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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-36620

Tokai Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**20-1000967**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
255 State Street, 6th floor Boston, MA	**02109**
(Address of principal executive offices)	**(Zip Code)**

(617) 225-4305
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2016 there were 22,641,651 shares of Common Stock, $0.001 par value per share, outstanding.

Tokai Pharmaceuticals, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, 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 results of our analysis of the unblinded study data from ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone that we announced our plan to discontinue in July 2016 following the recommendation of the trial's independent data monitoring committee, and our efforts to complete the clinical development of galeterone for patients with metastatic castration resistant prostate cancer, or mCRPC;
- the anticipated expenses associated with a workforce reduction that we effected in July 2016 and other costs associated with the discontinuation of the ARMOR3-SV trial, as well as estimated cost savings from this workforce reduction and trial discontinuation;
- our board of directors' review of strategic alternatives;
- the anticipated timing, cost and conduct of additional clinical trials of, and formulation development and manufacturing activities for, galeterone;
- the development of galeterone for the treatment of prostate cancer or other indications or patient populations, and of any other future product candidates, including compounds under our ARDA program 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 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 Quarterly Report on Form 10-Q, 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. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q 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 to the extent required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Tokai Pharmaceuticals, Inc.

Balance Sheets

(In thousands, except share and per share data)
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 18,630	$ 24,023
Marketable securities	16,088	39,934
Prepaid expenses and other current assets	1,616	3,213
Total current assets	36,334	67,170
Property and equipment, net	117	489
Restricted cash	270	270
Other assets	—	45
Total assets	$ 36,721	$ 67,974
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 886	$ 1,208
Accrued expenses	5,458	4,954
Total current liabilities	6,344	6,162
Long-term liabilities	120	88
Total liabilities	6,464	6,250
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 22,641,651 and 22,597,144 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	23	23
Additional paid-in capital	195,891	193,194
Accumulated other comprehensive income (loss)	3	(55)
Accumulated deficit	(165,660)	(131,438)
Total stockholders' equity	30,257	61,724
Total liabilities and stockholders' equity	$ 36,721	$ 67,974

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	6,162	8,491	23,988	24,905
General and administrative	3,146	3,416	10,375	9,284
Total operating expenses	9,308	11,907	34,363	34,189
Loss from operations	(9,308)	(11,907)	(34,363)	(34,189)
Interest income and other income, net	38	54	141	119
Net loss	$ (9,270)	$ (11,853)	$ (34,222)	$ (34,070)
Net loss per share, basic and diluted	$ (0.41)	$ (0.53)	$ (1.51)	$ (1.52)
Weighted average common shares outstanding, basic and diluted	22,636,977	22,540,876	22,632,287	22,449,484
Comprehensive loss:				
Net loss	$ (9,270)	$ (11,853)	$ (34,222)	$ (34,070)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	(3)	10	58	8
Total other comprehensive income (loss)	(3)	10	58	8
Total comprehensive loss	$ (9,273)	$ (11,843)	$ (34,164)	$ (34,062)

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Statements of Cash Flows

(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (34,222)	$ (34,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,660	2,044
Depreciation expense	154	53
Impairment of property and equipment	235	—
Release of reserve for loan to former advisor	—	(49)
Premium on purchase of marketable securities	(2)	(186)
Amortization of premium on marketable securities	109	34
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,642	(1,507)
Accounts payable	(322)	887
Accrued expenses	504	429
Other assets	—	(45)
Other long-term liabilities	32	51
Net cash used in operating activities	(29,210)	(32,359)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	24,297	—
Purchases of marketable securities	(500)	(39,775)
Purchases of property and equipment	(17)	(349)
Change in restricted cash	—	(70)
Net cash provided by (used in) investing activities	23,780	(40,194)
Cash flows from financing activities:		
Repayment of notes receivable	—	49
Proceeds from exercise of common stock options	37	416
Net cash provided by financing activities	37	465
Net decrease in cash and cash equivalents	(5,393)	(72,088)
Cash and cash equivalents at beginning of period	24,023	105,256
Cash and cash equivalents at end of period	$ 18,630	$ 33,168
Supplemental disclosure of non-cash investing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 98

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the "Company") was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company's lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct third mechanism – androgen receptor degradation. Since its inception, the Company has devoted substantially all of its efforts to research and development, in-licensing technology and raising capital.

In July 2016, the Company announced its plan to discontinue the ARMOR3-SV Phase 3 clinical trial of galeterone following the recommendation made by the trial's independent data monitoring committee ("DMC"). The Company anticipates that all patients enrolled in the ARMOR3-SV clinical trial will discontinue treatment by the end of this year. The Company is analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and its drug discovery program, known as the Androgen Receptor Degradation Agents ("ARDA") program. Based on preliminary data reviewed to date, however, there is a substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive metastatic castration resistant prostate cancer ("mCRPC") in the future. Following the announcement regarding the discontinuation of the ARMOR3-SV trial, the Company reduced its workforce in the third quarter of 2016 by approximately 60% and incurred a charge of $1,200 during the three months ended September 30, 2016 related to the workforce reduction including severance, benefits and related costs of which $500 and $700 were recorded in research and development expenses and general and administrative expenses, respectively. The Company paid $300 of these costs during the three months ended September 30, 2016 and expects to pay $600 in the fourth quarter of 2016 and $300 in the first quarter of 2017. As of September 30, 2016, the Company had a balance of $900 in accrued expenses related to these severance, benefits and related costs.

In addition, in August 2016, the Company determined to discontinue enrollment in its ongoing Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with the planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). While no new patients are being enrolled in the ARMOR 2 trial, the Company is continuing to follow the patients who remain in the ARMOR2 trial.

In September 2016, the Company announced that the board of directors had initiated a review of strategic alternatives that could result in changes to its business strategy and future operations. The objective of this review, which is being conducted in parallel with the review of development options for galeterone and the ARDA program, is to maximize shareholder value.

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 under the ARDA program or otherwise, will require significant additional research and development efforts, including extensive preclinical and clinical testing, formulation development and manufacturing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance capabilities.

There can be no assurance that the Company's research and development activities will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary 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, consultants and contracted service providers.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The Company has incurred losses and negative cash flows from operations since inception. As of September 30, 2016, the Company had an accumulated deficit of $165,660 and had cash and investments of $34,718. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, the Company expects its cash and investments as of September 30, 2016 to be sufficient to fund operations for at least the next twelve months. The Company is currently evaluating potential paths forward for galeterone and its ARDA program and is reviewing strategic alternatives. If the Company

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

determines to pursue an alternate strategy or engage in a strategic transaction, its future business, prospects, financial positon and operating results could be significantly different than those in historical periods or projected by management. If the Company determines to further develop galeterone, proceed with its ARDA program, or both, substantial additional funding will be needed. Because of the significant uncertainty regarding its future plans, the Company is not able to accurately predict the impact of a potential change of the business strategy on future funding requirements. If the Company's cash and investments are not sufficient to fund a revised strategy and the Company is unable to raise capital when needed or on acceptable terms, the Company may be forced to delay, reduce, terminate or eliminate its product development programs and its commercialization efforts.

The balance sheet at December 31, 2015 was derived from audited financial statements, but does not include all disclosures required by U.S. generally accepted accounting principles ("GAAP"). The accompanying unaudited financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 10, 2016. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2016 and results of operations for the three and nine months ended September 30, 2016 and 2015 and cash flows for the nine months ended September 30, 2016 and 2015 have been made. The results of operations for the three and nine months ended September 30, 2016 and 2015 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of 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.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest income and other income, net based on the specific identification method. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

At September 30, 2016, marketable securities by security type consisted of:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificates of Deposit (due within one year)	$ 5,579	$ —	$ —	$ 5,579
United States Treasury Notes (due within one year)	10,506	3	—	10,509
Total	$ 16,085	$ 3	$ —	$ 16,088

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

At December 31, 2015 marketable securities by security type consisted of:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificates of Deposit (due within one year)	$ 13,709	$ —	$ —	$ 13,709
Certificates of Deposit (due after one year through two years)	1,178	—	—	1,178
United States Treasury Notes (due within one year)	22,596	—	(47)	22,549
United States Treasury Notes (due after one year through two years)	2,506	—	(8)	2,498
Total	$ 39,989	$ —	$ (55)	$ 39,934

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.
- 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 following tables present the Company's fair value hierarchy for its cash equivalents and marketable securities, which are measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015:

	Fair Value Measurements at September 30, 2016 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	$ —	$ 13,113	$ —	$ 13,113
Marketable securities:				
Certificates of Deposit	—	5,579	—	5,579
United States Treasury Notes	—	10,509	—	10,509
Total	$ —	$ 29,201	$ —	$ 29,201

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

	Fair Value Measurements at December 31, 2015 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	$ —	$ 18,361	$ —	$ 18,361
Marketable securities:				
Certificates of Deposit	—	14,887	—	14,887
United States Treasury Notes	—	25,047	—	25,047
Total	$ —	$ 58,295	$ —	$ 58,295

The carrying values of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Because the inclusion of common share equivalents in the calculation would be anti-dilutive for all periods presented, diluted net loss per share is the same as basic net loss per share.

The following common share equivalents outstanding as of September 30, 2016 and 2015 were excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2016 and 2015 because they had an anti-dilutive impact:

	September 30, 2016	December 31, 2015
Stock options to purchase common stock	2,117,531	2,861,011
Unvested restricted common stock units	—	40,953
	2,117,531	2,901,964

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-15, *Presentation of Financial Statements — Going Concern* (*Subtopic 205-40).* The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. This standard will be effective for fiscal years ending after December 15, 2016. Early adoption is permitted. This guidance relates to footnote disclosure only and its adoption will not impact the Company's financial position, results of operations or liquidity.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"), which applies to all leases and will require lessees to put most leases on the balance sheet, but recognize expense in a manner similar to the current standard. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating this guidance.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation* ("ASU 2016-09"). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 will be effective for the first interim period within fiscal years beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on the Company's financial position, results of operations and liquidity.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

3. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2016	December 31, 2015
Accrued research and development expenses	$ 3,565	$ 3,188
Accrued payroll and related expenses	1,045	900
Accrued professional fees	734	699
Accrued other	114	167
	$ 5,458	$ 4,954

4. Income Taxes

The Company did not provide for any income taxes in the nine months ended September 30, 2016 or 2015. The Company had gross deferred tax assets of $51,028 at December 31, 2015, which increased by approximately $13,000 at September 30, 2016. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at each of September 30, 2016 and December 31, 2015, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2016 or December 31, 2015. As of September 30, 2016 and December 31, 2015, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since December 31, 2012 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

5. Stock-Based Compensation

The Company grants stock-based awards under its 2014 Stock Incentive Plan and is authorized to issue, but has not issued as of September 30, 2016, common stock under its 2014 Employee Stock Purchase Plan. The Company also has outstanding stock options under its 2007 Stock Incentive Plan, but is no longer granting awards under this plan. As of September 30, 2016, 2,799,965 shares of common stock were available for issuance under the 2014 Stock Incentive Plan. As of September 30, 2016, 225,000 shares of common stock were available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded stock-based compensation expense related to stock options and restricted common stock units in the following expense categories of its statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 93	$ 156	$ 498	$ 464
General and administrative	553	648	2,162	1,580
	$ 646	$ 804	$ 2,660	$ 2,044

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

6. Commitments and Contingencies

Leases

In February 2015, the Company entered into a sublease with a Massachusetts limited liability company (the "Sublandlord") for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease between the Sublandlord and the prime landlord. The term of the sublease commenced on April 1, 2015 and expires on December 31, 2016. If the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will terminate immediately and the Company will have no recourse against the Sublandlord for such termination. In June 2015, the Company entered into a lease (the "New Lease") for the existing space with the prime landlord (the "Landlord"), which effectively extends the term until July 31, 2018. Payment escalations specified in the lease agreements are accrued such that rent expense per square foot is recognized on a straight-line basis over the terms of occupancy.

Prior to April 2015, the Company leased office space in Cambridge, Massachusetts, and obtained certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. The Company recorded exit costs of $133 in connection with the termination of the Cambridge lease, which are included in rent expense during the nine months ended September 30, 2015.

During each of the three months ended September 30, 2016 and 2015, the Company recognized $174 of rental expense related to office space. During the nine months ended September 30, 2016 and 2015, the Company recognized $521 and $661, respectively, of rental expense related to office space.

As of September 30, 2016, future minimum lease payments under noncancelable office leases were as follows:

Remainder of 2016	$ 140
2017	839
2018	489
	$1,468

Restricted Cash and Letters of Credit

The Company held a money market account of $200 to collateralize a credit card account with its bank, which was classified as restricted cash on the balance sheet as of September 30, 2016 and December 31, 2015. The Company is required to maintain a letter of credit totaling $70 for the benefit of the Landlord of the New Lease. The Landlord can draw against the letter of credit in the event of default by the Company. The Company held $70 in a money market account to collateralize the letter of credit, which amount was also included in restricted cash on the balance sheet as of September 30, 2016 and December 31, 2015.

Intellectual Property Licenses

The Company has 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 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 its option and acquired exclusive rights to licensed improvements under four amendments to the license agreement. 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 milestone payments of an additional $50 for the filing of each additional investigational new drug application filed for a licensed product, aggregate milestone payments of up to $150 associated with the development of a licensed product for a particular non-prostate disease indication, and a $100 milestone payment upon the approval by the U.S. Food and Drug Administration ("FDA") of each new drug application ("NDA") for a licensed product. There were no milestones achieved during the nine months ended September 30, 2016 or 2015.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

The Company must also pay UMB a low-single digit percentage royalty 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 September 30, 2016 the Company has not yet developed a commercial product using the licensed technologies, nor has it entered into any sublicense agreements for the technologies.

In January 2015, the Company entered into an exclusive license agreement with The Johns Hopkins University ("Johns Hopkins") pursuant to which Johns Hopkins granted the Company an exclusive, worldwide license under certain patents and patent applications, and a non-exclusive license under certain know-how, in each case with the right to sublicense, to make, have made, use, sell, offer to sell and import certain assays to identify androgen receptor variants for use as a companion diagnostic with galeterone. In addition, Johns Hopkins granted the Company an option to negotiate an exclusive license to Johns Hopkins's rights in certain improvements to the licensed intellectual property.

In consideration for the rights granted to the Company under the license agreement, the Company made an upfront payment to Johns Hopkins of $75 following the execution of the license agreement, which was recognized as research and development expense during the nine months ended September 30, 2015. The Company is obligated to pay Johns Hopkins an annual minimum royalty of up to $30 and to make milestone payments to Johns Hopkins upon the achievement of specified technical and commercial milestones. If all such milestones were achieved, the total milestone payments owed to Johns Hopkins would equal $700 in the aggregate. During the year ended December 31, 2015, the Company expensed $50 upon the achievement of two of these milestones. The Company has not achieved any other milestones and, therefore, no additional liabilities for such milestone payments have been recorded in the Company's financial statements.

The Company must also pay Johns Hopkins single digit percentage royalties on aggregate worldwide net sales of licensed products (but not galeterone), 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. These royalty obligations are subject to specified reductions in the event that additional licenses from third parties are required. The Company must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse Johns Hopkins for patent costs. As of September 30, 2016, the Company has not yet developed a commercial product using the licensed technologies.

Companion Diagnostic Development Agreement

In March 2015, the Company entered into a project work plan with Qiagen Manchester Limited ("Qiagen") under a Master Collaboration Agreement, dated January 12, 2015, between the Company and Qiagen (together with the project work plan, the "CDx Agreement"). Pursuant to the CDx Agreement, Qiagen has agreed to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. Qiagen has also developed under the CDx Agreement a clinical trial assay that was used in the Company's pivotal Phase 3 clinical trial of galeterone in order to identify mCRPC patients whose tumor cells express AR-V7, and that may be used in future clinical trials of galeterone.

Subject to the terms of the CDx Agreement, the Company paid Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test, which was recognized as research and development expense during the nine months ended September 30, 2015. The Company also paid Qiagen fees for the development of the AR-V7 clinical trial assay. On October 28, 2016, the Company and Qiagen entered into an agreement terminating the project work plan effective September 27, 2016. The Company is responsible for making a final payment of $1,099 to Qiagen at which time there will be no future financial obligations by the Company or Qiagen under the project work plan. The Company recorded research and development expense of $1,099 in the three and nine months ended September 30, 2016 related to this final payment to Qiagen, which amount is included in accrued expenses at September 30, 2016.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

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. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers, which provide, among other things, that the Company will indemnify such directors and executive officers to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer. 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 material costs as a result of the indemnification agreements described above. In addition, the Company maintains directors and officers insurance coverage. The Company is unable to predict if any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows and has not accrued any material liabilities related to such possible obligations in its financial statements as of September 30, 2016.

Legal Proceedings

On August 1, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against the Company, Jodie P. Morrison, and Lee H. Kalowski, entitled *Doshi v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:16-cv-06106 ("*Doshi* Action"). The plaintiff seeks to represent a class of purchasers of Company securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about the Company's clinical trials for its drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against the Company, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company's initial public offering ("IPO"), entitled *Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al.*, No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), the Company's registration statement for its IPO made false and misleading statements and omissions about the Company's clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of Company common stock in and/or traceable to the Company's IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of *forum non conveniens*, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction.

On September 29, 2016, two purported stockholders of the Company filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against the Company, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company's IPO, entitled *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:16-cv-11963 ("*Garbowski* Action"). The lawsuit alleges that the defendants and the Company's registration statement for its IPO made false and misleading statements and omissions about the Company's clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of Company common stock in or traceable to the Company's IPO as well as a class of purchasers of Company common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. The plaintiff in the *Doshi* Action has filed a motion to consolidate the *Doshi* and *Garbowski* Actions for all purposes.

The Company believes it has valid defenses, and intends to engage in a vigorous defense of the litigation. However, the Company is unable to predict the ultimate outcome of these actions, and, therefore cannot estimate possible losses or ranges of losses, if any, or the materiality thereof. An unexpected unfavorable resolution of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

7. 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. Since January 1, 2016, the Company has made matching contributions for the plan year ending December 31, 2016 at a rate of 100% of each employee's contribution up to a maximum matching contribution of 3% of the employee's eligible plan compensation and at a rate of 50% of each employee's contribution in excess of 3% up to a maximum of 5% of the employee's eligible plan compensation.

For the nine months ended September 30, 2016, the Company made matching contributions of $119 for the plan year ending December 31, 2016.

8. Related Party Transaction

In September 21, 2016, the Company entered into a consulting agreement with Apple Tree Life Sciences, Inc. ("Apple Tree") under which Apple Tree agreed to provide consulting, advisory and related services to and for the Company from time to time. There is no fee for these services except for reimbursement of out of pocket expenses. Affiliates of Apple Tree beneficially own approximately 35% of the Company, and Dr. Seth Harrison, a member of the Company's board of directors, is a principal of Apple Tree.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2015 included in our Annual Report on Form 10-K that was filed with the SEC on March 10, 2016. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. Our lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct third mechanism – androgen receptor degradation.

In July 2016, we announced our plan to discontinue ARMOR3-SV, our pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve metastatic castration resistant prostate cancer, or mCRPC, patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee, or the DMC, in July 2016. Based on a review of all available safety and efficacy data, the DMC determined that the ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival for galeterone versus enzalutamide in men with AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. We anticipate that all patients enrolled in the ARMOR3-SV clinical trial will discontinue treatment by the end of this year. We are analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our drug discovery program, known as ARDA (Androgen Receptor Degradation Agents). Based on preliminary data reviewed to date, however, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC in the future.

Following the announcement regarding the discontinuation of the ARMOR3-SV trial, in July 2016 we announced that our board of directors approved a plan to reduce the size of our workforce by approximately 60% to a total of 10 full-time equivalent employees. The workforce reduction, which was completed in September 2016, was designed to reduce our operating expenses while we conducted our review of development options for galeterone and our ARDA program. We incurred $1.2 million of expenses during the three months ended September 30, 2016 related to the workforce reduction including severance, benefits and related costs of which $0.5 million and $0.7 million were recorded in research and development expenses and general and administrative expenses, respectively. We paid $0.3 million of these costs during the three months ended September 30, 2016 and expect to pay $0.6 million in the fourth quarter of 2016, and $0.3 million in the first quarter of 2017.

In addition, in August 2016, we determined to discontinue enrollment in our ongoing Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). While no new patients are being enrolled in the ARMOR 2 trial, we continue to follow the 11 patients who remain in the ARMOR2 trial as of October 31, 2016. In addition to our galeterone program, we also have our ARDA program, under which we are identifying and developing novel compounds designed to have potent androgen receptor degradation activity. Our most advanced series of compounds from this program are currently in preclinical development. We are evaluating the ARDA program in light of the discontinuation of the ARMOR3-SV clinical trial.

In September 2016, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, which is being conducted in parallel with our review of development options for galeterone and our ARDA program, our board of directors is reviewing alternatives with the goal of maximizing stockholder value. Potential strategic alternatives that we may explore and evaluate during this process include a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets.

We cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction, nor any assurances that we will determine to pursue a potential sale, strategic partnership, business combination or other such arrangement. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial positon and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements.

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. To date, we have financed our operations primarily through our initial public offering of our common stock, and prior to our initial public offering, through private placements of our redeemable convertible preferred stock and convertible promissory notes. In September 2014, we completed the initial public offering of our common stock through the issuance and sale of 6,480,000 shares of our common stock at a price to the public of $15.00 per share, resulting in net proceeds of $87.1 million after deducting underwriting discounts and commissions and offering expenses. In October 2014, we issued and sold an additional 540,000 shares of our common stock as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock at the public offering price of $15.00 per share, and received additional net proceeds of $7.5 million after deducting underwriting discounts and commissions.

We have never generated any revenue and have incurred net losses in each year since our inception. Our net loss was $34.2 million for the nine months ended September 30, 2016 and $45.1 million for the year ended December 31, 2015. As of September 30, 2016, we had an accumulated deficit of $165.7 million. This deficit has 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. Following our review of development options, if we determine to further develop galeterone, proceed with our ARDA program, or both, we anticipate that we will continue to incur significant expenses if and as we:

- conduct clinical trials with galeterone or any other product candidates in the future;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under our ARDA program;
- enter into agreements with third parties to manufacture galeterone or other product candidates;
- establish a sales, marketing and distribution infrastructure to support the commercialization of our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; and
- operate as a public company.

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 September 30, 2016, we had cash and investments of $34.7 million. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, we expect our cash and investments as of September 30, 2016 to be sufficient to fund operations for at least the next twelve months. We are currently evaluating potential paths forward for galeterone and our ARDA program and are reviewing strategic alternatives. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements. If our cash and investments are not sufficient to fund our approved strategy and 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.

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 consist 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, include the following:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- third-party contract costs relating to development of a companion diagnostic test for use with galeterone, including the AR-V7 clinical trial used to identify eligible patients for ARMOR3-SV;
- 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;
- payments made under intellectual property license agreements with third parties; and
- allocated facility-related costs.

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 license agreements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses in the tables below. See “Results of Operations.”

Research and development activities have been 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. To date, we have focused substantially all of our research and development efforts on the development of galeterone. We incurred total research and development expenses of $24.0 million for the nine months ended September 30, 2016 and $24.9 million for the nine months ended September 30, 2015. We anticipate that overall research and development expenses will decrease in the near future compared to prior periods due to the discontinuation of our ARMOR3-SV clinical trial and discontinuation of enrollment in our ARMOR2 expansion trial pending our review of potential paths forward for galeterone and our ARDA program. However, if we determine to further develop galeterone, proceed with our ARDA program, or both, following our review of development options, we anticipate that we would continue to incur significant research and development expenses as we conduct clinical trials and NDA-enabling activities for galeterone or future product candidates.

In July 2016 we announced our decision to discontinue ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone, following the recommendation of the trial’s independent data monitoring committee and ceased enrollment in this trial. We are analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. We cannot determine with certainty the duration and completion costs of any future clinical trials of galeterone, if any, or any future product candidates we develop 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 trials 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 galeterone or any future product candidates could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration, or the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, if we experience significant delays in patient enrollment in any of our clinical trials, if we are required to enroll more patients than we currently anticipate in order to complete any of our clinical trials, or if we are required to make any changes to the formulation of, or the manufacturing process for, a product candidate, we could be required to expend significant additional financial resources and time on the completion of development and receipt of regulatory approval.

General and Administrative Expenses

General and administrative expenses consist 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 protection of our intellectual property, pre-commercialization costs, insurance costs, travel expenses and allocated facility-related costs.

Interest Income and Other Income, net

Interest income and other income, net, consists of interest income and miscellaneous income and expense unrelated to our core operations. Interest income consists of interest earned on our cash and investments. Our interest income has not been significant due to low interest earned on invested balances.

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 2015, we had federal and state net operating loss carryforwards of $27.9 million and $24.2 million respectively. Our federal and state net operating loss carryforwards begin to expire in 2024 and 2030, respectively. We also had federal and state research and development tax credit carryforwards of $1.0 million and $0.4 million, respectively, as of December 31, 2015, 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 $96.1 million that we have capitalized for income tax purposes as of December 31, 2015.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2015, the following involve the most judgment and complexity:

- accrued research and development costs; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

There have been no material changes in these policies since December 31, 2015.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	6,162	8,491	(2,329)
General and administrative	3,146	3,416	(270)
Total operating expenses	9,308	11,907	(2,599)
Loss from operations	(9,308)	(11,907)	2,599
Interest income and other income, net	38	54	(16)
Net loss	$(9,270)	$(11,853)	$ 2,583

Research and Development Expenses

	Three Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Galeterone for prostate cancer	$ 4,593	$ 7,161	$(2,568)
Other early-stage development programs and additional indications for galeterone	269	263	6
Unallocated research and development expenses	1,300	1,067	233
Total research and development expenses	$ 6,162	$ 8,491	$(2,329)

The decrease in research and development expenses associated with our galeterone for prostate cancer program for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was due primarily to a decrease in the costs of clinical trials of $2.2 million and a decrease in manufacturing costs of $0.4 million, partially offset by increased costs associated with our AR-V7 clinical trial assay and companion diagnostic test of $0.3 million. The decrease in clinical trials was primarily due to the discontinuation of the ARMOR3-SV clinical trial announced in July 2016 following the recommendation of the trial's independent data monitoring committee. The decrease in manufacturing costs was primarily due to higher costs in the prior year for process optimization and validation studies required to support the submission of a new drug application, or NDA for galeterone. The increased costs associated with our AR-V7 clinical trial assay and companion diagnostic test were primarily due to costs related to the wind down of the contract with the supplier as a result of the discontinuation of the ARMOR3-SV trial. The increase in unallocated research and development expenses was primarily due to an impairment charge of $0.2 million related to assets that had been used in the discontinued ARMOR3-SV trial and increased personnel related costs in our research and development function primarily related to severance costs as a result of the workforce reduction that occurred in the third quarter of 2016, partially offset by cost savings related to the workforce reduction.

General and Administrative Expenses

	Three Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$1,490	$1,551	$ (61)
Professional and consultant fees	1,111	1,358	(247)
Facility related and other	545	507	38
Total general and administrative expenses	$3,146	$3,416	$ (270)

The decrease in personnel related costs for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to cost savings as a result of the workforce reduction that occurred in the third quarter of 2016, partially offset by the severance costs related to the workforce reduction. The decrease in professional and consultant fees for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was due to a decrease in patent and pre-commercialization costs as a result of the trial discontinuation, partially offset by an increase in legal expenses primarily related to the outstanding litigation against us and certain of our directors and officers filed in the third quarter of 2016.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	23,988	24,905	(917)
General and administrative	10,375	9,284	1,091
Total operating expenses	34,363	34,189	174
Loss from operations	(34,363)	(34,189)	(174)
Interest income and other income, net	141	119	22
Net loss	$(34,222)	$(34,070)	$ (152)

Research and Development Expenses

	Nine Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Galeterone for prostate cancer	$18,669	$21,181	$(2,512)
Other early-stage development programs and additional indications for galeterone	831	460	371
Unallocated research and development expenses	4,488	3,264	1,224
Total research and development expenses	$23,988	$24,905	$ (917)

The decrease in research and development expenses associated with our galeterone for prostate cancer program for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was due primarily to decreased costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test of $1.4 million and decreased manufacturing costs of $0.9 million. Costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test for the nine months ended September 30, 2015 included a one-time fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the assay and related companion diagnostic test. The decrease in manufacturing costs primarily reflected a large purchase of raw materials during the nine months ended September 30, 2015 for use in manufacturing process optimization and validation studies required to support the submission of an NDA for galeterone. The increase in unallocated research and development expenses was primarily due to increased personnel related costs in our research and development function primarily related to severance costs as a result of the workforce reduction that occurred in the third quarter of 2016 as well as an impairment charge of $0.2 million related to assets that had been used in the discontinued ARMOR3-SV trial.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2016	2015	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 5,421	$4,095	$1,326
Professional and consultant fees	3,337	3,603	(266)
Facility related and other	1,617	1,586	31
Total general and administrative expenses	$10,375	$9,284	$1,091

The increase in personnel related costs for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to an increase in headcount in the general and administrative function associated with operating as a public company, including an increase in stock-based compensation expense of $0.6 million as well as severance costs related to the workforce reduction that occurred in the third quarter of 2016. This was partially offset by cost savings as a result of this workforce reduction.

Liquidity and Capital Resources

Since our inception in March 2004, 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 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.

To date, we have funded our operations primarily through our initial public offering of our common stock and, prior to our initial public offering, private placements of our redeemable convertible preferred stock and convertible promissory notes. In September 2014, we completed the initial public offering of our common stock through the issuance and sale of 6,480,000 shares of our common stock at a price to the public of $15.00 per share, resulting in net proceeds of $87.1 million after deducting underwriting discounts and commissions and offering expenses. In October 2014, we issued and sold an additional 540,000 shares of our common stock as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock at the public offering price of $15.00 per share and received additional net proceeds of $7.5 million after deducting underwriting discounts and commissions.

Cash Flows

As of September 30, 2016, our principal sources of liquidity were cash and investments of $34.7 million.

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	$(29,210)	$(32,359)
Cash provided by (used in) investing activities	23,780	(40,194)
Cash provided by financing activities	37	465
Net decrease in cash and cash equivalents	$ (5,393)	$(72,088)

Operating activities. During the nine months ended September 30, 2016, cash used in operating activities consisted of our net loss of $34.2 million, partially offset by net non-cash charges of $3.2 million and by net cash provided by changes in our operating assets and liabilities of $1.9 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash provided by changes in our operating assets and liabilities consisted primarily of a decrease in prepaid expenses and other current assets of $1.7 million during the nine months ended September 30, 2016.

During the nine months ended September 30, 2015, cash used in operating activities consisted of our net loss of $34.1 million, partially offset by net non-cash charges of $1.9 million. Our net non-cash charges during the period consisted almost entirely of stock-based compensation expense. Cash used in changes in our operating assets and liabilities consisted primarily of an increase in prepaid expenses and other current assets of $1.5 million, partially offset by a net increase in accounts payable and accrued expenses of $1.3 million.

Our prepaid expenses and other current assets and accounts payable and accrued expense balances have historically been affected by the volume of business and the timing of vendor invoicing and payments.

Investing activities. During the nine months ended September 30, 2016, proceeds from maturities of marketable securities was $24.3 million and purchases of marketable securities were $0.5 million. We used a small amount of cash during the nine months ended September 30, 2016 related to purchases of property and equipment.

During the nine months ended September 30, 2015, net cash used in investing activities was primarily attributable to purchases of marketable securities of $39.8 million and purchases of property and equipment of $0.3 million primarily related to the purchase of lab equipment.

Financing activities. During the nine months ended September 30, 2016, net cash provided by financing activities was due to proceeds from the exercise of stock options. During the nine months ended September 30, 2015, net cash provided by financing activities was attributable to proceeds from the exercise of stock options and the repayment of notes receivable.

Capital Requirements

Galeterone is still in clinical development. Following our review of development options, if we determine to further develop galeterone, proceed with our ARDA program, or both, we anticipate that we will continue to incur significant expenses if and as we:

- conduct clinical trials of galeterone or any other product candidates in the future;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under our ARDA program;
- enter into agreements with third parties to manufacture galeterone or other product candidates;
- establish a sales, marketing and distribution infrastructure to support the commercialization of our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; and
- operate as a public company.

As of September 30, 2016, we had cash and investments of $34.7 million. In light of the discontinuation of the ARMOR3-SV trial and reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, we expect our cash and investments as of September 30, 2016 to be sufficient to fund operations for at least the next twelve months. We are currently evaluating potential paths forward for galeterone and our ARDA program and are reviewing strategic alternatives. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements. If our cash and investments are not sufficient to fund our approved strategy and 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 outcome of our board of directors' review of our strategic alternatives;
- our determination regarding potential paths forward for galeterone and our ARDA program;
- our analysis of the available unblinded data from ARMOR3-SV;
- the scope, progress and results of any additional clinical trials of galeterone that we decide to conduct;
- the timing and outcome of regulatory review of galeterone and of any other future product candidates;
- 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;
- 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.

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 and licensing arrangements. To this end, in October 2015, we filed and the Securities and Exchange Commission, or the SEC, declared effective a shelf registration statement registering an aggregate of $150 million in various equity and debt securities. We have not issued or sold any securities under this registration statement. 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 the rights of our common stockholders. Debt financing, if available, may involve agreements that require liens to be placed on our property and 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 our common stockholders' 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, research programs or current or future product candidates or to 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.

Contractual Obligations and Commitments

On October 28, 2016, we agreed with Qiagen to terminate our project work plan. Upon making a final payment to Qiagen, we will have no further financial obligations to Qiagen. For further details see *Commitments and Contingencies*, of the Notes to the Financial Statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 SEC rules.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in Note 2 to the financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Fluctuation Risk

Our cash and investments as of September 30, 2016 consisted of cash, money market accounts, certificates of deposit and government bonds. 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 interest rates. 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.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On August 1, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against us, Jodie P. Morrison, and Lee H. Kalowski, entitled *Doshi v. Tokai Pharmaceuticals, Inc., et al*., No. 1:16-cv-06106 ("*Doshi* Action"). The plaintiff seeks to represent a class of purchasers of our securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about our clinical trials for our drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against us, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our initial public offering ("IPO"), entitled *Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al*., No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of our common stock in and/or traceable to our IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of *forum non conveniens*, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction.

On September 29, 2016, two purported stockholders filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our IPO, entitled *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al*., No. 1:16-cv-11963 ("*Garbowski* Action"). The lawsuit alleges that the defendants and our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of our common stock in or traceable to our IPO as well as a class of purchasers of our common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. The plaintiff in the *Doshi* Action has filed a motion to consolidate the *Doshi* and *Garbowski* Actions for all purposes.

We believe we have valid defenses, and intend to engage in a vigorous defense of the litigation. However, we are unable to predict the ultimate outcome of these actions, and, therefore cannot estimate possible losses or ranges of losses, if any, or the materiality thereof. An unexpected unfavorable resolution of these matters in any reporting period may have a material adverse effect on our results of operations and cash flows for that period.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this quarterly report on Form 10-Q. 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.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to continue to incur losses and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $45.1 million for the year ended December 31, 2015, $23.3 million for the year ended December 31, 2014 and $15.7 million for the year ended December 31, 2013. As of September 30, 2016, we had an accumulated deficit of $165.7 million. To date, we have financed our operations primarily through our initial public offering of our common stock, and prior to our initial public offering, through private placements of our redeemable convertible preferred stock and convertible promissory notes. 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 have devoted a significant portion of our financial resources to the development of galeterone. However, in July 2016, we announced our plan to discontinue the ARMOR3-SV clinical trial, our pivotal Phase 3 study comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve metastatic castration-resistant prostate cancer, or mCRPC, patients whose prostate tumors express the AR-V7 splice variant, following the recommendation of the trial's independent Data Monitoring Committee, or DMC, and ceased enrollment in this trial. In addition, in August 2016, we determined to discontinue enrollment in our ongoing Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). We are analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. As a result of this evaluation, we may determine to proceed with the clinical development of galeterone and our ARDA program, terminate the galeterone clinical development program and focus on our ARDA program or proceed in other strategic directions. Our determination as to our next steps will necessarily impact the amount of expenses we incur and the size of our operating losses for the foreseeable future.

In September 2016, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, which is being conducted in parallel with our review of development options for galeterone and our drug discovery program, known as ARDA (Androgen Receptor Degradation Agents), our board of directors is reviewing alternatives with the goal of maximizing stockholder value. Potential strategic alternatives that we may explore and evaluate during the ongoing review process include, among others, a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of corporate assets of the company.

If we determine to further develop galeterone, proceed with our ARDA program, or both, we anticipate that we will continue to incur significant expenses if and as we:

- conduct clinical trials with galeterone or any other product candidates in the future;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under our ARDA program;
- enter into agreements with third parties to manufacture galeterone or other product candidates;
- establish a sales, marketing and distribution infrastructure to support the commercialization of our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; and
- operate as a public company.

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 and any of our future product candidates, obtaining marketing and regulatory approval for these product candidates, 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 our stockholders to lose all or part of their investment.

We will need substantial additional funding to continue our development of, and to commercialize, galeterone or any future product candidate, which funding 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.

As of September 30, 2016, we had cash and investments of $34.7 million. We have devoted a significant portion of our cash resources to the development of galeterone and our ARMOR3-SV trial. However, in July 2016, we announced our plan to discontinue the ARMOR3-SV clinical trial. We are currently evaluating potential paths forward for galeterone and our ARDA program and are reviewing strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, our board of directors is reviewing alternatives with the goal of maximizing stockholder value. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial positon and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict our future funding requirements.

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

- the outcome of our board of director's review of our strategic alternatives;
- our determination regarding potential paths forward for galeterone and our ARDA program;
- our analysis of the available unblinded data from ARMOR3-SV clinical trial;
- the scope, progress and results of any additional clinical trials of galeterone that we decide to conduct;
- the timing and outcome of regulatory review of galeterone and of any other future product candidates;
- 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;
- 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, and collaborations, strategic alliances and licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that require liens to be placed on our property and 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 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.

We are conducting a review of strategic alternatives for the company, including evaluating potential paths forward for galeterone and our ARDA program that could significantly impact our future operations and financial position.

In July 2016, we announced our plan to discontinue the ARMOR3-SV clinical trial. We are analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. In September 2016, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, which is being conducted in parallel with our review of development options for galeterone and our ARDA program, our board of directors is reviewing alternatives with the goal of maximizing stockholder value. Potential strategic alternatives that we may explore and evaluate during the ongoing review process include, among others, a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of corporate assets of the company. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial positon and operating results could be significantly different than those in historical periods or projected by our management. Pending any decision to change strategic direction, we have limited our research and development activities to manage our cash position. We cannot provide any commitment as to the timing of our determination or the strategy we may adopt. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our business strategy and future funding requirements.

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

We have depended heavily on the success of our lead product candidate, galeterone, which was in clinical development for the treatment of AR-V7 positive mCRPC patients. Any failure to successfully develop galeterone 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. In July 2016, we announced our plan to discontinue the ARMOR3-SV clinical trial following the recommendation made by the DMC. Based on a review of all safety and efficacy data, the DMC determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival, or rPFS, for galeterone versus Xtandi in AR-V7 positive mCRPC. We are analyzing the totality of the unblinded study data in detail to evaluate potential paths forward for galeterone and our ARDA program. Based on preliminary data reviewed to date, however, there is a substantial likelihood that we will determine not to pursue the development of galeterone in AR-V7 positive mCRPC in the future. As part of this analysis, we also closed enrollment of our ARMOR2 expansion trial in mCRPC patients with acquired resistance to Xtandi, and announced our intention not to proceed with our planned study in patients who rapidly progress on either Xtandi or Zytiga.

If we determine to proceed with the development of galeterone, 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 mCRPC patients or for other indications or patient populations. In light of our plan to discontinue ARMOR3-SV, there is a significant risk that we will be unable to successfully develop galeterone.

The success of galeterone or other future product candidates, under our ARDA program or otherwise, 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;
- 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 under our ARDA program, 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, under our ARDA program or otherwise, 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. For instance, in July 2016, we announced that we plan to discontinue our ARMOR3-SV clinical trial, following the recommendation made by the DMC. Based on a review of all safety and efficacy data, the DMC determined that our ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an improvement in rPFS for galeterone versus Xtandi in AR-V7 positive mCRPC.

We have also closed enrollment in our ARMOR2 expansion trial in mCRPC patients with acquired resistance to enzalutamide and announced our intention not to proceed with our planned study in patients who rapidly progress on either Xtandi or Zytiga. We are currently evaluating potential paths forward for galeterone and our ARDA program. Based on preliminary data reviewed to date, however, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC in the future. If we are unable to successfully complete clinical trials or other testing of galeterone or our future product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety or efficacy 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, under our ARDA program or otherwise, 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, under our ARDA program or otherwise. For instance, in July 2016, we announced our plan to discontinue our ARMOR3-SV clinical trial following the recommendation of the DMC. 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 the following:

- 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;
- 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 of our planned clinical trials will begin as planned, or whether our ongoing or planned clinical trials will need to be restructured or will be completed on schedule, or completed 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.

Galeterone has been administered to several hundred prostate cancer patients and healthy volunteers in clinical trials. Despite this experience, we have yet to fully explore the safety and efficacy of galeterone. In our clinical trials prior to ARMOR3-SV, galeterone had been well tolerated and had 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. In July 2016, we announced our plan to discontinue our ARMOR3-SV trial, following the recommendation by the DMC. Based on a review of all available safety and efficacy data, the DMC determined that our ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an

improvement in rPFS for galeterone versus Xtandi in AR-V7 positive mCRPC. We are analyzing the totality of the available unblinded data from our ARMOR3-SV trial in detail as we evaluate potential paths forward for galeterone and our ARDA program. Based on preliminary data reviewed to date, however, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC in the future.

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 from our analysis of the available data from ARMOR3-SV or otherwise 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.

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 complete any clinical trials we may conduct in the future 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. In particular, if we determine to proceed with the development of galeterone after analyzing the available unblinded data from ARMOR3-SV, our recent set back with ARMOR3-SV will likely negatively impact our ability to enroll patients in ongoing and future trials of galeterone.

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.

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.

As of September 30, 2016, nine of the 126 patients enrolled in ARMOR2 experienced a serious adverse event that was assessed by the investigator as related or possibly related to the administration of galeterone. No single treatment-related serious adverse event occurred in more than one patient. To date, no adverse events have resulted in interruptions or delays of our clinical trials. In addition, in making its recommendation with respect to ARMOR3-SV, the DMC did not cite any safety concerns with galeterone in the trial.

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 mCRPC patients or for 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 or any other product candidate 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 the product candidate'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. Our product candidates 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 any of 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 product 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 galeterone or our future product candidates.

We have obtained fast track designation from the FDA for galeterone for the treatment of mCRPC. 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 mCRPC. 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 or any future product candidates, we will not be able to expand the indications for which such product 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 the product.

We focused our development of galeterone on the treatment of AR-V7 positive mCRPC patients and planned to seek marketing and regulatory approvals for galeterone for this patient population. Based on our review of preliminary data from the ARMOR3-SV trial, we believe there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC in the future. We are also evaluating our plan to develop galeterone for the treatment of other indications and patient populations in prostate cancer in light of the discontinuation of the ARMOR3-SV study. In order to market and sell galeterone in the United States for any additional indications or any future products or 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 or any future products, the size of the commercial market for the product 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 or any future product candidate 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 or any future product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If such product 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;
- our understanding of the market and development of an effective commercial strategy;
- the strength of sales, marketing, medical affairs 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;
- 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 limited 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. 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.

If galeterone is approved for the treatment of mCRPC, it may compete with other commonly-used oral hormonal treatments being marketed, such as Zytiga and Xtandi, chemotherapeutic agents, or with drug candidates currently in development. Galeterone could compete in the future with products, marketed by several of the world's largest and most experienced pharmaceutical companies. These companies have substantially more financial resources than we do and greater flexibility to engage in aggressive price competition to gain revenues and market share. Approved second-generation hormonal treatments in the United States for mCRPC include Zytiga, marketed by Janssen Biotech, Inc. and Xtandi, marketed by Astellas Pharma US, Inc. and Medivation, Inc. Approved non-hormonal agents for mCRPC include Taxotere® (docetaxel) and Jevtana® (cabazitaxel), marketed by sanofi-aventis U.S. LLC; Provenge® (sipuleucel-T), marketed by Valeant Pharmaceuticals International Inc.; 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. These include hormonal treatments such as Johnson & Johnson's ARN-509, Orion Corporation's ODM-201, Innocrin Pharmaceuticals Inc.'s VT-464 and Essa Pharma's Inc.'s EPI-506. Other compounds that are not hormonal treatments in clinical development include Bavarian Nordic A/S's Prostvac and AstraZeneca plc's olaparib.

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 will also 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 $10 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 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 our 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.

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 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 processes, 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 manufacturers' 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.

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 the University of Maryland, Baltimore, or 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, and an exclusive, worldwide license with Johns Hopkins under which we license patents, patent applications and know-how covering certain assays to identify androgen receptor variants for use as a companion diagnostic with galeterone. We may enter into additional license agreements in the future. Our license agreements with UMB and Johns Hopkins impose, 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.

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. As of October 31, 2016, we owned and/or licensed 18 issued U.S. patents, 10 non-provisional patent applications, five pending International patent applications (PCTs), 88 granted foreign patents and 69 pending foreign applications in our galeterone patent portfolio. Our owned and/or licensed patents and patent applications, if issued, are expected to expire on various dates from 2017 through 2036, without taking into account any possible patent term extensions. Upon the expiration of these patents, we, UMB and Johns Hopkins, as applicable, 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. 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 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. A U.S. patent we have exclusively licensed from UMB covering galeterone-related compounds and their use expires in 2017. For this reason, we have filed for or licensed additional patents and patent applications relating to galeterone covering methods of use, pharmaceutical compositions, combination treatments, prodrugs, metabolites and analogs of galeterone and their use.

We also have an exclusive license from Johns Hopkins for patents and patent applications in the United States, Europe, and Canada covering methods of determining whether a subject may respond to androgen therapy, and methods of determining a subject's risk of recurrence of hormone-refractory or hormone-naïve prostate cancer that are expected to expire in 2029. These patents applications may provide protection for an AR-V7 specific assay or a companion diagnostic test using this assay that we and Qiagen may develop and commercialize. However, these patent applications do not provide any protection for galeterone or for galeterone's pharmaceutical formulations or uses.

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 our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors 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 our licensors 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 our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that 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 U.S. 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 or the first to conceive or reduce to practice 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 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 any future product candidate or the manufacture, use or sale of galeterone or any future product candidate 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 the manufacture, use or sale of galeterone or any future product candidate, 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 that 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, we do not believe our proposed products or activities would be found to infringe any valid claims of these patents if any of the above third-party patents or patent applications, if issued, were asserted against us. If we were to challenge the validity of an issued U.S. patent in court, however, 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 or directors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and certain of our directors 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 and directors 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 or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director'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.

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 in the discovery, development and manufacture of 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.

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.

In addition, our third-party 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 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, or HIPAA, 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, 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 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, as well as the other members of our executive 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.

In July 2016, we implemented a reduction in force, which impacted virtually all of our functions. As part of the reduction in force, Lee Kalowski, our former Chief Financial Officer, and Gerald Quirk, our former Executive Vice President, Business Operations and General Counsel, ceased their employment with us at the end of August 2016. In addition, Karen Ferrante, our former Chief Medical Officer, retired at the end of August 2016. With any change in leadership and reduction in force, there is a risk to retention of employees, as well as the potential for disruption to business operations, initiatives, plans and strategies.

Recruiting and retaining qualified personnel will 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 have recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

In July 2016, we implemented a reduction in force that reduced the number of our employees by approximately 60 percent to a total of 10 full-time equivalent employees. The reduction in force, and the attrition thereafter, resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain of roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the reduction in force described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in force and reduced employee morale. In addition, the reduction in force may result in employees who were not affected by the reduction in force seeking alternate employment which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the reduction in force. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and reduction in force and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders maintain the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their affiliates and related persons, in the aggregate, beneficially own shares representing approximately 65% of our common stock, based on the number of shares of our common stock outstanding as of September 30, 2016. 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.

We believe our two largest stockholders, Apple Tree Partners and Novartis BioVentures, Ltd., in the aggregate, beneficially own shares representing approximately 55% of our common stock in the aggregate, based on the number of shares of our common stock outstanding as of September 30, 2016. As a result, each of these stockholders acting individually, as well as together, may 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 may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their 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.

An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid.

Although we have listed our common stock on The NASDAQ Global Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the prices at which they acquired their shares or at the time that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our stock price has been and may in the future be volatile, which could cause purchasers of our common stock to incur substantial losses.

Our stock price has been and in the future may be subject to substantial volatility. 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. For example, our stock traded within a range of a high price of $30.00 per share and a low price of $0.98 per share for the period beginning September 17, 2014, our first day of trading on The NASDAQ Global Market, through October 31, 2016. Our stock price experienced significant volatility in July 2016 after we announced our plan to discontinue our ARMOR3-SV clinical trial. As a result of this volatility, our stockholders could incur substantial losses. The market price for our common stock may be influenced by many factors, including:

- our analysis of available unblinded data from our ARMOR3-SV trial and our determination as to the potential paths forward in the development of galeterone and our ARDA program;
- 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 product 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.

On August 1, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against us, Jodie P. Morrison, and Lee H. Kalowski, entitled *Doshi v. Tokai Pharmaceuticals, Inc., et al*., No. 1:16-cv-06106 ("*Doshi* Action"). The plaintiff seeks to represent a class of purchasers of our securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about our clinical trials for our drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against us, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our initial public offering ("IPO"), entitled *Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al*., No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of our common stock in and/or traceable to our IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of *forum non conveniens*, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction.

On September 29, 2016, two purported stockholders filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our IPO, entitled *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al*., No. 1:16-cv-11963 ("*Garbowski* Action"). The lawsuit alleges that the defendants and our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of our common stock in or traceable to our IPO as well as a class of purchasers of our common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. The plaintiff in the *Doshi* Action has filed a motion to consolidate the *Doshi* and *Garbowski* Actions for all purposes.

An unfavorable resolution of any of these matters may have a material adverse effect on our results of operations and cash flows.

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, as a public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, 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.

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 are 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 are 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 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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years from the date of our initial public offering, 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. 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.

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

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 the sole source of gain for our stockholders for the foreseeable future.

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. We do not have any control over these analysts. 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Initial Public Offering

On September 22, 2014, we completed the initial public offering of our common stock through the issuance and sale of 6,480,000 shares of our common stock at a price to the public of $15.00 per share. In addition, on October 9, 2014, we issued and sold an additional 540,000 shares of common stock at the initial public offering price of $15.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock.

The offer and sale of all of the shares in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-198052), which was declared effective by the SEC on September 16, 2014, and a registration statement on Form S-1MEF (File No. 333-198792), which was automatically effective upon filing with the SEC on September 16, 2014. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. The offering commenced on September 16, 2014 and did not terminate until the sale of all of the shares offered.

We received aggregate gross proceeds from the offering of $105.3 million, or aggregate net proceeds of $94.6 million after deducting underwriting discounts and commissions and offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

As of September 30, 2016, we estimate that we have used approximately $79.9 million of the net proceeds from our initial public offering to fund the clinical development of galeterone and for working capital and other general corporate purposes. We have invested the unused proceeds from the offering in marketable securities and money market accounts. Following our announcement in July 2016 to discontinue the ARMOR3-SV clinical trial, we are currently evaluating potential paths forward for galeterone and our ARDA program, and the potential use of the remaining net proceeds from our initial public offering.

Item 5. Other Information.

On October 28, 2016, we entered into an agreement with Qiagen terminating the project work plan effective September 27, 2016. We are responsible for making a final payment of $1.1 million to Qiagen at which time there will be no future financial obligations by us or Qiagen under the project work plan.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TOKAI PHARMACEUTICALS, INC.

Date: November 3, 2016

By: /s/ John S. McBride
John S. McBride
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014).
10.1*+	Consulting Agreement dated August 31, 2016 between the Registrant and Lee H. Kalowski
10.2*+	Consulting Agreement dated August 31, 2016 between the Registrant and Karen J. Ferrante
10.3*	Consulting Agreement dated September 21, 2016 between the Registrant and Apple Tree Life Sciences, Inc.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

\# This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

\+ Indicates management contract or plan.

Exhibit 10.1

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement"), effective as of the 31 day of August, 2016 (the "Effective Date"), is entered into between Tokai Pharmaceuticals, Inc., having offices located at 255 State Street, 6th Floor, Boston, MA 02109 ("Tokai") and Lee Kalowski having an address of 207 E. 74th Street #PH D, New York, NY 10021 ("Consultant"). Tokai and Consultant may be referred to in this Agreement, individually, as a "Party" and, collectively, as the "Parties".

WHEREAS, Tokai wishes to engage Consultant to provide certain consulting and other services to Tokai, and Consultant is willing to provide such services to Tokai, in each case on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing, and of the mutual covenants set forth in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Performance of Services. During the term of this Agreement, Consultant shall, from time to time, as requested by Tokai, perform for Tokai the consulting and other services described in Exhibit A (the "Services"). Consultant shall use commercially reasonable efforts to perform Services in accordance with the timelines and other specifications, if any, specified in Exhibit A. In performing Services, Consultant shall comply with all applicable laws and regulations, and shall perform Services in a manner that is consistent with relevant industry and professional standards. While on Tokai premises or dealing with Tokai personnel or interacting with third parties in connection with Services, Consultant shall comply with any Tokai policies, instructions, rules and procedures of which Consultant is made aware to the extent consistent with applicable laws. Consultant may not subcontract the performance of any of Consultant's obligations under this Agreement to any third party.

2. Relationship of Parties.

(a) Independent Contractor. Consultant shall perform all Services as an independent contractor, and not as an employee, agent, joint venture party or partner of Tokai. Except as otherwise set forth in Exhibit A, the manner in which Consultant performs Services and the times and locations for performance of Services shall be determined by Consultant, provided Consultant meets the timelines, specifications and standard for performance set forth in this Agreement and in Exhibit A. Nothing in this Agreement shall be deemed to authorize Consultant to transact business, or assume or create any obligation or responsibility, or make any representation or warranty, express or implied, on behalf of, or in the name of, Tokai or to bind Tokai in any manner unless expressly authorized in writing to do so by an authorized representative of Tokai.

(b) Taxes, Insurance and Benefits. Neither Consultant nor any employee used by Consultant in the performance of Services shall be entitled to any benefits, coverage or privileges, including, without limitation, social security, unemployment, medical or pension payments, made available to employees of Tokai. Consultant will be fully responsible for all taxes and insurance coverage

applicable to Consultant and Consultant's employees, and for maintaining workers' compensation and employer's liability insurance to the extent required by applicable laws. By way of clarity, because Consultant is an independent contractor, Tokai will not withhold or make payments for social security, federal, state or any other employee payroll taxes; make unemployment insurance or disability insurance contributions; or obtain worker's compensation insurance on Consultant's behalf. In further recognition of the fact that Consultant is not an employee of Tokai, Consultant agrees not to make, and waives and releases any rights to make, any claim Consultant might have against Tokai that relates to or arises from any illness or injury Consultant sustains while performing Services under this Agreement that may arise pursuant to applicable workers' compensation laws. Consultant agrees to accept exclusive liability for complying with all applicable federal, state and other laws governing self-employed individuals, including obligations such as payment of taxes, social security, disability and other contributions based on fees paid to Consultant, its agents or employees under this Agreement and any requirements to have health insurance care coverage applicable to Consultant and/or Consultant's employees. Consultant hereby agrees to indemnify and defend Tokai against any and all taxes, contributions and other amounts that Tokai may incur, but that are the responsibility of Consultant under this paragraph, including fines, penalties and interest.

3. Compensation.

(a) Fees. In full consideration of the Services performed and rights granted by Consultant under this Agreement, Tokai shall pay Consultant fees for Services rendered at Tokai's request as specified in Exhibit A.

(b) Expenses. In addition to the fees set forth in paragraph (a), Tokai shall reimburse Consultant for all reasonable out-of-pocket expenses incurred or paid by Consultant in connection with the performance of Services by Consultant under this Agreement, but in each case solely to the extent such expenses have been authorized in advance in writing by an authorized representative of Tokai or are otherwise specifically listed as reimbursable expenses on Exhibit A. Consultant shall furnish appropriate supporting documentation for authorized expenses to be reimbursed by Tokai under this Agreement. All fees and expenses incurred by Consultant in performing Services under this Agreement that are not specifically listed as part of fees and reimbursable expenses on Exhibit A or otherwise expressly authorized in advance in writing by an authorized representative of Tokai shall be borne by Consultant.

(c) Invoices. Consultant shall submit an invoice for fees and authorized expenses at the end of each calendar month during which Consultant provides Services to Tokai. Tokai shall pay undisputed invoices for amounts due within thirty (30) days of receipt of the applicable invoice.

4. Treatment of Confidential Information.

(a) Definition. "Confidential Information" means any information and materials, whether in tangible or intangible form, of a confidential, secret, or proprietary nature, disclosed or provided to Consultant by or on behalf of Tokai or any of its affiliates, either directly or indirectly, in writing, orally or by inspection, and, in each case, whether or not identified or marked as

"confidential". Confidential Information will also include information and data generated by Consultant as part of Services except to the extent such information is covered by one of the exceptions set forth in paragraph (b) below. Confidential Information may also include information obtained from Tokai's collaborators, customers, suppliers, licensors, licensees, vendors and other third parties who have entrusted their confidential information to Tokai.

(b) Exceptions. Notwithstanding anything in this Agreement to the contrary, "Confidential Information" shall not include any information which Consultant can show by written evidence (i) was publicly known and generally available in the public domain prior to the time of disclosure to Consultant or being generated under this Agreement; (ii) becomes publicly known and generally available after disclosure to Consultant or being generated under this Agreement other than through breach of this Agreement; (iii) was already in possession of Consultant immediately prior to the time of disclosure or being generated under this Agreement, and was not received from or on behalf of Tokai; (iv) was obtained by the Consultant from a third party who has a right to disclose such information free of any obligation of confidentiality and who is not providing such information on behalf of Tokai or in connection with Services; or (v) is independently developed by Consultant without use of or reference to Tokai's Confidential Information and other than as part of Services. Notwithstanding anything in this Agreement to the contrary, Consultant shall be permitted to disclose Confidential Information of Tokai to the extent such disclosure is required by applicable law, provided that, to the extent possible, Consultant gives Tokai prompt written notice of such requirement prior to such disclosure and, at Tokai's reasonable request, cooperates in Tokai's efforts to limit the scope of such disclosure or to obtain an order protecting all or part of the information from public disclosure.

(c) Non-Use and Non-Disclosure of Confidential Information. Consultant agrees not to use any Confidential Information for any purpose except in connection with the Services contemplated under this Agreement or as otherwise approved in writing by Tokai. Consultant agrees not to disclose any Confidential Information to any third party except to those employees of Consultant who have a need to know such information in connection with Services and who are bound by written obligations of confidentiality and restrictions on use that would cover Confidential Information and are at least as stringent as those set forth in this Agreement.

(d) Maintenance of Confidentiality. Consultant agrees to take all reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information.

(e) Publication. Consultant shall not have the right to publish all or any other part of the results of Services without the prior written consent of Tokai which such consent Tokai may withhold in its sole discretion.

(f) Return of Information and Materials. All documents and other tangible objects provided to Consultant by or on behalf of Tokai or generated by Consultant containing or representing Confidential Information, and all copies thereof, which are in possession of Consultant, shall, as between Tokai and Consultant, be and remain the property of Tokai and, at Tokai's request, shall be promptly returned to Tokai or destroyed, as directed in writing by Tokai, and, upon Tokai's written request, any memoranda, notes, reports and the like generated by Consultant and incorporating such Confidential Information shall be destroyed.

(g) Remedies. Consultant acknowledges that any breach of the provisions of this Section may result in serious and irreparable injury to Tokai for which monetary damages may not be adequate. As a result, Consultant agrees that, in addition to any other remedy it may have, Tokai shall be entitled to seek specific performance of these provisions and to seek injunctive relief without the need to post a bond or to show harm.

(h) Survival. The obligations of Consultant under this Section 4 shall survive the termination or expiration of this Agreement for a period of seven (7) years.

5. Proprietary Rights.

(a) Tokai Materials. If any biological, chemical or other materials owned or controlled by Tokai and/or its affiliates are furnished to Consultant in connection with Services (the "Materials"), such Materials and all associated intellectual property rights will remain the exclusive property of Tokai. Consultant will use Materials provided by Tokai only as necessary to perform Services. Consultant agrees to retain control over the Materials and not to transfer Materials to any person or entity other than those employees working on the Services under the direct supervision of Consultant. Consultant shall not transfer the Materials to any location other than the facilities used by Consultant to provide Services, without the prior written consent of Tokai. Consultant will provide access to Materials only to those of its employees who have a need for such access for purposes of conducting the Services. Consultant acknowledges that the Materials are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and reasonable care in the use, handling, storage, transportation and disposition and containment of Materials. Consultant shall conduct Services utilizing the Materials under suitable containment conditions and in accordance with existing laws and regulations. Consultant may not undertake efforts (including but not limited to NMR, UV, IR, x-ray crystallography and mass spectroscopy and similar analyses) to ascertain the structure of any Materials provided hereunder without the prior written consent of Tokai. Consultant shall not reverse engineer, disassemble or decompile any Materials or any other composition, software or other items that are provided to Consultant in connection with the Materials. Upon completion or termination of the applicable Services, Consultant shall return any unused Materials to Tokai or its designee or destroy such Materials, as directed by Tokai.

(b) Results of Services. All data, information, reports and tangible materials generated by Consultant in the performance of Services shall be the exclusive property and Confidential Information of Tokai.

(c) Intellectual Property. Consultant hereby assigns to Tokai all of Consultant's rights to inventions, discoveries, ideas, designs, processes, methods, compositions, formulations, works of authorship, trade secrets, know-how, information, data, reports, research and other creations that are generated by Consultant in the performance of the Services or using Confidential Information or Materials of Tokai (whether or not patentable or subject to patent, copyright or trade secret

protection) and all related intellectual property rights worldwide (the "Service-related I.P."). Service-related I.P. will constitute "works made for hire" to the extent permitted under applicable law. In the event Service-related I.P. cannot be assigned under applicable law, Consultant shall be deemed to have granted to Tokai a perpetual, exclusive, fully paid-up, royalty-free, transferable worldwide license to such Service-related I.P. for all purposes. Tokai shall have the right to use the deliverables and other results of Services and the Service-related I.P. for any and all purposes. During and after the term of this Agreement, Consultant shall, at Tokai's reasonable request, cooperate fully in connection with Tokai's efforts to obtain patent and other proprietary protection for Service-related I.P., all in the name of Tokai or its designee. Without limiting the foregoing, Consultant agrees that Consultant shall execute and deliver all requested applications, assignments and other documents, and take such other measures as Tokai may reasonably request, in order to perfect, protect and enforce Tokai's rights in Service-related I.P. Tokai shall reimburse Consultant for Consultant's out-of-pocket expenses incurred in connection with cooperation provided at Tokai's request under the preceding sentence. Each such employee, if any, that Consultant engages in the performance of Services, to the extent engagement of additional employees is permitted under this Agreement, must have agreed in writing to effectively vest in Consultant any and all rights that such personnel might otherwise have in the results of their work.

(d) Work at Third Party Facilities. Except as Tokai may otherwise consent in writing, Consultant agrees not to make use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing Services, nor shall Consultant take any other action that would result in a third party owning or having a right in the results of the Services or the Service-related I.P.

(e) Information, Record Retention and Storage. Consultant shall promptly provide to Tokai such information related to Services as Tokai may from time to time reasonably request, including, but not limited to, information related to the results of Services and the processes, procedures and facilities used in connection with performance of Services. In no event shall Consultant dispose of any data, information, records, reports or tangible materials (collectively, the "Records") generated in connection with Services without first giving Tokai sixty (60) days' prior written notice of Consultant's intent to do so and an opportunity to have the Records transferred to Tokai.

6. Limitation of Liability.

EXCEPT FOR AMOUNTS FOR WHICH A PARTY BECOMES OBLIGATED UNDER THE INDEMNITY PROVISIONS OF SECTIONS 2(b) and 7, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR LOST PROFITS OR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES ARISING FROM ANY BREACH OF THIS AGREEMENT.

7. Indemnification. Consultant shall defend, indemnify and hold harmless Tokai, its affiliates and their respective directors, officers, employees and agents from and against any and all damages, fines, liabilities, losses, costs and expenses, including, but not limited to court costs

and reasonable attorneys' fees, (collectively, "Losses") in connection with any third party claim arising from (i) any misrepresentation or breach by Consultant of any term of this Agreement, or (ii) the negligence or willful misconduct of Consultant or any of its agents or employees. Tokai shall give Consultant prompt written notice describing any claim for which indemnification is sought under this Section. Consultant shall have the right to assume full responsibility to investigate, prepare for and defend against any such indemnified claim. Tokai shall reasonably assist Consultant, at Consultant's reasonable request and expense, in the investigation of, preparation for, and defense of any such indemnified claim. Neither Party shall settle any claim for which indemnification is sought under this Section without the other Party's prior written consent.

8. Representation, Warranties and Covenants.

(a) Authority. Each Party represents that it has full right, power and authority to enter into this Agreement.

(b) No Conflict. Consultant represents that Consultant is not currently a party to, and covenants that Consultant will not, during the term of this Agreement, become a party to, any contractual or other obligation or restriction that would cause Consultant to be unable to fulfill Consultant's obligations under this Agreement. Consultant represents that neither Consultant's execution of this Agreement nor the performance by Consultant of this Agreement will breach any agreement, arrangement or understanding to which Consultant is a party or by which Consultant is bound.

(c) No Use of Third Party I.P. Consultant will not in the performance of Services, knowingly or without due regard, infringe or misappropriate any third party intellectual property or share with Tokai any confidential or proprietary information of a third party.

(d) Non-compete. Consultant retains the right to consult and provide Services to other companies, provided that, during the term of this Agreement, Consultant shall not provide consulting or other services to any third party in connection with such third party's research, development, manufacture, marketing, sale or use of any product candidate, product, technology or program which is competitive with the product candidate, product, technology or program with respect to which Consultant has provided Services to Tokai under this Agreement.

(e) No Debarment. Neither Consultant nor any of Consultant's employees has been or is under consideration to be, excluded, suspended or debarred from, or otherwise declared ineligible to participate in, federal healthcare programs, federal procurement or non-procurement programs, or any other activities or programs related to the Services contemplated by this Agreement, including under the provisions of the Generic Drug Enforcement Act of 1992. Consultant shall notify Tokai immediately in writing upon receipt of notice of such debarment or any threatened or scheduled debarment proceedings involving Consultant or any of its employees.

(f) No Use of Name. Neither Party may use the other Party's name in any form of advertising, promotion or publicity, including press releases, without the prior written consent of the other Party.

9. Term; Termination.

(a) Term. The term of this Agreement shall commence on the Effective Date and shall continue in effect until February 28, 2017, unless earlier terminated by either Party as set forth in Section 9(b) below.

(b) Termination. Either Party may terminate this Agreement for any reason at any time upon at least fourteen (14) days' prior written notice to the other Party. In addition, either Party may terminate this Agreement upon twenty-four (24) hours' prior written notice to the other Party in the event the other Party has materially breached this Agreement.

(c) Effect of Termination. In the event of termination or expiration of this Agreement, Tokai shall pay Consultant all amounts due under this Agreement for Services performed in accordance with the terms of this Agreement and authorized expenses incurred by Consultant in connection with Services as of the date of such termination or expiration. Promptly after termination of this Agreement, Consultant shall return to Tokai all equipment and unused materials in Consultant's possession provided to Consultant by or on behalf of Tokai for the conduct of Services under this Agreement and any remaining deliverables and any other data, information or documentation to be delivered to Tokai in connection with Services. Return of Confidential Information is addressed in Section 4(f).

(d) Survival. The termination or expiration of this Agreement shall not affect the rights or obligations which have accrued prior to the effective date of such termination or expiration. Sections 4, 5, 6, 7, 8(f), 9, 10, 11, and 12 of this Agreement shall survive any termination or expiration of this Agreement.

10. Notice. All notices required or permitted under this Agreement will be in writing and will be given by addressing the same to the address or facsimile number for the recipient set forth on the signature page of this Agreement or to such other address or facsimile number as the recipient may specify in writing under this procedure. Notices will be deemed to have been given (i) three (3) business days after deposit in the U.S. mail with proper postage for registered or certified mail prepaid, return receipt requested; (ii) one (1) business day after facsimile transmission, with receipt of transmission confirmed in writing; or (iii) one (1) business day after sending by a nationally recognized courier service for next day delivery.

11. Force Majeure. Neither party shall be responsible for any failure of, or delay in, its performance under this Agreement which may be due, in whole or in part, to any occurrence, cause or causes beyond such Party's reasonable control. The performance schedule, if any, shall be adjusted to account for any such delays.

12. Miscellaneous.

(a) Assignment. This Agreement shall be binding upon and enure to the benefit of the Parties and their respective successors and permitted assigns. Neither Party may assign any of its rights or obligations under this Agreement without the prior written consent of the other Party except that this Agreement may be assigned by Tokai to an affiliate or successor in interest who agrees to be bound by its terms.

(b) Severability. Each and every provision set forth in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable by virtue of the fact that, for any reason, any other provision may be invalid or unenforceable in whole or in part. If any provision of this Agreement is invalid or unenforceable for any reason whatsoever, that provision will be appropriately limited and reformed to the maximum extent provided by applicable law. If the scope of any restriction contained in this Agreement is too broad to permit enforcement to its full extent, then such restriction will be enforced to the maximum extent permitted by law so as to be judged reasonable and enforceable. In the event any provision of this Agreement is required to be limited or reformed under this paragraph, the Parties shall make good faith effort to amend this Agreement to replace any such invalid or unenforceable provision and to reform this Agreement in such a way that the objectives contemplated by the Parties when entering into this Agreement may be realized.

(c) Governing Law. This Agreement shall be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts, without reference to its conflict-of-laws principles.

(d) Entire Agreement. This Agreement constitutes the entire agreement between the Parties pertaining to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between Consultant and Tokai related to the subject matter of this Agreement.

(e) Amendments and Waivers. No amendment of this Agreement or any Work Order shall be binding unless executed in writing by both Parties. Any waiver of any term of this Agreement must be in writing signed by the waiving party. A waiver of compliance of any provision in one instance shall not be deemed a waiver of any future breach or of failure to comply with any other provision of this Agreement.

(f) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which, taken together, shall constitute one and the same legal instrument.

IN WITNESS WHEREOF, Tokai and Consultant have caused this Agreement to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.	LEE KALOWSKI
By: /s/ Jodie Morrison	/s/ Lee Kalowski
Name: Jodie Morrison	Name: Lee Kalowski
Title: Chief Executive Officer	

Taxpayer ID /EIN: _____

Exhibit A

I. DESCRIPTION OF SERVICES

Consultant shall provide to Tokai such consulting, advisory and related services as may be reasonably requested from time to time by Tokai, including but not limited to services with respect to the Company's assessment and pursuit of strategic alternatives *(eg attendance at the org meeting, assessment of potential target opportunities, etc.)*

Consultant shall devote not more than 60 hours per month without prior written approval. Work may occur on site or remote. Schedule to be determined on ongoing basis.

II. FEES AND PAYMENT SCHEDULE

Tokai shall pay Consultant for Services rendered at Tokai's request at the rate of $325 per hour.

Tokai shall reimburse Consultant for reasonable travel-related expenses incurred in connection with travel specifically authorized in writing by Tokai in connection with Services, subject to Tokai's then current travel policy, if provided to Consultant.

Exhibit 10.2

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement"), effective as of the 31 day of August, 2016 (the "Effective Date"), is entered into between Tokai Pharmaceuticals, Inc., having offices located at 255 State Street, 6th Floor, Boston, MA 02109 ("Tokai") and Karen Ferrante, MD having an address of 150 Adirondack Drive, East Greenwich, RI 02818 ("Consultant"). Tokai and Consultant may be referred to in this Agreement, individually, as a "Party" and, collectively, as the "Parties".

WHEREAS, Tokai wishes to engage Consultant to provide certain consulting and other services to Tokai, and Consultant is willing to provide such services to Tokai, in each case on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing, and of the mutual covenants set forth in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Performance of Services. During the term of this Agreement, Consultant shall, from time to time, as requested by Tokai, perform for Tokai the consulting and other services described in Exhibit A (the "Services"). Consultant shall use commercially reasonable efforts to perform Services in accordance with the timelines and other specifications, if any, specified in Exhibit A. In performing Services, Consultant shall comply with all applicable laws and regulations, and shall perform Services in a manner that is consistent with relevant industry and professional standards. While on Tokai premises or dealing with Tokai personnel or interacting with third parties in connection with Services, Consultant shall comply with any Tokai policies, instructions, rules and procedures of which Consultant is made aware to the extent consistent with applicable laws. Consultant may not subcontract the performance of any of Consultant's obligations under this Agreement to any third party.

2. Relationship of Parties.

(a) Independent Contractor. Consultant shall perform all Services as an independent contractor, and not as an employee, agent, joint venture party or partner of Tokai. Except as otherwise set forth in Exhibit A, the manner in which Consultant performs Services and the times and locations for performance of Services shall be determined by Consultant, provided Consultant meets the timelines, specifications and standard for performance set forth in this Agreement and in Exhibit A. Nothing in this Agreement shall be deemed to authorize Consultant to transact business, or assume or create any obligation or responsibility, or make any representation or warranty, express or implied, on behalf of, or in the name of, Tokai or to bind Tokai in any manner unless expressly authorized in writing to do so by an authorized representative of Tokai.

(b) Taxes, Insurance and Benefits. Neither Consultant nor any employee used by Consultant in the performance of Services shall be entitled to any benefits, coverage or privileges, including, without limitation, social security, unemployment, medical or pension payments, made available

to employees of Tokai. Consultant will be fully responsible for all taxes and insurance coverage applicable to Consultant and Consultant's employees, and for maintaining workers' compensation and employer's liability insurance to the extent required by applicable laws. By way of clarity, because Consultant is an independent contractor, Tokai will not withhold or make payments for social security, federal, state or any other employee payroll taxes; make unemployment insurance or disability insurance contributions; or obtain worker's compensation insurance on Consultant's behalf. In further recognition of the fact that Consultant is not an employee of Tokai, Consultant agrees not to make, and waives and releases any rights to make, any claim Consultant might have against Tokai that relates to or arises from any illness or injury Consultant sustains while performing Services under this Agreement that may arise pursuant to applicable workers' compensation laws. Consultant agrees to accept exclusive liability for complying with all applicable federal, state and other laws governing self-employed individuals, including obligations such as payment of taxes, social security, disability and other contributions based on fees paid to Consultant, its agents or employees under this Agreement and any requirements to have health insurance care coverage applicable to Consultant and/or Consultant's employees. Consultant hereby agrees to indemnify and defend Tokai against any and all taxes, contributions and other amounts that Tokai may incur, but that are the responsibility of Consultant under this paragraph, including fines, penalties and interest.

3. Compensation.

(a) Fees. In full consideration of the Services performed and rights granted by Consultant under this Agreement, Tokai shall pay Consultant fees for Services rendered at Tokai's request as specified in Exhibit A.

(b) Expenses. In addition to the fees set forth in paragraph (a), Tokai shall reimburse Consultant for all reasonable out-of-pocket expenses incurred or paid by Consultant in connection with the performance of Services by Consultant under this Agreement, but in each case solely to the extent such expenses have been authorized in advance in writing by an authorized representative of Tokai or are otherwise specifically listed as reimbursable expenses on Exhibit A. Consultant shall furnish appropriate supporting documentation for authorized expenses to be reimbursed by Tokai under this Agreement. All fees and expenses incurred by Consultant in performing Services under this Agreement that are not specifically listed as part of fees and reimbursable expenses on Exhibit A or otherwise expressly authorized in advance in writing by an authorized representative of Tokai shall be borne by Consultant.

(c) Invoices. Consultant shall submit an invoice for fees and authorized expenses at the end of each calendar month during which Consultant provides Services to Tokai. Tokai shall pay undisputed invoices for amounts due within thirty (30) days of receipt of the applicable invoice.

4. Treatment of Confidential Information.

(a) Definition. "Confidential Information" means any information and materials, whether in tangible or intangible form, of a confidential, secret, or proprietary nature, disclosed or provided to Consultant by or on behalf of Tokai or any of its affiliates, either directly or indirectly, in

writing, orally or by inspection, and, in each case, whether or not identified or marked as "confidential". Confidential Information will also include information and data generated by Consultant as part of Services except to the extent such information is covered by one of the exceptions set forth in paragraph (b) below. Confidential Information may also include information obtained from Tokai's collaborators, customers, suppliers, licensors, licensees, vendors and other third parties who have entrusted their confidential information to Tokai.

(b) Exceptions. Notwithstanding anything in this Agreement to the contrary, "Confidential Information" shall not include any information which Consultant can show by written evidence (i) was publicly known and generally available in the public domain prior to the time of disclosure to Consultant or being generated under this Agreement; (ii) becomes publicly known and generally available after disclosure to Consultant or being generated under this Agreement other than through breach of this Agreement; (iii) was already in possession of Consultant immediately prior to the time of disclosure or being generated under this Agreement, and was not received from or on behalf of Tokai; (iv) was obtained by the Consultant from a third party who has a right to disclose such information free of any obligation of confidentiality and who is not providing such information on behalf of Tokai or in connection with Services; or (v) is independently developed by Consultant without use of or reference to Tokai's Confidential Information and other than as part of Services. Notwithstanding anything in this Agreement to the contrary, Consultant shall be permitted to disclose Confidential Information of Tokai to the extent such disclosure is required by applicable law, provided that, to the extent possible, Consultant gives Tokai prompt written notice of such requirement prior to such disclosure and, at Tokai's reasonable request, cooperates in Tokai's efforts to limit the scope of such disclosure or to obtain an order protecting all or part of the information from public disclosure.

(c) Non-Use and Non-Disclosure of Confidential Information. Consultant agrees not to use any Confidential Information for any purpose except in connection with the Services contemplated under this Agreement or as otherwise approved in writing by Tokai. Consultant agrees not to disclose any Confidential Information to any third party except to those employees of Consultant who have a need to know such information in connection with Services and who are bound by written obligations of confidentiality and restrictions on use that would cover Confidential Information and are at least as stringent as those set forth in this Agreement.

(d) Maintenance of Confidentiality. Consultant agrees to take all reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information.

(e) Publication. Consultant shall not have the right to publish all or any other part of the results of Services without the prior written consent of Tokai which such consent Tokai may withhold in its sole discretion.

(f) Return of Information and Materials. All documents and other tangible objects provided to Consultant by or on behalf of Tokai or generated by Consultant containing or representing Confidential Information, and all copies thereof, which are in possession of Consultant, shall, as between Tokai and Consultant, be and remain the property of Tokai and, at Tokai's request, shall be promptly returned to Tokai or destroyed, as directed in writing by Tokai, and, upon Tokai's written request, any memoranda, notes, reports and the like generated by Consultant and incorporating such Confidential Information shall be destroyed.

(g) Remedies. Consultant acknowledges that any breach of the provisions of this Section may result in serious and irreparable injury to Tokai for which monetary damages may not be adequate. As a result, Consultant agrees that, in addition to any other remedy it may have, Tokai shall be entitled to seek specific performance of these provisions and to seek injunctive relief without the need to post a bond or to show harm.

(h) Survival. The obligations of Consultant under this Section 4 shall survive the termination or expiration of this Agreement for a period of seven (7) years.

5. Proprietary Rights.

(a) Tokai Materials. If any biological, chemical or other materials owned or controlled by Tokai and/or its affiliates are furnished to Consultant in connection with Services (the "Materials"), such Materials and all associated intellectual property rights will remain the exclusive property of Tokai. Consultant will use Materials provided by Tokai only as necessary to perform Services. Consultant agrees to retain control over the Materials and not to transfer Materials to any person or entity other than those employees working on the Services under the direct supervision of Consultant. Consultant shall not transfer the Materials to any location other than the facilities used by Consultant to provide Services, without the prior written consent of Tokai. Consultant will provide access to Materials only to those of its employees who have a need for such access for purposes of conducting the Services. Consultant acknowledges that the Materials are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and reasonable care in the use, handling, storage, transportation and disposition and containment of Materials. Consultant shall conduct Services utilizing the Materials under suitable containment conditions and in accordance with existing laws and regulations. Consultant may not undertake efforts (including but not limited to NMR, UV, IR, x-ray crystallography and mass spectroscopy and similar analyses) to ascertain the structure of any Materials provided hereunder without the prior written consent of Tokai. Consultant shall not reverse engineer, disassemble or decompile any Materials or any other composition, software or other items that are provided to Consultant in connection with the Materials. Upon completion or termination of the applicable Services, Consultant shall return any unused Materials to Tokai or its designee or destroy such Materials, as directed by Tokai.

(b) Results of Services. All data, information, reports and tangible materials generated by Consultant in the performance of Services shall be the exclusive property and Confidential Information of Tokai.

(c) Intellectual Property. Consultant hereby assigns to Tokai all of Consultant's rights to inventions, discoveries, ideas, designs, processes, methods, compositions, formulations, works of authorship, trade secrets, know-how, information, data, reports, research and other creations that are generated by Consultant in the performance of the Services or using Confidential Information or Materials of Tokai (whether or not patentable or subject to patent, copyright or trade secret

protection) and all related intellectual property rights worldwide (the "Service-related I.P."). Service-related I.P. will constitute "works made for hire" to the extent permitted under applicable law. In the event Service-related I.P. cannot be assigned under applicable law, Consultant shall be deemed to have granted to Tokai a perpetual, exclusive, fully paid-up, royalty-free, transferable worldwide license to such Service-related I.P. for all purposes. Tokai shall have the right to use the deliverables and other results of Services and the Service-related I.P. for any and all purposes. During and after the term of this Agreement, Consultant shall, at Tokai's reasonable request, cooperate fully in connection with Tokai's efforts to obtain patent and other proprietary protection for Service-related I.P., all in the name of Tokai or its designee. Without limiting the foregoing, Consultant agrees that Consultant shall execute and deliver all requested applications, assignments and other documents, and take such other measures as Tokai may reasonably request, in order to perfect, protect and enforce Tokai's rights in Service-related I.P. Tokai shall reimburse Consultant for Consultant's out-of-pocket expenses incurred in connection with cooperation provided at Tokai's request under the preceding sentence. Each such employee, if any, that Consultant engages in the performance of Services, to the extent engagement of additional employees is permitted under this Agreement, must have agreed in writing to effectively vest in Consultant any and all rights that such personnel might otherwise have in the results of their work.

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(d) Non-compete. Consultant retains the right to consult and provide Services to other companies, provided that, during the term of this Agreement, Consultant shall not provide consulting or other services to any third party in connection with such third party's research, development, manufacture, marketing, sale or use of any product candidate, product, technology or program which is competitive with the product candidate, product, technology or program with respect to which Consultant has provided Services to Tokai under this Agreement.

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(a) Term. The term of this Agreement shall commence on the Effective Date and shall continue in effect until February 28, 2017, unless earlier terminated by either Party as set forth in Section 9(b) below.

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(c) Effect of Termination. In the event of termination or expiration of this Agreement, Tokai shall pay Consultant all amounts due under this Agreement for Services performed in accordance with the terms of this Agreement and authorized expenses incurred by Consultant in connection with Services as of the date of such termination or expiration. Promptly after termination of this Agreement, Consultant shall return to Tokai all equipment and unused materials in Consultant's possession provided to Consultant by or on behalf of Tokai for the conduct of Services under this Agreement and any remaining deliverables and any other data, information or documentation to be delivered to Tokai in connection with Services. Return of Confidential Information is addressed in Section 4(f).

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11. Force Majeure. Neither party shall be responsible for any failure of, or delay in, its performance under this Agreement which may be due, in whole or in part, to any occurrence, cause or causes beyond such Party's reasonable control. The performance schedule, if any, shall be adjusted to account for any such delays.

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(c) Governing Law. This Agreement shall be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts, without reference to its conflict-of-laws principles.

(d) Entire Agreement. This Agreement constitutes the entire agreement between the Parties pertaining to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between Consultant and Tokai related to the subject matter of this Agreement.

(e) Amendments and Waivers. No amendment of this Agreement or any Work Order shall be binding unless executed in writing by both Parties. Any waiver of any term of this Agreement must be in writing signed by the waiving party. A waiver of compliance of any provision in one instance shall not be deemed a waiver of any future breach or of failure to comply with any other provision of this Agreement.

(f) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which, taken together, shall constitute one and the same legal instrument.

In witness whereof, Tokai and Consultant have caused this Agreement to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.	KAREN FERRANTE, MD
By: /s/ Jodie Morrison	/s/ Karen Ferrante
Name: Jodie Morrison	Name: Karen Ferrante
Title: Chief Executive Officer	

Taxpayer ID /EIN: _____

Exhibit A

I. DESCRIPTION OF SERVICES

Consultant shall provide to Tokai such consulting, advisory and related services as may be reasonably requested from time to time by Tokai, including but not limited to services with respect to the following areas:

Closure of the ARMOR program and assessment of the Company's strategic alternatives.

Consultant shall devote no more than 50 hours per month without prior written approval. Work may occur remote or on site. Schedule to be determined on an ongoing basis.

II. FEES AND PAYMENT SCHEDULE

Tokai shall pay Consultant for Services rendered at Tokai's request at the rate of $475 per hour.

Tokai shall reimburse Consultant for reasonable travel-related expenses incurred in connection with travel specifically authorized in writing by Tokai in connection with Services, subject to Tokai's then current travel policy, if provided to Consultant.

Exhibit 10.3

TOKAI PHARMACEUTICALS, INC.

CONSULTING AGREEMENT

This Consulting Agreement (the "**Agreement**"), made this 21 day of September, 2016 is entered into by Tokai Pharmaceuticals, Inc., with offices at 255 State Street, 6th Floor, Boston, Massachusetts 02109 (the "**Company**"), and Apple Tree Life Sciences, Inc., with offices at 230 Park Avenue, Suite 2800, New York, New York 10169 (the "**Consultant**").

WHEREAS, the Company and the Consultant desire to establish the terms and conditions under which the Consultant will provide services to the Company.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1.1 Services. The Consultant agrees to perform such consulting, advisory and related services to and for the Company as may be reasonably requested from time to time by the Company and agreed to by the Consultant. The Consultant shall not engage the services of third party contractors, subcontractors or consultants in the performance of the services without the prior written consent of the Company, which may be granted or withheld in its sole discretion.

2. Term. This Agreement shall be deemed to have commenced on September 9, 2016 and shall continue until terminated in accordance with the provisions of Section 4 (such period being referred to as the "**Consultation Period**").

3. Compensation.

3.1 Consulting Fees. The Company shall not pay to the Consultant, and the Consultant shall not be entitled to, any fees hereunder for the services performed pursuant to this Agreement.

3.2 Expenses. The Company shall reimburse the Consultant for all reasonable and necessary documented out of pocket expenses incurred or paid by the Consultant in connection with, or related to, the performance of its services under this Agreement. The Consultant shall submit to the Company itemized monthly statements, in a form reasonably satisfactory to the Company, of such expenses incurred in the previous month. The Company shall pay to the Consultant amounts shown on each such statement within thirty (30) days after receipt thereof. Notwithstanding the foregoing, the Consultant shall not incur total expenses in excess of $5000.00 per month without the prior written approval of the Company.

3.3 Benefits. The Consultant and its employees shall not be entitled to any benefits, coverages or privileges, including, without limitation, health insurance, social security, unemployment, medical or pension payments, made available to employees of the Company.

4. Termination. This Agreement may be terminated by either the Company or the Consultant at any time upon prior written notice to the other party.

5. Cooperation. The Consultant shall use commercially reasonable efforts in the performance of its obligations under this Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Consultant to perform its obligations hereunder. The Consultant shall cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business and shall observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

6. Proprietary Information. The Consultant and the Company acknowledge that they have previously executed that certain non-disclosure agreement (the "NDA"), dated as of February 25, 2016, as amended and supplemented, and that any information provided to or learned of by the Consultant in the course of the performance of services hereunder shall be Confidential Information (as defined therein).

7. Other Agreements. The Consultant represents that the performance by it and its employees of all the terms of this Agreement and the performance of the services as a consultant to the Company do not and will not breach any agreement with any third party to which the Consultant and/or its employees are a party (including, without limitation, any nondisclosure or non-competition agreement), and that the Consultant and its employees will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any third party.

8. Independent Contractor Status.

8.1 The Consultant and its employees shall perform all services under this Agreement as "independent contractors" and not as employees or agents of the Company. The Consultant and its employees are not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner.

8.2 The Consultant and its employees shall have the right to control and determine the time, place, methods, manner and means of performing the services. In performing the services, the amount of time devoted by the Consultant and its employees on any given day will be entirely within the Consultant's and its employees' control, and the Company will rely on the Consultant and its employees to put in the amount of time necessary to fulfill the requirements of this Agreement. The Consultant and its employees will provide all equipment and supplies required to perform the services. The Consultant and its employees are not required to attend regular meetings at the Company.

8.3 In the performance of the services, the Consultant and its employees shall have the authority to control and direct the performance of the details of the services, the Company being interested only in the results obtained. However, the services contemplated by the Agreement must meet the Company's standards and approval and shall be subject to the Company's general right of inspection and supervision to secure their satisfactory completion.

8.4 The Consultant and its employees shall not use the Company's trade names, trademarks, service names or servicemarks without the prior approval of the Company.

8.5 The Consultant and its employees shall be solely responsible for all state and federal income taxes, unemployment insurance and social security taxes in connection with this Agreement and for maintaining adequate workers' compensation insurance coverage.

9. Non-Exclusivity. The Consultant and its employees retain the right to contract with other companies or entities for their consulting services without restriction. The Company retains a right to contract with other companies and/or individuals for consulting services without restriction.

10. Indemnification.

10.1 The Company agrees to indemnify the Consultant, any of its affiliates, its and their respective directors, officers, employees and agents and each other person controlling the Consultant or any of its affiliates (each, an "Indemnified Party") and hold each of them harmless from and against any and all losses, claims, damages and liabilities (collectively, "Liabilities") to which any of the Indemnified Parties may become subject relating to, arising in any manner out of or in connection with the retention of the Consultant pursuant to this Agreement, or the performance of services by the Consultant hereunder, except to the extent it is finally judicially determined that such Liability resulted from the gross negligence, bad faith or willful misconduct of an Indemnified Party. The Company also agrees to reimburse each Indemnified Party for any legal and other expenses reasonably incurred in connection with investigating, preparing for, defending, responding to third party subpoenas, preparing to serve or serving as a witness with respect to, providing evidence in, or otherwise relating to any pending or threatened action, claim, suit, proceeding or investigation (each and collectively, an "Action"); provided that the Company shall not be liable for such expenses (and the Consultant shall repay any such reimbursed expenses) to the extent that it is finally judicially determined that such Action resulted from the gross negligence, bad faith or willful misconduct of an Indemnified Party.

10.2 Promptly after becoming aware of any claim that would reasonably be expected to lead to an Action for which indemnification may be sought hereunder, any Indemnified Party will notify the Company in writing thereof; but omission so to notify the Company will not relieve the Company from any liability which the Company may have to any Indemnified Party, except to the extent that the Company suffers actual prejudice as a result of such failure. If the Company so elects, the Company may assume the defense of such Action in a timely manner, including the employment of counsel (reasonably satisfactory to the Consultant), provided the Company permits an Indemnified Party and counsel retained by an Indemnified Party at its expense to participate in such defense. Notwithstanding the foregoing, in the event (i) the Company fails promptly to assume the defense and employ counsel reasonably satisfactory to the Consultant, or (ii) the Indemnified Party has been advised by counsel that there exist actual or potential conflicting interests between the Company or the Company's counsel and such Indemnified Party, an Indemnified Party may employ separate counsel (in addition to any local counsel) to represent or defend such Indemnified Party in such Action, and the Company agree to pay the fees and disbursements of such separate counsel as incurred; provided however, that the Company will not, in connection with any one such Action, or separate but substantially similar Actions arising out of the same general allegations, be liable for fees and expenses of more than one separate firm of attorneys (in addition to any local

counsel). The Company shall not be liable for any settlement of, compromise or consent to the entry of any judgment in or other termination of (each and collectively, a "Settlement") any Action in respect of which indemnification could be sought hereunder (whether or not the Consultant or any other Indemnified Party is an actual or potential party to such Action) without its prior written consent.

10.3 The Company agrees that, without the Consultant's prior written consent, it will not agree to any Settlement of any Action in respect of which indemnification could be sought hereunder (whether or not the Consultant or any other Indemnified Party is an actual or potential party to such Action), unless such Settlement includes an unconditional release from the party bringing such Action of all Indemnified Parties. The rights of the Indemnified Parties referred to in this Section 10 shall be in addition to any rights that any Indemnified Party may have at common law or otherwise.

11. Representations, Warranties and Covenants. The Consultant hereby covenants that it shall be liable for the acts and omissions of its employees and subcontractors, if any, including without limitation any breach of this Agreement or violation of law.

12. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party at the address shown above, or at such other address or addresses as either party shall designate to the other in accordance with this Section 12.

13. Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

14. Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

15. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Consultant.

16. Non-Assignability of Contract. The Consultant shall not have the right to assign any of its rights or delegate any of its duties without the express written consent of the Company. Any non-consented-to assignment or delegation, whether express or implied or by operation of law, shall be void and shall constitute a breach and a default by the Consultant.

17. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without giving effect to any choice or conflict of law provision or rule that would cause the application of laws of any other jurisdiction.

18. Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business, provided, however, that the obligations of the Consultant are personal and shall not be assigned by Consultant.

19. Survival. Sections 4 through 20 shall survive the expiration or termination of this Agreement.

20. Miscellaneous.

20.1 No delay or omission by the Company in exercising any right under this 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 or waiver of any right on any other occasion.

20.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

20.3 In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the date and year first above written.

COMPANY:

TOKAI PHARMACEUTICALS, INC.

By: Jodie P. Morrison
Name: /s/ Jodie P. Morrison
Title: President and CEO

CONSULTANT:

APPLE TREE LIFE SCIENCES, INC.

By: Seth Harrison
Name: /s/ Seth Harrison
Title: President

SIGNATURE PAGE TO CONSULTING AGREEMENT

Exhibit 31.1

CERTIFICATIONS

I, Jodie P. Morrison, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2016

By: /s/ Jodie P. Morrison
Jodie P. Morrison
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, John S. McBride, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2016

By: /s/ John S. McBride
John S. McBride
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jodie P. Morrison, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2016

By: /s/ Jodie P. Morrison
Jodie P. Morrison
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John S. McBride, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3 , 2016

By: /s/ John S. McBride
John S. McBride
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)