days from acceptance", the offer will be deemed withdrawn.

Sincerely,

By: /s/ Jodie P. Morrison
Jodie P. Morrison
President and Chief Executive Officer

The foregoing correctly sets forth the terms of my at-will employment with Tokai Pharmaceuticals, Inc. I am not relying on any representations other than those set forth above.

/s/ John McBride
John McBride

2/7/14
Date

Solely for purposes of Section 13

ALLIANCE LIFE SCIENCES ADVISORS, INC.

/s/ John McBride
By: John McBride
Title: President

Exhibit A

Payments Subject to Section 409A

1. Subject to this Exhibit A, payments or benefits under Section 12(a) of the offer letter shall begin only following the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to you under Section 12(a) of the offer letter, as applicable:

(a) It is intended that each installment of the payments and benefits provided under Section 12(a) of the offer letter shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code of 1986 and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the payments and benefits shall be made on the dates and terms set forth in Section 12(a) of the offer letter.

(c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the payments and benefits due under Section 12(a) of the offer letter that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the Short-Term Deferral Period (as hereinafter defined) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A. For purposes of the offer letter, the "Short-Term Deferral Period" means the period ending on the later of the 15th day of the third month following the end of your tax year in which the separation from service occurs and the 15th day of the third month following the end of the Company's tax year in which the separation from service occurs; and

(ii) Each installment of the payments and benefits due under Section 12(a) of the offer letter that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following your separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms

set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation Section 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when your separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the offer letter shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A.

4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the offer letter (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

Exhibit 10.16

tōkai pharmaceuticals

April 7, 2014

Karen Ferrante
150 Adirondack Drive
East Greenwich, RI 02818

Dear Karen:

It is my pleasure to extend to you this offer of employment with Tokai Pharmaceuticals, Inc. (the "Company"). On behalf of the Company, I set forth below the terms of your employment:

1. **Employment.** You will be employed to serve on a full-time basis as CMO and Head of Research and Development, effective April 7, 2014. As CMO and Head of Research and Development, you will be responsible for the oversight of development plus any other duties as may from time to time be assigned to you by the Company. You shall report to the Chief Executive Officer or his/her designee, and you agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. Notwithstanding the foregoing, you may continue to serve on the Board of Directors of Progenics Pharmaceuticals, Inc., provided that doing so does not interfere with you fulfilling your responsibilities as CMO and Head of Research and Development of Tokai. You agree to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

2. **Base Salary.** Your base salary will be at the rate of $13,541.67 per semi-monthly pay period (which if annualized equals $325,000), less all applicable taxes and withholdings, to be paid in installments in accordance with the Company's regular payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company. In addition, the Company agrees to compensate you for the employer paid portion of the current family medical and dental plans offered to employees as long as you are not participating in the plans.

3. **Signing Bonus.** Your signing bonus will be in the amount of $50,000 payable in the first full pay period following the commencement of your employment. Notwithstanding the foregoing, if you resign for any reason or are terminated by the Company for Cause (as defined below), in either case, prior to July 7, 2014, then you

shall be obligated to and shall repay the signing bonus in full within 30 days of such resignation or termination.

4. **Discretionary Bonus.** Following the end of each calendar year and subject to the approval of the Company's Board of Directors (the "Board"), you will be eligible for a retention and performance bonus of up to 20% of your annualized base salary, based on your performance and the Company's performance during the applicable calendar year, as determined by the Company in its sole discretion. In any event, you must be an active employee of the Company on the date any bonus is distributed in order to be eligible for and to earn any such bonus award, as it also serves as an incentive to remain employed by the Company.

5. **Equity.** Subject to approval by the Board, you will receive an option to purchase, 2,701,653 shares of the Company's Common Stock at an exercise price per share equal to the fair market value of one share of the Common Stock as determined by the Board in its sole discretion (the "Option"). The Option would be granted pursuant and subject to the terms of a stock option agreement to be entered into with the Company and under the Company's 2007 Stock Incentive Plan (the "Option Agreement").

   The Option would vest over a four year period, with the first twelve and a half percent (12.5%) of the Option vesting on July 1, 2014 and the balance of the Option vesting in 42 equal monthly installments on the first day of each month thereafter, subject to your continued employment with the Company through each vesting date.

   Notwithstanding the foregoing, in the event that a Change in Control Event (as defined in the Option Agreement) occurs or a definitive agreement that results in a Change of Control Event is entered into, in either case, prior to July 7, 2014, then immediately prior to the Change in Control Event, the Option with respect to 50% of the underlying shares originally covered by the Option (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar events affecting the Common Stock) will terminate and be of no further force or effect, and the balance of the Option shall continue in force or effect as if it had originally been granted for a number of shares equal to 50% of the underlying shares originally covered by the Option (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar events affecting the Common Stock).

   You may also be eligible for other grants of stock or stock options as determined by and in the sole discretion of the Board. Nothing in this section shall affect your status as an employee at will, as set for below.

6. **Benefits.** You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion.

7. **Business Expenses:** The Company will reimburse you for all submitted reasonable and documented business expenses in accordance with Company policy.

8. **Vacation.** You will be eligible for a maximum of four weeks of paid vacation per calendar year to be taken at such times as may be approved in advance by the Company. The number of vacation days for which you are eligible shall accrue at the rate of 1.67 days per month that you are employed during such calendar year. Pursuant to Company policy, vacation time cannot be carried over from year to year.

9. **Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement.** You will be required to execute the attached Confidentiality, Inventions, Non-Competition and Non-Solicitation Agreement (the "Non-Competition Agreement") as a condition of employment.

10. **No Conflict.** You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this offer letter.

11. **Proof of Legal Right to Work.** You agree to provide to the Company, within three (3) days of your date of hire, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

12. **At-Will Employment.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the Chief Executive Officer of the Company, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein. This letter supersedes all prior understandings, whether written or oral, relating to the terms of your employment.

13. **Termination Without Cause**

    a. Severance. In the event the Company terminates your employment without "Cause" , then, subject to the terms and conditions set forth in Exhibit A, and provided that you have been employed by the Company for at least six (6) months, and provided further that you execute and return to the Company a

severance and release of claims agreement provided by and satisfactory to the Company (the "Severance Agreement") and such Severance Agreement becomes binding and enforceable within 60 calendar days after your termination of employment, the Company will, during the "Severance Period" (as defined below), continue to pay to you as severance pay your then current base salary in accordance with the Company's then current payroll practices. As used herein, the "Severance Period" shall commence on the Company's first payroll period after your Severance Agreement becomes binding (the "Effective Date"), and shall continue until the earlier of (x) the last day of the Stated Period (as defined herein), and (y) the date on which you commence employment with or begin providing services to another person, employer, or entity; provided, however, that if the foregoing 60 day period would end in a calendar year subsequent to the year in which your employment ends, payments will not be made before the first payroll period of the subsequent year. The Stated Period means (i) if the termination occurs prior to the first anniversary of the Effective Date, the greater of the number of full months worked from the Effective Date through the date of termination and six (6) months, and (ii) if the termination occurs on the first anniversary of the Effective Date or thereafter, twelve (12) months. You are required to immediately provide the Company with written notice upon your commencement of employment with or provision of services to another person, employer, or entity. Any severance pay hereunder will be subject to all applicable taxes and withholdings. You shall not be entitled to any severance pay if your employment is terminated by the Company for Cause, or if you resign your employment with the Company for any reason.

b. Cause. For purposes of this Section 13, the term "Cause" means: (x) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (y) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence,(ii) breached or threatened to breach the Non-Competition Agreement, (iii) violated Company policies or procedures, and/or (iv) failed to perform your assigned duties to the Company's satisfaction, following notice of such failure by the Company and a period of fifteen (15) days to cure.

14. **Legal Costs.** You have represented to the Company that the Invention, Non-Disclosure and Non-Competition Agreement between Millennium Pharmaceuticals, Inc. ("Millennium") and you, dated August 20, 2007 (the "Millennium Agreement"), contains the only restrictive covenants purporting to bind you, and that you have notified Millennium of the services that you would provide to the Company as contemplated by this letter. You have further represented to the Company that Millennium has informed you that it does not believe such services would breach the Millennium Agreement or cause you to breach any other agreement or obligation to Millennium, and that Millennium does not object to your employment with the Company and has represented to you that it will not take any action against you or the Company in connection with your employment with the Company. Further, you and the Company have agreed that, in performing your services on behalf of the Company, there will be no reason or need for you to disclose or use any information proprietary to

any other person or entity, and the Company has explicitly instructed you not to disclose any such information to the Company or to any other person or entity or to use it in any way. However, as we have also discussed, it is the Company's desire not to have any potential dispute with Millennium that might be harmful to, or distract you or other Company representatives from, the Company's business. Therefore, provided that you have truthfully represented to the Company Millennium's position and statements regarding your employment with the Company, the Company shall indemnify you in an amount not to exceed $100,000 against legal costs that you may incur should Millennium or any or its representatives threaten or bring any action against you for breach of the Millennium Agreement. Nothing herein, however, shall be construed as a promise of employment for any specific term or alter in any way your status as an employee at will.

15. **Entire Agreement**. This letter, together with the Non-Competition Agreement and the Option Agreement , constitute the entire agreement between you and the Company pertaining to their subject matter, and supersede all previous written or oral representations, agreements and understandings between you and the Company related to the subject matter of this letter and those agreements. Accordingly, upon the Effective Date, the Consulting Agreement dated December 6, 2013 between you and the Company shall terminate and be of no further force or effect except as provided therein, and your obligations under the Non-Competition Agreement shall apply to Confidential Information, the Materials and Service-related IP (each as defined in the Consulting Agreement) as if the effective date of this letter and the Non-Competition Agreement were December 6, 2013.

If this letter correctly sets forth the terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me, along with a signed copy of the Non-Competition Agreement. If you do not accept this offer by April __, 2014, the offer will be deemed withdrawn.

Sincerely,

By: /s/ Jodie P. Morrison
Jodie P. Morrison
President and Chief Executive Officer

The foregoing correctly sets forth the terms of my at-will employment with Tokai Pharmaceuticals, Inc. I am not relying on any representations other than those set forth above.

/s/ Karen Ferrante
Karen Ferrante

April 7, 2014
Date

Exhibit A

Payments Subject to Section 409A

1. Subject to this Exhibit A, payments or benefits under Section 12(a) of the offer letter shall begin only following the date of your "separation from service" (determined as set forth below) which occurs on or after the termination of your employment. The following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to you under Section 12(a) of the offer letter, as applicable:

(a) It is intended that each installment of the payments and benefits provided under Section 12(a) of the offer letter shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code of 1986 and the guidance issued thereunder ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the payments and benefits shall be made on the dates and terms set forth in Section 12(a) of the offer letter.

(c) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the payments and benefits due under Section 12(a) of the offer letter that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the Short-Term Deferral Period (as hereinafter defined) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A. For purposes of the offer letter, the "Short-Term Deferral Period" means the period ending on the later of the 15th day of the third month following the end of your tax year in which the separation from service occurs and the 15th day of the third month following the end of the Company's tax year in which the separation from service occurs; and

(ii) Each installment of the payments and benefits due under Section 12(a) of the offer letter that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following your separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms

set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation Section 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when your separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the offer letter shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A.

4. The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of the offer letter (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form S-1 of Tokai Pharmaceuticals, Inc. of our report dated May 2, 2014 relating to the consolidated financial statements of Tokai Pharmaceuticals, Inc., which appears in such Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
August 11, 2014