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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 No.)**
255 State Street, 6th Floor Boston, Massachusetts	**02109**
(Address of principal executive offices)	**(Zip code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	**Name of Exchange on Which Registered**
Common Stock, $0.001 par value	**NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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. (Check one):

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 June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was $53,968,136, based on the last reported sale price of such stock on the NASDAQ Global Market as of such date.

As of January 31, 2017, the registrant had 22,641,651 shares of Common Stock, $0.001 par value per share, outstanding.

Portions of the registrant's definitive proxy statement for its 2017 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end December 31, 2016, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

TOKAI PHARMACEUTICALS, INC.
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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, 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:

- our board of directors' review of strategic alternatives and our pending transaction with Otic Pharma Ltd as a result of such review;
- 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 evaluation of potential paths forward for galeterone and our ARDA program;
- 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;
- 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 seek 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K speak only as of the date of such statement.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

ITEM 1. *BUSINESS*

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. We have focused substantially all of our research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC. We also have a drug discovery program, known as ARDA (androgen receptor degradation agents), under which we identified novel compounds for patients with androgen receptor signaling diseases, including prostate cancer.

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 mCRPC patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee, or 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 conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. All patients enrolled in the ARMOR3-SV clinical trial have discontinued treatment.

In addition, in August 2016, we determined to discontinue enrollment in our Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga ® (abiraterone acetate). Ten patients in the ARMOR2 trial continue treatment as of January 31, 2017.

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 a review of development options for galeterone and the ARDA program. As of January 31, 2017, we had eight full-time employees.

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 was conducted in parallel with a review of development options for galeterone and the ARDA program, our board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets.

On December 21, 2016, we entered into a Share Purchase Agreement, or Share Purchase Agreement, with Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel, or Otic, and the shareholders of Otic named therein, or the Selling Shareholders, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Share Purchase Agreement, each Selling Shareholder agreed to sell to us, and we agreed to purchase from each Selling Shareholder, all of the ordinary and preferred shares of Otic, the Otic Shares, owned by such Selling Shareholder. We refer to our acquisition of all the outstanding equity of Otic as the Otic Transaction. We amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of our common stock among the Selling Shareholders and to extend to May 31, 2017, the date after which we or Otic may terminate the Share Purchase Agreement.

Subject to the terms and conditions of the Share Purchase Agreement, at the closing of the Otic Transaction, the Selling Shareholders will collectively receive up to 36,911,631 shares of our common stock, assuming that all

of Otic's outstanding options and warrants are exercised prior to closing. Immediately following the closing of the Otic Transaction, the Selling Shareholders are expected to own approximately 60% of our outstanding common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing).

We, Otic and the Selling Shareholders have agreed to customary representations, warranties and covenants in the Share Purchase Agreement including, among others, covenants relating to (1) using commercially reasonable efforts to obtain the requisite approvals of our stockholders to the Tokai Voting Proposal described below, (2) non-solicitation of competing acquisition proposals by each of us and Otic, (3) our use of commercially reasonable efforts to maintain the existing listing of our common stock on The NASDAQ Stock Market, Inc., or NASDAQ, (4) ours and Otic's conduct of ours and its respective businesses during the period between the date of signing the Share Purchase Agreement and the closing of the Otic Transaction and (5) restrictions on our ability to make any capital expenditures or other expenditures, other than those contemplated by our financial model provided to Otic on the date of the Share Purchase Agreement.

Consummation of the Otic Transaction is subject to certain closing conditions, including, among other things, (1) approval by the our stockholders in accordance with applicable NASDAQ rules of the issuance of the shares of our common stock in the Otic Transaction, which we refer to as the Tokai Voting Proposal, (2) the absence of any order or injunction preventing the consummation of the Otic Transaction or any legal requirement that makes the consummation of the Otic Transaction illegal, (3) the approval by NASDAQ of the NASDAQ Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of our common stock to be issued in connection with the Otic Transaction and (4) obtaining certain governmental authorizations or consents, including certain Israeli tax rulings. Each party's obligation to consummate the Otic Transaction is also subject to other specified customary conditions, including (1) the representations and warranties of the other party being true and correct as of the date of the Share Purchase Agreement and as of the closing date of the Otic Transaction, generally subject to an overall material adverse effect qualification, and (2) the performance in all material respects by the other party of its obligations under the Share Purchase Agreement. The Share Purchase Agreement contains certain termination rights for both us and Otic, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, we may be required to pay Otic a termination fee of $1 million, or Otic may be required to pay us a termination fee of $1.5 million.

Under the Share Purchase Agreement, we agreed that promptly following the closing of the Otic Transaction, we would take all action necessary to fix the number of members of our board of directors at seven; to cause to be elected to our board of directors four persons identified by Otic, who are each reasonably acceptable to the Company; and to cause (i) the resignations of three members of our board of directors or (ii) the resignations of four members of our board of directors, and the election of one person identified by us, who is reasonably acceptable to Otic. In addition, we have agreed to take all action necessary to cause the persons identified by Otic to be appointed as executive officers of Tokai.

Upon consummation of the Otic Transaction, we will change our name to OticPharma, Inc. In addition, we intend to seek stockholder approval to effect a reverse split of our common stock at a ratio that we will determine, which is intended to ensure that the listing requirements of NASDAQ are satisfied.

Also in connection with the Share Purchase Agreement, our directors and certain entities affiliated with Apple Tree Partners holding in the aggregate approximately 36.3% of our outstanding common stock as of the date of the Share Purchase Agreement have each entered into a support agreement in favor of Otic, or the Support Agreement. The Support Agreement places certain restrictions on the transfer of the shares of our common stock held by the respective signatories thereto and covenants on the voting of such shares in favor of approving the Tokai Voting Proposal and against any actions that could adversely affect the consummation of the Otic Transaction.

In addition, we have entered into a commitment letter with Otic and certain purchasers set forth therein under which the purchasers have agreed to invest up to $7.0 million of new capital in Otic and/or Tokai prior to

or upon the closing of the Otic Transaction. Pursuant to the commitment letter, on January 31, 2017 we entered into a stock purchase agreement with the purchasers under the commitment letter under which such purchasers agreed to purchase 3,603,601 shares of our common stock at a price of $1.11 per share. The purchase and sale of our common stock pursuant to this stock purchase agreement will occur at the time of the closing of the Otic Transaction. The remaining $3.0 million will be invested in Otic prior to the closing of the Otic Transaction through the exercise of outstanding warrants.

The Treatment of Prostate Cancer

Prostate Cancer Overview

According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States, approximately 215,000 new cases of prostate cancer are diagnosed annually, and approximately 28,000 men will die from the disease each year.

Prostate cancer is most frequently diagnosed at an early stage, when it is confined to the prostate gland and its immediate surroundings. Patients with early-stage disease are typically treated with surgery or radiation therapy, or in limited circumstances, with both. For the majority of men, these procedures are successful in curing the disease. However, for others, these procedures are not curative and their prostate cancer ultimately recurs. Men with recurrent prostate cancer are considered to have advanced prostate cancer. In addition, about 15% of men diagnosed with prostate cancer have metastatic disease at the time of diagnosis. Men with metastatic disease are also considered to have advanced prostate cancer.

Treatment of Advanced Prostate Cancer

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

Because testosterone fuels prostate cancer growth, first-line therapy for advanced prostate cancer typically entails androgen deprivation therapy, or ADT, with luteinizing hormone releasing hormone, or LHRH, analogs such as the drug Lupron® (leuprolide). ADT reduces testosterone to levels that are commensurate with the levels of a male who has had surgical castration to minimize the testosterone that would otherwise fuel prostate cancer growth.

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

During the course of ADT or following diagnosis of CRPC, most patients are treated with anti-androgens, which block the binding of androgens to the androgen receptor. An example of an anti-androgen marketed in the United States is the drug Casodex® (bicalutamide). Like LHRH analogs, the anti-androgens suppress tumor growth for a period of time in many CRPC patients. However, almost all CRPC patients develop resistance to anti-androgen therapy.

Prior to 2010, the next line of treatment for patients who became resistant to treatment with LHRH analogs and anti-androgens was chemotherapy and there were no effective FDA-approved treatments for CRPC patients following chemotherapy. Since 2010, the U.S. Food and Drug Administration, or the FDA has approved five new

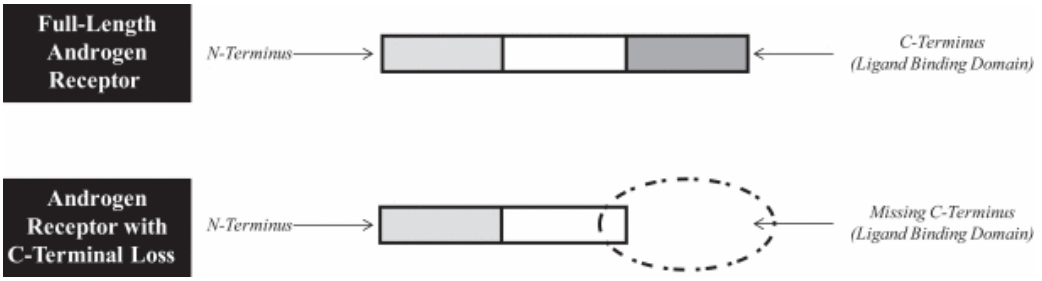
agents for the treatment of patients with CRPC. Of these new agents, the two with the highest worldwide sales in 2016 were Zytiga and Xtandi. Zytiga and Xtandi are members of a class of new oral drugs that act by disrupting the androgen receptor signaling pathway. Zytiga disrupts the androgen receptor signaling pathway by inhibiting CYP17 and reducing production of testosterone in the testes, adrenal glands and prostate cancer tumor cells. Xtandi is an androgen receptor antagonist that disrupts the androgen receptor signaling pathway by blocking the binding of testosterone or the androgen DHT with the androgen receptor. We refer to Zytiga and Xtandi as second-generation androgen signaling inhibitors.

Despite the new therapies, including Zytiga and Xtandi and additional drug candidates in late-stage clinical development, we believe that there continues to be an unmet need as there are patient populations that may not be effectively addressed by these therapies, such as mCRPC patients with C-terminal loss.

Unmet Need in Prostate Cancer Patients with C-Terminal Loss

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. The pathway and tumor cell growth is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. All proteins, including androgen receptors, are made up of a chain of amino acids that has an N-terminus at one end of the chain and a C-terminus at the other end of the chain as shown in the full-length androgen receptor depicted in Figure 1 below. In the case of androgen receptors, the C-terminus contains the ligand binding domain. The effectiveness of therapies like Zytiga and Xtandi, which act solely through CYP17 inhibition or androgen receptor antagonism, requires a functional ligand binding domain. As depicted in Figure 1 below, in the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, there is no functional ligand binding domain. This lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. As a result, we believe that patients with truncated androgen receptors with C-terminal loss may not be effectively treated by these therapies.

Figure 1: Full-Length Androgen Receptor and Androgen Receptor with C-Terminal Loss



These limitations of CYP17 inhibitors and androgen receptor antagonists have been supported by investigator-initiated studies conducted at several leading academic medical centers in which the presence of C-terminal loss or AR-V7 in patients was associated with poor responsiveness of patients' prostate tumors to Zytiga and Xtandi. Published data, however, have shown activity of docetaxel, a chemotherapeutic agent, in AR-V7 positive mCRPC patients.

Galeterone

Overview

Our lead product candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct mechanism—androgen receptor degradation. We are developing galeterone for the treatment of patients with mCRPC.

In June 2015, we initiated ARMOR3-SV, a pivotal Phase 3 clinical trial comparing galeterone to Xtandi in approximately 148 treatment-naive mCRPC patients whose prostate tumors express the AR-V7 splice variant. We believe that the AR-V7 splice variant is the most common form of C-terminal loss, or the loss of the portion of the androgen receptor that contains the ligand-binding domain. C-terminal loss generally, and AR-V7 specifically, has been clinically associated with poor responsiveness to commonly-used oral therapies for mCRPC.

On July 25, 2016, the independent Data Monitoring Committee, or DMC, for the ARMOR3-SV trial met to review safety and efficacy data from the trial. 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 and recommended that enrollment in the trial be ceased. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. In July 2016, we announced our plan to discontinue the ARMOR3-SV trial. In addition, in August 2016, we determined to discontinue enrollment in our Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga. Enrollment in the ARMOR3-SV and ARMOR2 trials has now been closed, with only ten patients in the ARMOR2 trial continuing treatment as of January 31, 2017.

We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. Moreover, if the Otic Transaction is consummated, we do not expect Otic to proceed with the development of galeterone. However, we have agreed with Otic that Otic will continue the treatment of the continuing patients in the ARMOR2 trial.

Galeterone Clinical Development

We referred to our clinical development program for galeterone as the Androgen Receptor Modulation Optimized for Response, or ARMOR, program. We submitted an investigational new drug application, or IND, to the FDA for galeterone for the treatment of CRPC in August 2009 and began clinical trials of galeterone in November 2009. Prior to suspending our ARMOR3-SV Phase 3 clinical trial, we had enrolled 213 CRPC patients and 102 healthy volunteers in our ARMOR program.

ARMOR2

In December 2012, we initiated our ARMOR2 trial, an open label Phase 2 clinical trial of galeterone. The trial was designed as a two-part trial. Part 1 of the trial was a dose escalation phase designed to confirm the dose of galeterone to be evaluated in Part 2 of the trial. Part 2 of the trial was designed to evaluate the efficacy and safety of galeterone at the dose selected in Part 1 in distinct CRPC patient populations. The primary efficacy endpoints of our ARMOR2 trial were based on a decrease in PSA levels. In August 2016, we determined to discontinue enrollment in this clinical trial. As of January 2017, 10 patients were still receiving treatment in the trial.

Part 1 of ARMOR2 Trial. In Part 1 of the trial, we enrolled 25 CRPC treatment-naïve patients with progressive disease and three patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga-refractory patients. The CRPC treatment-naïve patients were enrolled in one of three escalating dose cohorts: six patients at 1700 mg/day, 11 patients at 2550 mg/day and eight patients at 3400 mg/day. The Zytiga-refractory patients all received doses of 2550 mg/day. All patients in Part 1 of the trial received treatment for up to an initial period of 12 weeks followed by optional continued dosing for those patients who tolerated treatment and did not show signs of disease progression. Treatment was continued until disease progression or patient withdrawal due to adverse events or other reasons.

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

Part 2 of ARMOR2 Trial. In Part 2 of ARMOR2, we enrolled 98 patients and evaluated galeterone dosed at 2550 mg/day in the following CRPC populations:

- non-metastatic CRPC and mCRPC treatment-naïve patients;
- Zytiga-refractory patients; and
- patients whose disease progressed during treatment with Xtandi, whom we refer to as Xtandi-refractory patients.

The primary endpoints for Part 2 of ARMOR2 were as follows:

- Treatment-naïve patients: percentage of patients having a maximal reduction in PSA levels of at least 30% from baseline to the end of the primary treatment phase; and
- Zytiga-refractory and Xtandi-refractory patients: percentage of change in PSA levels from baseline to the end of the primary treatment phase.

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

Patients enrolled in Part 2 of the trial received treatment with galeterone at a dose of 2550 mg/day for an initial period of up to 12 weeks, followed by optional continued dosing in an extension phase for those patients who tolerated treatment and did not show signs of disease progression. Treatment continued until disease progression or patient withdrawal due to adverse events or other reasons.

Phase 2 Data Presentation. In November 2014, we presented interim efficacy and safety data from our ARMOR2 trial for patients who received the 2550 mg/day dose of galeterone at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, or EORTC.

In 60 evaluable treatment-naïve CRPC patients in Part 1 and Part 2 of the trial who received the 2550 mg/day dose of galeterone, during the first 12 weeks of dosing, 83% had a maximal reduction in PSA levels of at least 30%, and 70% had a maximal reduction in PSA levels of at least 50%. In 38 treatment-naïve mCRPC patients who received the 2550 mg/day dose, during the first 12 weeks of dosing, 84% had a maximal reduction in PSA levels of at least 30%, and 76% had a maximal reduction in PSA levels of at least 50%.

We also reported 12-week data for 37 Zytiga-refractory patients, 13 of whom showed a reduction in PSA levels, and nine Xtandi-refractory patients, five of whom showed a reduction in PSA levels.

Of the 16 treatment-naïve patients evaluable by Response Evaluation Criteria in Solid Tumors, or RECIST, three patients had a partial response and 11 patients had stable disease. Fifteen of the Zytiga-refractory patients and three of the Xtandi-refractory patients were evaluable by RECIST. Of these patients, five Zytiga-refractory patients had stable disease, and one Xtandi-refractory patient had stable disease. As measured by RECIST criteria, stable disease is achieved when the tumor has not increased in size by 20% and has not decreased by 30%, a partial response occurs when the tumor has decreased in size by at least 30%, and progressive disease occurs when the tumor has increased in size by at least 20% or new tumor lesions are identified.

Our ARMOR2 trial included CTC enumeration and characterization. At EORTC, we presented data from a retrospective subset analysis in which seven treatment-naïve CRPC patients in ARMOR2 were identified as having C-terminal loss as determined by the evaluation of C-terminal androgen receptor expression in relation to N-terminal androgen receptor expression. Six of these patients had maximal reductions in PSA levels of at least 50%. The seventh patient, who did not show any PSA reduction, discontinued therapy due to an adverse event unrelated to galeterone after approximately six weeks in the trial and did not receive the full treatment regimen.

At EORTC, we also presented interim safety results from all 107 patients treated in the 2550 mg/day dose cohort as of October 14, 2014 in ARMOR2. In these patients, galeterone was well tolerated. Approximately 90% of all treatment-emergent related adverse events reported were grade 1 or 2 in severity and were generally manageable and reversible. The majority of these events were assessed as not related or unlikely related to galeterone. In addition, there were no reported cases of seizure or mineralocorticoid excess. The most common treatment-emergent related adverse events were nausea, fatigue, pruritus, decreased appetite, diarrhea, hypokalemia and vomiting.

As of January 31, 2017, nine of the 126 patients enrolled in ARMOR2 had 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 and no adverse events had resulted in interruptions or delays of the clinical trial.

ARMOR3-SV

In June 2015, we initiated ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone. The ARMOR3-SV trial was designed to compare galeterone to Xtandi in approximately 148 treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant. Under the trial protocol, patients were randomized on a one-to-one basis to receive either galeterone or the control arm treatment, Xtandi. Patients in the galeterone arm received a dose of 2550 mg/day, and patients in the Xtandi arm received a dose of 160 mg/day. Treatment was continued until radiographic evidence of disease progression as determined by a blinded, independent central imaging assessment or patient withdrawal due to adverse events or other reasons.

Only patients with the AR-V7 splice variant were enrolled in the trial. These patients were identified by analysis of a blood sample at a central laboratory using an AR-V7 specific clinical trial assay developed under our collaboration with Qiagen Manchester Limited, or Qiagen, which we terminated effective September 2016 following our discontinuation of the trial.

The primary endpoint of the trial was rPFS as determined by a blinded, independent central imaging assessment measured from the time of patient randomization to the time of radiographic evidence of disease progression or time of death from any cause. In order to achieve the primary endpoint, results from the trial needed to demonstrate an 82% increase in median rPFS in the galeterone arm as compared to the Xtandi arm. Such a result would be statistically significant and would likely have been considered a clinically relevant outcome. The secondary endpoints included overall survival, safety, and time to next anti-cancer intervention or time to next cytotoxic therapy.

ARMOR3-SV was conducted at over 100 clinical sites in several countries in North America, Western Europe and Australia.

On July 25, 2016, the independent data monitoring committee, or DMC, for the ARMOR3-SV trial met to review safety and efficacy data from the trial. 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 and recommended that enrollment in the trial be ceased. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. On July 26, 2016, we

publicly disclosed our plans to discontinue the ARMOR3-SV trial. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC in the future.

Androgen Receptor Degradation Compounds

In conjunction with a license from the University of Maryland, Baltimore, or UMB, we have a drug discovery program, known as ARDA (androgen receptor degradation agents), under which we identified novel compounds designed to have potent androgen receptor degradation activity. Our most advanced series of compounds from this program is currently in preclinical development. We planned to target compounds developed under our ARDA program for patients with androgen receptor signaling diseases, including prostate cancer, either alone or in combination with other products. We are evaluating potential paths forward for our ARDA program in connection with our review of galeterone.

Manufacturing

Galeterone is a small molecule drug candidate that is manufactured through a reproducible synthetic process from readily available raw materials. Galeterone is manufactured in a proprietary formulation based on spray dried dispersion technology that is designed to produce a product that provides consistent drug exposure.

We do not have our own manufacturing facilities. We currently rely, and expect to continue to rely, on a limited number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials. We do not have long-term agreements with any of these third parties.

Competition

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 were 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 were pursuing, or indications that we may in the future seek to address, are widely accepted by physicians, patients and payors, which may make it difficult for us to replace them with any products that we successfully develop and are permitted to market.

We were developing galeterone for multiple prostate cancer patient populations. If galeterone were approved for any of these indications, it would compete with 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, either hormonal or non-hormonal, 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 CRPC include Zytiga, marketed by Janssen Biotech, Inc. and Xtandi, marketed by Astellas Pharma US, Inc. and Medivation, Inc. Approved non-hormonal agents for CRPC include Taxotere® (docetaxel) and Jevtana® (cabazitaxel), marketed by sanofi-aventis U.S. LLC; Provenge® (sipuleucel-T), marketed by 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.

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.

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

Intellectual Property

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

Because patent applications in the United States and certain other jurisdictions can be maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention or in post-grant challenge proceedings at the USPTO or at a foreign patent office, such as *inter partes* review and post grant review proceedings at the USPTO and opposition proceedings at the European Patent Office, that challenge priority of invention or other features of patentability. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

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

Galeterone Patent Portfolio

Our success will depend, in part, on our ability to obtain and maintain patent protection for 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 January 31, 2017, we owned and/or licensed 18 issued U.S. patents, seven pending U.S. non-provisional patent applications, three pending international patent applications, 88 granted foreign patents and 67 pending foreign applications in our galeterone patent portfolio. Our owned and/or licensed patent 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 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.

We have no patent protection specifically covering the chemical structure of galeterone. As a result, a third party that obtains regulatory approval of a product with the same active ingredient as galeterone may be able to market such product so long as the third party does not infringe any other patents owned or licensed by us with respect to galeterone. For this reason, we have filed for or licensed patents and patent applications relating to galeterone covering methods of use, pharmaceutical compositions, combination treatments, prodrugs, metabolites, and analogs of galeterone and their use.

Method of Use. We have licensed from UMB a U.S. patent covering a method of treating prostate cancer in a human subject by administering galeterone, which is expected to expire in 2027. The license also includes

granted patents in the European Patent Convention and Japan covering the use of galeterone to treat prostate disease, including prostate cancer and prostatic hyperplasia. Similar patents have been granted or allowed in Australia, Canada, Hong Kong, South Korea, Mexico, New Zealand, Singapore, South Africa, and the Eurasian Patent Organization. These patents are expected to expire in 2026. In addition, we have pending applications in Brazil, China, India, Israel and Indonesia. We have also licensed from UMB a PCT patent application covering the use of galeterone to inhibit proliferation of a cell having a specific splice variant form of the androgen receptor. The term of a patent derived from this PCT application, if issued, would be expected to expire in 2034.

We have also filed a PCT patent application covering the use of galeterone in treating prostate cancer mediated by androgen receptor variants, including splice variants such as AR-V7, as well as the use of biomarkers in identifying patients who are expected to respond to treatment with galeterone. This application is jointly owned with UMB and the University of Washington, and we have exclusively licensed those institutions' undivided interest in such application and any resulting patents. The term of a patent derived from this PCT application, if issued, would be expected to expire in 2034.

Pharmaceutical Compositions. We have filed U.S. and international patent applications relating to a galeterone formulation and its use where the galeterone is present in a spray dried dispersion. We have pending applications in the United States, the European Union, Australia, Brazil, Canada, China, India and Japan. The term of any patent in this family, if issued, would be expected to expire in 2032. In addition, we have licensed from UMB a U.S. patent application covering a pharmaceutical composition of galeterone. The term of any patent, if issued, claiming priority to this application would be expected to expire in 2026.

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

AR-V7 Specific Assay and Companion Diagnostic Test. We have an exclusive license from The Johns Hopkins University, or Johns Hopkins, for 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. If issued, the term of the resulting patents would be expected to expire in 2029. These patent applications may provide protection for an AR-V7 specific assay or companion diagnostic test using this assay that we may develop and commercialize. However, these patent applications do not provide any protection for galeterone or for galeterone's pharmaceutical formulations or uses.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining

term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

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

License Agreement with University of Maryland, Baltimore

In May 2006, we entered into a master license agreement with UMB. Pursuant to the license agreement, UMB granted us an exclusive worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen steroids including galeterone, which we refer to as licensed products, and to otherwise practice the patent rights in any manner, for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted us a first option to receive an exclusive license to UMB's rights in certain improvements to the licensed products, which improvements we refer to as licensed improvements. We have exercised our option and acquired exclusive rights to licensed improvements under four amendments to the license agreement. In March 2009, the license agreement was amended to grant us an exclusive license to oral prodrugs of the licensed products. In April 2012, the license agreement was amended to grant us an exclusive license to compositions and methods of inducing endoplasmic reticulum stress. In October 2013, the license agreement was amended to grant us an exclusive license to a patent application directed to analogs of galeterone that disrupt androgen receptor signaling by degrading the androgen receptor. In March 2016, the license agreement was amended to grant us an exclusive license for the use of galeterone and other compounds previously licensed from UMB for the treatment of pancreatic cancer.

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

country-by-country basis as of the later of the expiration date of the last to expire of the claims of the patent rights licensed to us under the agreement in such country or ten years after the first commercial sale of a licensed product in such country.

In consideration for the rights granted to us, we made an upfront payment to UMB of $20,000 following the execution of the license agreement and a payment of $10,000 following the execution of each of the March 2009, April 2012, October 2013 and March 2016 amendments. We are obligated to pay UMB an annual maintenance fee of $10,000 each year until the first commercial sale. In addition, we paid UMB a $50,000 milestone payment in 2009 upon the submission of our investigational new drug application, or IND, for galeterone and a $40,000 milestone payment in 2013 upon the issuance of the first patent related to UMB's prodrug patent application. We are obligated to make an additional $50,000 milestone payment to UMB for each additional IND we file for a licensed product and a $100,000 milestone payment upon the approval of each NDA for a licensed product by the FDA. In addition, under the March 2016 amendment to the license agreement, we are obligated to make milestone payments of $50,000 upon the first-in-human dosing of a patient with a pancreatic cancer licensed product and $100,000 upon dosing of the first patient in the first Phase 3 clinical trial of a pancreatic cancer licensed product. We must also pay UMB a low-single digit percentage royalty on aggregate worldwide net sales of licensed products, including sales by our sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. Our royalty obligations are subject to specified reductions in the event that we are required to obtain additional licenses from third parties or in the event of specified competition from third-party products licensed by UMB. Our minimum annual royalty payment to UMB is $50,000 beginning in the year following the year in which the first commercial sale occurs. We must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, as of April 10, 2012, we assumed responsibility for all patent expenses related to the prosecution and maintenance of the licensed patents.

License Agreement with The Johns Hopkins University

In January 2015, we entered into an exclusive license agreement with Johns Hopkins. Pursuant to the license agreement, Johns Hopkins granted us an exclusive worldwide license under certain patent applications and a non-exclusive license under certain know-how, 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 us an option to negotiate an exclusive license to Johns Hopkins's rights in certain improvements to the licensed products.

Under the terms of the license agreement, we are obligated to diligently develop, manufacture and sell licensed products. We are also obligated to use commercially reasonable efforts to achieve specified milestone events by specified dates. Unless the license agreement with Johns Hopkins is terminated earlier as provided below, the license from Johns Hopkins expires on a country-by-country basis as of the later of the expiration date of the last to expire of the claims of the patent rights licensed under the agreement in such country or ten years after the first commercial sale of a licensed product in such country. Johns Hopkins may terminate the agreement if we fail to achieve such milestone events and do not cure such failure within a specified termination notice period. Johns Hopkins may also terminate the agreement upon a material breach by us under the agreement if we do not cure such breach within a specified notice period or upon bankruptcy or insolvency. We may terminate the agreement at any time upon 90 days' notice.

In consideration for the rights granted to us under the license agreement, we made an upfront payment to Johns Hopkins of $75,000 following the execution of the license agreement. We are obligated to pay Johns Hopkins an annual minimum royalty of up to $30,000. We are also obligated to make milestone payments to Johns Hopkins upon the achievement of specified technical and commercial milestones. We paid $50,000 during 2015 related to the achievement of two of these milestones. If all such milestones are achieved, the total milestone payments owed to Johns Hopkins would equal in the aggregate $700,000. We must also pay Johns

Hopkins single digit percentage royalties on aggregate worldwide net sales of licensed products (and 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. We must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse them for patent costs.

Government Regulation and Product Approvals

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

Review and Approval of Drugs in the United States

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

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

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

- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, as applicable, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Additional preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Human Clinical Studies in Support of an NDA

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

Typically, the FDA will require one IND for early development studies where the sponsor is uncertain of the indication or dosage form of the proposed product, where the drug is being developed for closely related indications within a single review division at FDA, or where there are multiple closely-related routes of administration using the same dosage formulation. On the other hand, multiple INDs may be required where there are two or more unrelated conditions being developed or where multiple dosage forms are being extensively investigated or where multiple routes of administration are being evaluated.

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

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

Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease such as cancer or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: Phase 3 clinical trials are commonly referred to as "pivotal" trials, which typically denotes a trial which generates the principal data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. In Phase 3 trials, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

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

Section 505(b)(2) NDAs

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

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

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, which for federal fiscal year 2017 is $2,038,100. The sponsor of an approved NDA is also subject to annual product and establishment user fees, which for 2017 are $97,750 per product and $512,200 per establishment.

The FDA conducts a preliminary review of an NDA within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA has agreed to specified performance goals in the review process of NDAs. Under the agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which the FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that the FDA receives the application. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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

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

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

Fast Track, Breakthrough Therapy and Priority Review Designations

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

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a

fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

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

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

Accelerated Approval Pathway

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

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

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

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

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

Post-Approval Requirements

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and

impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, as well as the Drug Supply Chain Security Act, or DSCA, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the federal level, and set minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The DSCA imposes requires to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

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

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

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred

to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

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

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

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

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

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

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

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

Orphan Drug Designation and Exclusivity

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

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

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent restoration of up to five

years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

The 21st Century Cures Act

On December 13, 2016, President Obama signed the 21st Century Cures Act ("Cures Act") into law. The Cures Act is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increasing funding for FDA to spend on innovation projects. The new law also amends the Public Health Service Act to reauthorize and expand funding for the National Institutes of Health. The Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directs the Centers for Disease Control and Prevention to expand surveillance of neurological diseases.

With amendments to the FDCA and the Public Health Service Act ("PHSA"), Title III of the Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the priority review voucher program for certain drugs intended to treat rare pediatric diseases; creates a new priority review voucher program for drug applications determined to be material threat medical countermeasure applications; revises the FDCA to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Clinical Trial Approval in the EU

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a

competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. In April 2014, the EU adopted a new Clinical Trials Regulation, which will be directly applicable to and binding without the need for any national implementing legislation. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial will be required to submit a single application for approval of a clinical trial to a reporting EU Member State (RMS) through an EU Portal. The submission procedure will be the same irrespective of whether the clinical trial is to be conducted in a single EU Member State or in more than one EU Member State. The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting for clinical trials.

Approval of Drug Products in the EU

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

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

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

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

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

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically

debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the EU. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In the European Union, pricing and

reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, 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 Health Care Reform Law, known as the federal Physician Payments Sunshine Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, within the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

Healthcare Reform in the United States

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the Affordable Care Act of importance to potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established the Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. The Affordable Care Act provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

With the new Administration and Congress, there will likely be additional legislative changes, including repeal and replacement of certain provisions of the Affordable Care Act. To that end, on January 20, 2017, the President issued an Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal. The Executive Order declares that, pending repeal of the Affordable Care Act, it is imperative for the executive branch to ensure that the law is being efficiently implemented, take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the Act, and prepare to afford the States more flexibility and control to create a more free and open healthcare market. The Order directs the Secretary of Health and Human Services and the heads of all other executive departments and agencies with authorities and responsibilities under the Affordable Care Act to exercise their authority and discretion to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Affordable Care Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.

With respect to repeal of the Affordable Care Act and its replacement with new legislation, it is unclear when such legislation will be enacted, what it will provide and what impact it will have on the availability of healthcare and containing or lowering the costs of healthcare.

Employees

In July 2016, we implemented a reduction in force that reduced the number of our employees by approximately 60 percent. As of January 31, 2017, we had eight full-time employees, two of whom were primarily engaged in research and development activities.

Corporate Information

We were incorporated under the laws of the State of Delaware on March 26, 2004 under the name Tokai Pharmaceuticals, Inc. Our principal executive office is located at 255 State Street, 6th Floor, Boston, Massachusetts 02109, and our telephone number is (617) 225-4305.

Information Available on the Internet

Our Internet website address is *www.tokaipharmaceuticals.com*. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form

10-K. We have included our website address in this in this Annual Report on Form 10-K solely as an inactive textual reference. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through the "SEC Filings" section of our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's website at *http://www.sec.gov*.

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 Annual Report on Form 10-K. 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.

The following sets forth certain risks and uncertainties related to us, including risks and uncertainties related to the Otic Transaction and risks and uncertainties to which Tokai, as an independent company, is subject, and will continue to be subject, to if the Otic Transaction is not consummated.

Risks Related to our Proposed Transaction with Otic

Our strategic transaction with Otic may not be consummated or may not deliver the anticipated benefits we expect.

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 was 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 determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets. As part of this process, in December 2016, we entered into a share purchase agreement, or the Share Purchase Agreement, with Otic Pharma, Ltd., or Otic, and the shareholders of Otic named therein, pursuant to which, among other things, each Otic shareholder agreed to sell to us, and we agreed to purchase from each Otic shareholder, all of the ordinary and preferred shares of Otic in exchange for shares of our common stock. We refer to this transaction as the Otic Transaction. As a result of the Otic Transaction, Otic will become our wholly owned subsidiary and the Otic shareholders are expected to own approximately 60% of our common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing). We are devoting substantially all of our time and resources to consummating this transaction, however, there can be no assurance that such activities will result in the consummation of this transaction or that such transaction will deliver the anticipated benefits or enhance stockholder value.

During the pendency of the Otic Transaction, we may not be able to enter into a business combination with another party under certain circumstances because of restrictions in the Share Purchase Agreement, which could adversely affect our business.

Covenants in the Share Purchase Agreement impede our ability to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Otic Transaction. As a result, if the Otic Transaction is not completed, we may be at a disadvantage to our competitors during that period.

Certain provisions of the Share Purchase Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Share Purchase Agreement.

The terms of the Share Purchase Agreement prohibit each of us and Otic from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and is reasonably capable of being consummated. In addition, if the Share Purchase Agreement is terminated by us or Otic under certain circumstances, including because of a decision of our board of directors to recommend a superior proposal, we would be required to pay a termination fee of $1.0 million to Otic. This termination fee may discourage third parties from submitting alternative takeover proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend an alternative proposal.

The announcement and pendency of the Otic Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.

The announcement and pendency of the Otic Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. In the event that the Otic Transaction is not completed, the announcement of the termination of the Share Purchase Agreement may also adversely affect the trading price of our common stock and our business prospects.

Failure to consummate the Otic Transaction may result in us paying a termination fee to Otic and could harm our common stock price and our future business and operations.

The Otic Transaction will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Share Purchase Agreement is terminated in accordance with its terms. If the Otic Transaction is not consummated, we are subject to the following risks:

- if the Share Purchase Agreement is terminated under certain circumstances, we will be required to pay Otic a termination fee of $1.0 million; and
- the price of our common stock may decline and remain volatile.

If the Otic Transaction does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets, dissolve or liquidate our assets or seek to continue to operate our business. If we seek another strategic transaction or attempt to sell or otherwise dispose of our various assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Otic Transaction or as to the timing of such transaction. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

If we were to seek to continue our business, we would need to complete our assessment of our galeterone and ARDA programs to determine whether and how to continue one or both of these development programs or acquire one or more other product candidates. We would also need to raise funds to support continued operations and re-assess our workforce requirements in consideration of our reduced workforce.

If we do not successfully consummate the transaction with Otic, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.

If the Otic Transaction does not close for any reason, our board of directors may elect to, among other things, dissolve or liquidate our assets. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the Otic Transaction. Further, the Share Purchase Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, we may be required to pay Otic a termination fee of $1.0 million, which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to

make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment and separation agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of us; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of us. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

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 $38.0 million for the year ended December 31, 2016, $45.1 million for the year ended December 31, 2015 and $23.3 million for the year ended December 31, 2014. As of December 31, 2016, we had an accumulated deficit of $169.4 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 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 and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future, however, we may still 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 was conducted in parallel with our review of development options for galeterone and our ARDA program, our board of directors determined to review alternatives with the goal of maximizing stockholder value. Potential strategic alternatives that we explored and evaluated during this review process included, 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. This review process culminated in us entering into the Share Purchase Agreement with Otic and the Otic shareholders. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the

Otic Transaction is consummated or if we determine to pursue an alternate strategy, 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.

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 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.

If we do not successfully consummate the Otic Transaction, our board of directors may attempt to continue our business. 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 December 31, 2016, we had cash and investments of $27.4 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, if we do not successfully consummate the Otic Transaction, we expect our cash and investments as of December 31, 2016 to be sufficient to fund operations

through at least the first quarter of 2018. We have devoted a significant portion of our cash resources to the development of galeterone and ARMOR3-SV trial. However, in July 2016, we announced our plan to discontinue the ARMOR3-SV clinical trial. While we have entered into the Share Purchase Agreement, our operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated and we determine to further develop galeterone, proceed with our ARDA program or both, we will need to obtain substantial additional funding. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, 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 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.

If the Otic Transaction is not consummated, and we decide to continue our historical business operations, our future capital requirements will depend on many factors, including:

- 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. If adequate funds are not available to us on a timely basis, we may be required to curtail our operations.

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.

If the Otic Transaction is not consummated, we will need to continue our 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. 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 was conducted in parallel with our review of development options for galeterone and our ARDA drug program, our board of directors determined to review alternatives with the goal of maximizing stockholder value. Potential strategic alternatives that we explored and evaluated during this review process included, 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. We entered into the Share Purchase Agreement with Otic and the Otic shareholders as a result of this process. If the Otic Transaction is not consummated, our board of directors will need to resume this review of strategic alternatives. 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 further change strategic direction, we have limited our research and development activities to manage our cash position. In such event, 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 would 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 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 the Otic Transaction is consummated, we do not expect Otic to proceed with the development of galeterone or our ARDA program. If the Otic Transaction is not consummated, we expect to continue to evaluate potential paths forward for galeterone and our ARDA program. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future.

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 discontinuance of 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 may develop 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 our 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 at the time, 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. If the Otic Transaction is consummated, we do not expect Otic to proceed with the development of galeterone or our ARDA program. If the Otic Transaction is not consummated, we will continue to evaluate potential paths forward for galeterone and our ARDA program. Based on 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 evaluating potential paths forward for galeterone and our ARDA program. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients 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 the Otic Transaction is not consummated and 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 January 31, 2017, nine of the 126 patients enrolled in ARMOR2 had 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 and no adverse events had resulted in interruptions or delays of the clinical trial. 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. Even if the Otic Transaction is not consummated, based on our review of unblinded data from the ARMOR3-SV clinical trial reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients 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 were 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.

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 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 January 31, 2017, we owned and/or licensed 18 issued U.S. patents, seven pending U.S. non-provisional patent applications, three pending international patent applications, 88 granted foreign patents and 67 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 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 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. In addition, there have been recent public announcements by members of the U.S. Congress and the new presidential administration regarding their plans to repeal and replace the Health Care Reform Law. However, it remains unclear how a repeal or replacements of these programs might affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

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, and as of January 31, 2017, we had eight full-time 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, employees who were not affected by the reduction in force may seek 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 December 31, 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 December 31, 2016. As a result, each of these stockholders acting individually, as well as together, may exercise significant control over our management and affairs. In particular, each of our directors and certain entities affiliated with Apple Tree Partners holding in the aggregate approximately 36.3% of our outstanding common stock have each entered into a support agreement in favor of Otic in connection with the Otic Transaction.

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 $0.73 per share for the period beginning September 17, 2014, our first day of trading on The NASDAQ Global Market, through January 31, 2017. 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:

- the outcome of our proposed Otic Transaction;
- 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. A lead plaintiff has yet to be appointed.

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 February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.

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. A prospective lead plaintiff has filed a motion to consolidate the Doshi and Garbowski Actions for all purposes. A lead plaintiff has yet to be appointed.

On December 5, 2016, a putative securities class action was filed in the Business Litigation Session of the Superior Court Department of the Suffolk County Trial Court, Massachusetts ("Massachusetts State Court") 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 IPO, entitled Wu v. Tokai Pharmaceuticals, Inc., et al., 16-3725 BLS ("Wu Action"). The lawsuit alleges that our IPO registration statement made false and misleading statements and omissions about our clinical trials for galeterone, in violation of the Securities Act. The plaintiff seeks to represent a class of purchasers of our common stock in or traceable to our IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On December 19, 2016, defendants removed the Wu Action to the U.S. District Court for the District of Massachusetts, where it was captioned Wu v. Tokai Pharmaceuticals, Inc., et al., 16-cv-12550, and assigned to the same judge presiding over the Doshi and Garbowski Actions. On December 22, 2016, defendants filed a motion to consolidate the Wu Action with the Doshi and Garbowski Actions. On January 6, 2017, plaintiff filed a motion to remand the Wu Action to Massachusetts State Court.

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 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

We conduct our operations in leased facilities. We lease 15,981 square feet of office space in Boston, Massachusetts under a lease with the prime landlord, 255 State Street, LLC. Under this lease, we are obligated to pay approximately $69,900 per month in lease payments from January 2017 through July 2018. Prior to January 2017, we leased the existing office space under a sublease agreement with Boston Private Wealth LLC which expired on December 31, 2016. Under this sublease, we were obligated to pay approximately $45,300 per month in lease payments through March 30, 2016 and, beginning on April 1, 2016, we were obligated to pay approximately $46,600 per month in lease payments through December 31, 2016.

ITEM 3. *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. A lead plaintiff has yet to be appointed.

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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. A prospective lead plaintiff has filed a motion to consolidate the Doshi and Garbowski Actions for all purposes. A lead plaintiff has yet to be appointed.

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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 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

PART II

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "TKAI" on the NASDAQ Global Market and has been publicly traded since September 17, 2014. Prior to this time, there was no public market for our common stock. The following table sets forth the high and low sales price of our common stock as reported on the NASDAQ Global Market for the periods indicated:

	High	Low
Year ended December 31, 2015:		
First Quarter	$16.10	$11.10
Second Quarter	$14.45	$ 9.77
Third Quarter	$14.71	$ 9.95
Fourth Quarter	$12.93	$ 8.50
Year ended December 31, 2016:		
First Quarter	$ 8.63	$ 4.93
Second Quarter	$ 8.80	$ 5.03
Third Quarter	$ 5.86	$ 0.98
Fourth Quarter	$ 2.09	$ 0.73

Holders of Our Common Stock

As of January 31, 2017, there were approximately 13 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

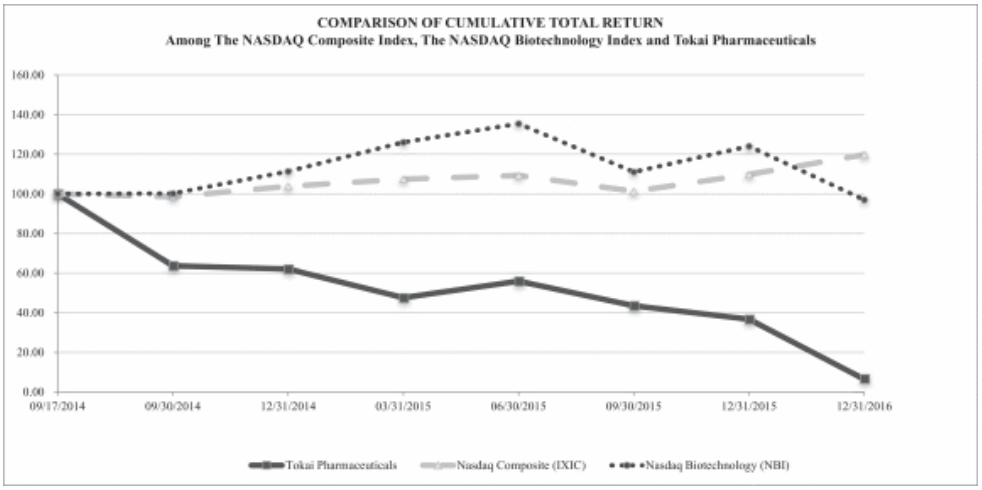
Dividends

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

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, for purposes of Section 18 of the Exchange Act , nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Composite Index and to the NASDAQ Biotechnology Index from September 17, 2014 (the first date that shares of our common stock were publicly traded) through December 31, 2016. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on September 17, 2014, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



Use of Proceeds from Registered Securities

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 December 31, 2016, we estimate that we have used approximately $87.2 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 6. ***SELECTED FINANCIAL DATA***

The selected statements of operations data for the years ended December 31, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 have been derived from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 are derived from our audited financial statements not included in this Annual Report on Form 10-K. The selected financial data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development (1)	25,024	32,638	14,577	12,201	7,370
General and administrative (1)	13,099	12,623	8,885	3,548	2,279
Total operating expenses	38,123	45,261	23,462	15,749	9,649
Loss from operations	(38,123)	(45,261)	(23,462)	(15,749)	(9,649)
Interest and other income, net	164	174	166	24	—
Net loss	(37,959)	(45,087)	(23,296)	(15,725)	(9,649)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(94)	(34)
Net loss attributable to common stockholders	$ (37,959)	$ (45,087)	$ (23,296)	$ (15,819)	$ (9,683)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.68)	$ (2.01)	$ (3.60)	$ (38.02)	$ (31.09)
Weighted average common shares outstanding, basic and diluted	22,634,641	22,484,343	6,469,289	416,037	311,474

(1) Amounts include stock-based compensation expense, as follows:

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Research and development	$ 526	$ 634	$ 552	$ 91	$ 87
General and administrative	2,476	2,267	1,556	147	123
	$3,002	$2,901	$2,108	$ 238	$ 210

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Balance Sheet Data:					
Cash and investments	$27,398	$63,957	$105,256	$ 31,753	$ 11,691
Working capital	26,724	61,008	103,268	29,969	9,908
Total assets	29,761	67,974	107,744	32,287	11,962
Redeemable convertible preferred stock	—	—	—	85,345	49,845
Total stockholders' equity (deficit)	26,858	61,724	103,501	(55,267)	(39,901)

ITEM 7. *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 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 this Annual Report on Form 10-K, 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. We have focused substantially all of our research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC. We also have a drug discovery program, known as ARDA (androgen receptor degradation agents), under which we identified novel compounds for patients with androgen receptor signaling diseases, including prostate cancer.

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 mCRPC patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee, or 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 conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. All patients enrolled in the ARMOR3-SV clinical trial have discontinued treatment.

In addition, in August 2016, we determined to discontinue enrollment in our Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi and not to proceed with our planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga ® (abiraterone acetate). Ten patients in the ARMOR2 trial continue treatment as of January 31, 2017.

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 a review of development options for galeterone and the ARDA program. We incurred $1.0 million of expenses during the year ended December 31, 2016 related to the workforce reduction including severance, benefits and related costs of which $0.3 million and $0.7 million were recorded in research and development expenses and general and administrative expenses, respectively. We paid $0.8 million of these costs during the year ended December 31, 2016 and expect to pay $0.2 million in the first quarter of 2017.

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 was conducted in parallel with a review of development options for galeterone and the ARDA program, our board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets.

As a result of this process, in December 2016, we entered into a share purchase agreement, or the Share Purchase Agreement, with Otic Pharma, Ltd., or Otic, and the shareholders of Otic named therein, pursuant to which, among other things, each Otic shareholder agreed to sell to us, and we agreed to purchase from each Otic shareholder, all of the ordinary and preferred shares of Otic in exchange for shares of our common stock. We refer to this transaction as the Otic Transaction. As a result of the Otic Transaction, Otic will become our wholly owned subsidiary and the Otic shareholders are expected to own approximately 60% of our common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing). We amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of our common stock among the Selling Shareholders and to extend to May 31, 2017, the date after which we or Otic may terminate the Share Purchase Agreement. See "Note 13. Share Purchase Agreement" of the Notes to the Financial Statements included elsewhere in this Annual Report on Form 10-K for further information regarding the Otic Transaction.

In January 2017 we entered into a stock purchase agreement, or the Stock Purchase Agreement, with certain purchasers named therein, or the purchasers, under which the purchasers agreed to purchase approximately $4.0 million of our common stock through the purchase of 3,603,601 shares of our common stock at a price of $1.11 per share. The Stock Purchase Agreement provides for the purchase and sale of our common stock to occur at the time of the closing of the Otic Transaction, subject to customary closing conditions, including the closing of the Otic Transaction.

We cannot provide any commitment regarding when or if the Otic Transaction or the Stock Purchase Agreement will be consummated as, among other conditions, the issuance of shares of our common stock in the Otic Transaction and under the Stock Purchase Agreement are subject to the approval of our stockholders. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, our future business, prospects, financial position 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 $38.0 million for the year ended December 31, 2016, $45.1 million for the year ended December 31, 2015 and $23.3 million for the year ended December 31, 2014. As of December 31, 2016, we had an accumulated deficit of $169.4 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. If the Otic Transaction is not consummated, and 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 or 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 December 31, 2016, we had cash and investments of $27.4 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, if we do not successfully consummate the Otic Transaction, we expect our cash and investments as of December 31, 2016 to be sufficient to fund operations through at least the first quarter of 2018. While we have entered into the Share Purchase Agreement, our operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, 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 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 that was 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 third-party license agreements; 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 licensing agreements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses in the 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 $25.0 million for the year ended December 31, 2016 and $32.6 million for the year ended December 31, 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 the Otic Transaction is not consummated and 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. Although the trial has been discontinued, we anticipate that we will have some continuing expenses related to the wind-down of the trial in 2017. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed to date, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. 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 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, 2016, we had federal and state net operating loss carryforwards of $38.2 million and $34.3 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 $1.3 million and $0.5 million, respectively, as of December 31, 2016, which begin to expire in 2025 and 2028, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of $121.2 million that we have capitalized for income tax purposes as of December 31, 2016.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have 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 the estimates, assumptions and judgments involved in the

accounting policies described below may have the greatest potential impact on our financial statements and, therefore, consider these to be our critical accounting policies. Accordingly, we evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also Note 2, *Summary of Significant Accounting Policies,* of the Notes to Financial Statements included elsewhere in this Annual Report on Form 10-K for information about these critical accounting policies, as well as a description of our other significant accounting policies.

Research and Development Expenses

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to our research and development activities, including manufacturing expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. We expense raw materials used to manufacture our drug substance when received.

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

- clinical research organizations in connection with clinical trials;
- investigative sites or other providers in connection with clinical trials;
- Qiagen Manchester Limited, our former collaborator, in connection with the development of the AR-V7 clinical trial assay and a companion diagnostic test;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple clinical research organizations and investigative sites that manage and conduct clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. For the years ended December 31, 2016, 2015 and 2014, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Accounting for Stock-Based Compensation

We measure all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant. The fair value of the awards is recognized as compensation expense, net of

estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions, while the graded vesting method is applied to all grants with both service and performance conditions. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested portion of the awards is re-measured using the then-current fair value of the award.

We classify stock-based compensation expense in our statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to September 2014, we were a privately-held company and lacked company-specific historical and implied volatility information. Therefore, we estimated our expected volatility based on the historical volatility of our publicly traded peer companies. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price following our initial public offering. The expected term assumption is based on the "simplified method" for estimating the expected term for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to U.S. Treasury bond yields at or near the time of grant for time periods similar to the expected term of the award. The relevant data used to determine the value of the stock option grants on a weighted average basis is as follows:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.52%	1.79%	1.83%
Expected term (in years)	5.91	6.01	5.95
Expected volatility	74.7%	74.2%	79.4%
Expected dividend yield	0%	0%	0%

The assumptions used in determining the fair value of stock-based awards represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different in the future. We recognize compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, we considered our historical experience of actual forfeitures to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from our estimate, we may be required to record adjustments to stock-based compensation expense in future periods.

JOBS Act

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. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company", we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection

Act, (iii) 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 (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015:

	Year Ended December 31,		
	2016	2015	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	25,024	32,638	(7,614)
General and administrative	13,099	12,623	476
Total operating expenses	38,123	45,261	(7,138)
Loss from operations	(38,123)	(45,261)	7,138
Interest income and other income, net	164	174	(10)
Net loss	$ (37,959)	$ (45,087)	$ 7,128

Research and Development Expenses

	Year Ended December 31,		
	2016	2015	Change
	(in thousands)		
Galeterone for prostate cancer	$ 19,320	$ 27,674	$(8,354)
Other early-stage development programs and additional indications for galeterone	1,041	685	356
Unallocated research and development expenses	4,663	4,279	384
Total research and development expenses	$ 25,024	$ 32,638	$(7,614)

The decrease in research and development expenses associated with our galeterone for prostate cancer program for the year ended December 31, 2016 compared to the year ended December 31, 2015 was due primarily to a decrease in the costs of clinical trials of $4.0 million, decreased costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test of $2.2 million and decreased manufacturing costs of $2.0 million. The decrease in clinical trial costs was primarily due to the discontinuation of the ARMOR3-SV clinical trial announced in July 2016 following the recommendation of the trial's DMC. Costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test for the year ended December 31, 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 year ended December 31, 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 ARMOR3-SV trial.

General and Administrative Expenses

	Year Ended December 31,		
	2016	2015	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 6,230	$ 5,671	$ 559
Professional and consultant fees	4,741	4,793	(52)
Facility related and other	2,128	2,159	(31)
Total general and administrative expenses	$ 13,099	$ 12,623	$ 476

The increase in personnel related costs for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily due to severance costs related to the workforce reduction that occurred in the third quarter of 2016.

Interest and Other Income, net

For the years ended December 31, 2016 and 2015, interest and other income, net consisted primarily of interest on investments.

Comparison of the Years Ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	32,638	14,577	18,061
General and administrative	12,623	8,885	3,738
Total operating expenses	45,261	23,462	21,799
Loss from operations	(45,261)	(23,462)	(21,799)
Interest and other income, net	174	166	8
Net loss	$ (45,087)	$ (23,296)	$(21,791)

Research and Development Expenses

	Year Ended December 31,		
	2015	2014	Change
	(in thousands)		
Galeterone for prostate cancer	$ 27,674	$ 10,970	$16,704
Other early-stage development programs and additional indications for galeterone	685	139	546
Unallocated research and development expenses	4,279	3,468	811
Total research and development expenses	$ 32,638	$ 14,577	$18,061

The increase in research and development expenses associated with our galeterone for prostate cancer program for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily

due to increased costs of clinical trials of $10.4 million, costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test of $3.9 million, and increased manufacturing costs of $2.1 million. The increase in clinical trial costs was primarily related to the initiation of ARMOR3-SV during 2015, and costs associated with other clinical trials to support the submission of an NDA for galeterone. ARMOR3-SV costs included the purchase of Xtandi to be used in the trial for comparison against galeterone. Costs associated with the development of our AR-V7 clinical trial assay and companion diagnostic test included a fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the assay and companion diagnostic test. The increase in manufacturing costs was primarily due to a large purchase of raw materials during the year ended December 31, 2015 for use in the manufacture of registration lots and process validation activities 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 and facility costs as a result of increased headcount in our research and development function.

General and Administrative Expenses

	Year Ended December 31,		
	2015	2014	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 5,671	$ 4,022	$1,649
Professional and consultant fees	4,793	3,863	930
Facility related and other	2,159	1,000	1,159
Total general and administrative expenses	$ 12,623	$ 8,885	$3,738

The increase in personnel related costs for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to increased headcount in our general and administrative function and an increase in overall compensation. Personnel related costs also increased in 2015 due to an increase in stock-based compensation expense of $0.7 million related to additional employee stock options granted and a higher value of our common stock. Professional and consultant fees increased in 2015 compared to 2014 primarily due to an increase of $2.0 million in patent costs and other fees associated with operating as a public company and costs associated with pre-commercialization activities, partially offset by a $1.1 million fee incurred in 2014 in connection with strategic and financial advisory services that was not incurred in 2015. Facility related and other costs increased primarily due to increased insurance premiums, facility costs related to our new office lease and other costs related to our growth and operating as a public company.

Interest and Other Income, net

For the year ended December 31, 2015, interest and other income, net consisted primarily of interest on investments. For the year ended December 31, 2014, interest and other income, net consisted primarily of the collection of a loan receivable which had been fully reserved for in prior years.

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 December 31, 2016, we had cash and cash equivalents of $23.2 million. We invest our cash equivalents in money market accounts in order to preserve principal.

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

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Cash used in operating activities	$ (36,520)	$ (41,236)	$(21,121)
Cash provided by (used in) investing activities	35,683	(40,510)	(175)
Cash provided by financing activities	37	513	94,799
Net increase (decrease) in cash and cash equivalents	$ (800)	$ (81,233)	$ 73,503

Operating activities. During the year ended December 31, 2016, cash used in operating activities consisted of our net loss of $38.0 million and net cash used in changes in our operating assets and liabilities of $2.1 million, partially offset by net non-cash charges of $3.5 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash used in changes in our operating assets and liabilities consisted primarily of a decrease in accounts payable and accrued expenses of $3.3 million, partially offset by a decrease in prepaid expenses and other current assets of $1.3 million.

During the year ended December 31, 2015, cash used in operating activities consisted of our net loss of $45.1 million, partially offset by net non-cash charges of $2.8 million and by net cash provided by changes in our operating assets and liabilities of $1.0 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 an increase in accounts payable and accrued expenses of $1.9 million, partially offset by an increase in prepaid expenses and other current assets of $1.0 million.

During the year ended December 31, 2014, cash used in operating activities was $21.1 million, resulting from our net loss of $23.3 million, partially offset by net non-cash charges of $2.0 million and by net cash provided by changes in our operating assets and liabilities of $0.2 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense of $2.1 million. Cash provided by changes in our operating assets and liabilities consisted primarily of a net increase in accounts payable and accrued expenses of $2.0 million, partially offset by an increase in prepaid expenses and other current assets of $1.8 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 year ended December 31, 2016, net cash provided by investing activities was primarily attributable to maturities of marketable securities of $36.2 million, partially offset by purchases of marketable securities of $0.5 million. We used a small amount of cash during the year ended December 31, 2016 related to purchases of property and equipment.

During the year ended December 31, 2015, net cash used in investing activities was primarily attributable to purchases of marketable securities of $39.9 million and purchases of property and equipment of $0.6 million primarily related to the purchase of lab equipment and computer equipment.

We used a small amount of cash during the year ended December 31, 2014 related to purchases of property and equipment and to increase our restricted cash balance related to our corporate credit cards.

Financing activities. During the year ended December 31, 2016, net cash provided by financing activities was attributable to proceeds from the exercise of stock options.

During the year ended December 31, 2015, net cash provided by financing activities was attributable to proceeds from the exercise of stock options and the repayment of notes receivable.

During the year ended December 31, 2014, net cash provided by financing activities was primarily due to proceeds, net of underwriting discounts and commissions, of $97.9 million from our initial public offering, partially offset by payments of $3.3 million of deferred offering costs related to our initial public offering that were paid during the period.

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 December 31, 2016, we had cash and investments of $27.4 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, if we do not successfully consummate the Otic Transaction, we expect our cash and investments as of December 31, 2016 to be sufficient to fund operations through at least the first quarter of 2018. While we have entered into the Share Purchase Agreement, our operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, our future business, prospects, financial positon and operating results could be significantly different than those in historical periods or projected by our management. If the Otic Transaction is not consummated and 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.

If the Otic Transaction is not consummated, and we decide to continue our historical business operations, our future capital requirements will depend on many factors, including:

- 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. Pursuant to General Instruction I.B.5 of Form S-3, however, in no event will we sell securities pursuant to such registration statement with a value of more than one-third of the aggregate market value of our common stock held by non-affiliates in any 12 calendar month period, so long as the aggregate market value of our common stock held by non-affiliates is less than $75 million. 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

The following table summarizes our contractual obligations at December 31, 2016:

	Payments Due By Period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More Than 5 Years
			(in thousands)		
Operating lease commitments (1)	$1,328	$ 839	$ 489	$ —	$ —
Total (2) (3)	$1,328	$ 839	$ 489	$ —	$ —

(1) We lease our headquarters in Boston, Massachusetts under an operating lease through July 2018.

(2) We are party to license agreements with University of Maryland, Baltimore and the Johns Hopkins University under which we are obligated to make future payments upon the achievement of certain contingent milestones or pay royalties upon selling a commercial product or sublicensing the licensed technology. We have not included these amounts in the table above as we cannot estimate or predict when, or if, these amounts will become due.

For further details regarding (1) and (2) above see *Commitments and Contingencies,* of the Notes to the Financial Statements included elsewhere in this Annual Report on form 10-K.

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

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 Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Fluctuation Risk

Our cash and investments as of December 31, 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 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

Tokai Pharmaceuticals, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Tokai Pharmaceuticals, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Tokai Pharmaceuticals, Inc. at December 31, 2016 and December 31, 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 3, 2017

Tokai Pharmaceuticals, Inc.

Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 23,223	$ 24,023
Marketable securities	4,175	39,934
Restricted cash	150	—
Prepaid expenses and other current assets	1,995	3,213
Total current assets	29,543	67,170
Property and equipment, net	98	489
Restricted cash	120	270
Other assets	—	45
Total assets	$ 29,761	$ 67,974
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 430	$ 1,208
Accrued expenses	2,389	4,954
Total current liabilities	2,819	6,162
Long-term liabilities	84	88
Total liabilities	2,903	6,250
Commitments and contingencies (Note 9)		
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 December 31, 2016 and December 31, 2015, respectively	23	23
Additional paid-in capital	196,233	193,194
Accumulated other comprehensive loss	(1)	(55)
Accumulated deficit	(169,397)	(131,438)
Total stockholders' equity	26,858	61,724
Total liabilities and stockholders' equity	$ 29,761	$ 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)

	Year Ended December 31,		
	2016	2015	2014
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	25,024	32,638	14,577
General and administrative	13,099	12,623	8,885
Total operating expenses	38,123	45,261	23,462
Loss from operations	(38,123)	(45,261)	(23,462)
Interest and other income, net	164	174	166
Net loss	$ (37,959)	$ (45,087)	$ (23,296)
Net loss per share, basic and diluted	$ (1.68)	$ (2.01)	$ (3.60)
Weighted average common shares outstanding, basic and diluted	22,634,641	22,484,343	6,469,289
Comprehensive loss:			
Net loss	$ (37,959)	$ (45,087)	$ (23,296)
Other comprehensive income (loss):			
Unrealized gains (losses) on marketable securities	54	(55)	—
Total other comprehensive income (loss)	54	(55)	—
Total comprehensive loss	$ (37,905)	$ (45,142)	$ (23,296)

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

Tokai Pharmaceuticals, Inc.

Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)

	Series A, B-1, B-2, C, D-1, D-2, D-3 and E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2013	155,586,141	$ 85,345	493,292	$ —	$ 7,788	$ —	$ (63,055)	$ (55,267)
Issuance of common stock upon exercise of stock options	—	—	8,875	—	16	—	—	16
Stock-based compensation expense	—	—	—	—	2,108	—	—	2,108
Conversion of preferred stock to common stock	(155,586,141)	(85,345)	14,860,173	15	85,330	—	—	85,345
Issuance of common stock upon initial public offering	—	—	7,020,000	7	97,922	—	—	97,929
Issuance costs	—	—	—	—	(3,334)	—	—	(3,334)
Net loss	—	—	—	—	—	—	(23,296)	(23,296)
Balances at December 31, 2014	—	—	22,382,340	22	189,830	—	(86,351)	103,501
Issuance of common stock upon exercise of stock options	—	—	201,153	1	463	—	—	464
Issuance of common stock upon vesting of restricted stock units	—	—	13,651	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,901	—	—	2,901
Unrealized loss on marketable securities	—	—	—	—	—	(55)	—	(55)
Net loss	—	—	—	—	—	—	(45,087)	(45,087)
Balances at December 31, 2015	—	—	22,597,144	23	193,194	(55)	(131,438)	61,724
Issuance of common stock upon exercise of stock options	—	—	30,856	—	37	—	—	37
Issuance of common stock upon vesting of restricted stock units	—	—	13,651	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3,002	—	—	3,002
Unrealized gain on marketable securities	—	—	—	—	—	54	—	54
Net loss	—	—	—	—	—	—	(37,959)	(37,959)
Balances at December 31, 2016	—	$ —	22,641,651	$ 23	$ 196,233	$ (1)	$ (169,397)	$ 26,858

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

Tokai Pharmaceuticals, Inc.

Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$(37,959)	$ (45,087)	$ (23,296)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	3,002	2,901	2,108
Depreciation expense	171	109	21
Impairment of property and equipment	237	—	—
Release of reserve for loan to former advisor	—	(49)	(158)
Premium on purchase of marketable securities	(2)	(186)	—
Amortization of premium on marketable securities	115	72	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,263	(958)	(1,830)
Accounts payable	(778)	443	760
Accrued expenses	(2,565)	1,476	1,274
Other assets	—	(45)	—
Other long-term liabilities	(4)	88	—
Net cash used in operating activities	(36,520)	(41,236)	(21,121)
Cash flows from investing activities:			
Proceeds from maturities of marketable securities	36,200	—	—
Purchases of marketable securities	(500)	(39,875)	—
Purchases of property and equipment	(17)	(565)	(25)
Change in restricted cash	—	(70)	(150)
Net cash provided by (used in) investing activities	35,683	(40,510)	(175)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	37	464	16
Repayment of notes receivable	—	49	158
Proceeds from initial public offering, net of underwriting discounts and commissions	—	—	97,929
Payments of initial public offering costs	—	—	(3,304)
Net cash provided by financing activities	37	513	94,799
Net increase (decrease) in cash and cash equivalents	(800)	(81,233)	73,503
Cash and cash equivalents at beginning of period	24,023	105,256	31,753
Cash and cash equivalents at end of period	$ 23,223	$ 24,023	$105,256
Supplemental disclosure of non-cash investing activities:			
Conversion of redeemable convertible preferred stock to common stock	$ —	$ —	$ (85,345)

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

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(amounts in thousands, except share and per share amounts)

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 has focused substantially all of its research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC. The Company also has a drug discovery program, known as ARDA (androgen receptor degradation agents), under which it identified novel compounds for patients with androgen receptor signaling diseases, including prostate cancer.

In July 2016, the Company announced its plan to discontinue the ARMOR3-SV, its pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve mCRPC patients whose prostate tumors expressed the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee ("DMC"). The Company conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and its ARDA program. Based on data reviewed to date, there is a substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. All patients enrolled in the ARMOR3-SV clinical trial have been discontinued. 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 $1,042 during the year ended December 31, 2016 related to the workforce reduction including severance, benefits and related costs of which $369 and $673 were recorded in research and development expenses and general and administrative expenses, respectively. The Company paid $842 of these costs during the year ended December 31, 2016 and expects to pay $200 in the first quarter of 2017. As of December 31, 2016, the Company had a balance of $200 in accrued expenses related to these severance, benefits and related costs.

In addition, in August 2016, the Company determined to discontinue enrollment in its Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi and not to proceed with its planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). Ten patients in the ARMOR2 trial continue treatment as of January 31, 2017.

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, was to maximize shareholder value.

On December 21, 2016, the Company entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic") and the shareholders of Otic (the "Selling Shareholders") pursuant to which, among other things, each Selling Shareholder agreed to sell to the Company, and the Company agreed to purchase from each Selling Shareholder, all of the ordinary and preferred shares of Otic (the "Otic Shares") owned by such Selling Shareholder (the "Otic Transaction"). See "Note 13. Share Purchase Agreement" for further information regarding the Otic Transaction. The Company amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of the Company's common stock among the Selling Shareholders and to extend to May 31, 2017, the date after which the Company or Otic may terminate the Share Purchase Agreement.

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 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 December 31, 2016, the Company had an accumulated deficit of $169,397 and had cash and investments of $27,398. 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, if the Company does not successfully consummate the Otic Transaction, the Company expects its cash and investments as of December 31, 2016 to be sufficient to fund operations through at least the first quarter of 2018. While the Company has entered into the Share Purchase Agreement, its operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, the Company will need to continue its review of strategic alternatives including evaluating potential paths forward for galeterone and its ARDA program. If the Otic Transaction is consummated or if the Company determines to pursue an alternate strategy, 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, the Company will need to obtain substantial additional funding. Because of the significant uncertainty regarding its future plans, the Company is not able to accurately predict the impact of a potential change on its business strategy and future funding requirements. If its cash and investments are not sufficient to fund its approved 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 commercialization efforts.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("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.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at date of purchase to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

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.

Concentration of Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company has all cash and cash equivalents and marketable securities' balances at two accredited financial institutions, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method based upon estimated useful lives as follows:

	Years
Lab equipment	3
Computer equipment	3
Furniture and fixtures	5
Leasehold improvements	Shorter of life of lease or estimated useful life

Upon retirement or sale of property and equipment, the cost and related accumulated depreciation of such property and equipment disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. During the year ended December 31, 2016, the Company recorded an impairment loss of $237 related to property and equipment, including lab equipment which will no longer be used as a result of the discontinuation of the ARMOR3-SV trial.

Research and Development Costs

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including manufacturing expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. The Company expenses raw materials used to manufacture its drug substance when received.

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

- clinical research organizations in connection with clinical trials;
- investigative sites or other providers in connection with clinical trials;
- Qiagen in connection with the development of the AR-V7 clinical trial assay and companion diagnostic test;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple clinical research organizations and investigative sites that manage and conduct clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the

clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or amount of prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low in any particular period. For the years ended December 31, 2016, 2015 and 2014, the Company has not made any material adjustments to its prior estimates of accrued research and development expenses.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions, while the graded vesting method is applied to all grants with both service and performance conditions. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested portion of the awards is re-measured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in its financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than- not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. No revenue has been generated since inception. All of the Company's assets are located in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2016 and 2015, the Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities. For the year ended December 31, 2014, there was no difference between net loss and comprehensive loss.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing the net income (loss) the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The following common stock equivalents outstanding as of December 31, 2016, 2015 and 2014 were excluded from the computation of diluted net loss per share for the years ended December 31, 2016, 2015 and 2014, because they had an anti-dilutive impact:

	December 31,		
	2016	2015	2014
Stock options to purchase common stock	1,896,169	2,861,011	2,146,927
Unvested restricted common stock units	—	40,953	54,604
	1,896,169	2,901,964	2,201,531

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that the statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 will be effective for the first interim period within fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on the Company's statement of cash flows.

3. Marketable Securities and Fair Value Measurements

As of December 31, 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)	$ 1,175	$ —	$ —	$ 1,175
United States Treasury Notes (due within one year)	3,001	—	(1)	3,000
Total	$ 4,176	$ —	$ (1)	$ 4,175

As of 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

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 as of December 31, 2016 and 2015:

	Fair Value Measurements at December 31, 2016 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	$ —	$ 17,748	$ —	$ 17,748
Marketable securities:				
Certificates of Deposit	—	1,175	—	1,175
United States Treasury Notes	—	3,000	—	3,000
Total	$ —	$ 21,923	$ —	$ 21,923

	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.

4. Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2016 and 2015:

	December 31,	
	2016	2015
Computer equipment	$ 162	$ 243
Leasehold improvements	66	66
Lab equipment	—	322
Furniture and fixtures	—	23
	228	654
Less: Accumulated depreciation	(130)	(165)
	$ 98	$ 489

Depreciation expense was $171, $109 and $21 for the years ended December 31, 2016, 2015 and 2014, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2016 and 2015:

	December 31,	
	2016	2015
Accrued research and development expenses	$ 907	$3,188
Accrued professional fees	871	699
Accrued payroll and related expenses	394	900
Accrued other	217	167
	$2,389	$4,954

6. Redeemable Convertible Preferred Stock

Prior to the completion of its initial public offering ("IPO") in September 2014 (Note 7), the Company had outstanding Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2, Series D-3 and Series E redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). The Company classified the Redeemable Preferred Stock outside of stockholders' equity (deficit) because the shares contained redemption features that were not solely within the Company's control. In connection with the closing of the Company's IPO, all of the Company's outstanding Redeemable Preferred Stock automatically converted into common stock on a 10.47-for-1 basis. No Redeemable Preferred Stock was outstanding as of December 31, 2016 or 2015.

7. Common Stock

On August 29, 2014, the Company effected a 1-for-10.47 reverse stock split of its issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split.

On September 22, 2014, the Company completed an IPO of its common stock through the issuance and sale of 6,480,000 shares of common stock at a price to the public of $15.00 per share, resulting in net proceeds of $87,062 after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 14,860,173 shares of the Company's common stock. On October 9, 2014, the Company issued and sold an additional 540,000 shares of its common stock at the 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, resulting in additional net proceeds to the Company of $7,533 after deducting underwriting discounts and commissions.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

8. Stock-Based Awards

The Company's 2014 Stock Incentive Plan (the "2014 Plan") permits the Company to make grants of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants and advisors; however, incentive stock options may only be granted to the Company's employees. The number of shares initially reserved for issuance under the 2014 Plan was 1,745,413 shares of common stock and may be increased by the number of shares under the 2007 Stock Incentive Plan (the "2007 Plan") that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company. The number of shares of common stock that may be issued under the plan is also subject to an annual increase on the first day of each fiscal year equal to the lesser of (i) 1,800,000 shares of the Company's common stock, (ii) 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year or (iii) an amount determined by the Company's board of directors. As of December 31, 2016, 3,021,327 shares remained available for issuance under the 2014 Plan. The number of authorized shares reserved for issuance under the 2014 Plan was increased by 905,666 shares effective as of January 1, 2017.

As required by the 2007 Plan and 2014 Plan, the exercise price for stock options granted is not to be less than the fair value of common stock as of the date of grant. The Company bases fair value of common stock on the quoted market price. Prior to the IPO, the value of common stock was determined by the Company's board of directors by taking into consideration its most recently available valuation of common stock performed by management and the board of directors as well as additional factors which might have changed since the date of the most recent contemporaneous valuation through the date of grant.

During the years ended December 31, 2016, 2015 and 2014, the Company granted options to purchase 324,900, 996,845 and 1,039,155 shares of common stock, respectively, to certain employees, consultants and directors. The vesting of most of these awards is time-based and the restrictions typically lapse over three to four years.

2014 Employee Stock Purchase Plan

Under the 2014 Employee Stock Purchase Plan (the "ESPP"), an aggregate of 225,000 shares of the Company's common stock are reserved for issuance. The number of shares of the Company's common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year equal to the

lesser of (1) 450,000 shares of the Company's common stock, (2) 1% of the total number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year and (3) an amount determined by the Company's board of directors. No offering periods have commenced under the ESPP. The number of shares reserved for issuance under the ESPP was increased by 226,416 shares effective as of January 1, 2017.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to its IPO, the Company was a private company and lacked company-specific historical and implied volatility information. Therefore, the Company estimated its expected stock volatility based on the historical volatility of a publicly traded group of peer companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

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

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.52%	1.79%	1.83%
Expected term (in years)	5.91	6.01	5.95
Expected volatility	74.7%	74.2%	79.4%
Expected dividend yield	0%	0%	0%

The following table summarizes the Company's stock option activity from January 1, 2016 through December 31, 2016:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2015	2,861,011	$ 7.57	8.3	$ 7,906
Granted	324,900	6.17		
Exercised	(30,856)	1.18		
Forfeited	(1,258,886)	8.90		
Outstanding as of December 31, 2016	1,896,169	$ 6.55	6.1	$ 13
Options vested and expected to vest as of December 31, 2016	1,889,406	$ 6.53	6.1	$ 13
Options exercisable as of December 31, 2016	1,434,904	$ 5.58	5.4	$ 13

The aggregate intrinsic value was calculated based on the positive differences between the market value of the Company's common stock on December 31, 2016 and 2015, of $0.98 and $8.72 per share, respectively, and the exercise prices of the options.

The weighted average grant date fair value of stock options granted was $4.02, $6.94 and $6.70 per share for the years ended December 31, 2016, 2015 and 2014, respectively.

The total intrinsic value of stock options exercised was $144, $2,236 and $35 for the years ended December 31, 2016, 2015 and 2014, respectively.

Restricted Common Stock Units

The 2014 Plan provides for the award of restricted common stock units. The Company has granted restricted common stock units with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award.

The table below summarizes the Company's restricted stock unit activity from January 1, 2016 through December 31, 2016:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock units as of December 31, 2015	40,953	$ 15.00
Issued	—	—
Vested	(13,651)	15.00
Forfeited	(27,302)	15.00
Unvested restricted common stock units as of December 31, 2016	—	

During 2014, the Company granted 54,604 restricted stock units with a fair value of $15.00 per share that were subject to time-based vesting conditions that lapse over four years. Upon vesting, the restricted stock units entitle the holder to one share of common stock for each restricted stock unit. All restricted stock units currently granted had been classified as equity instruments as their terms require settlement in shares. Restricted stock units with time-based vesting conditions are valued on the grant date using the grant date market price of the underlying shares. The Company did not grant restricted stock units in 2016 or 2015.

Stock-based Compensation

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:

	Year Ended December 31,		
	2016	2015	2014
Research and development	$ 526	$ 634	$ 552
General and administrative	2,476	2,267	1,556
	$3,002	$2,901	$2,108

Stock-based compensation expense for the year ended December 31, 2014 includes $880 of stock-based compensation expense related to a performance-based option grant which vested during 2014.

As of December 31, 2016, the Company had an aggregate of $2,675 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 2.2 years.

9. 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 was 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 expired on December 31, 2016. 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 year ended December 31, 2015.

During the years ended December 31 2016, 2015 and 2014, the Company recognized $696, $835 and $520 of rental expense related to office space.

As of December 31, 2016, future minimum lease payments under noncancelable office leases are as follows:

2017	$ 839
2018	489
	$1,328

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 December 31, 2016 and 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 December 31, 2016 and 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 years ended December 31, 2016, 2015 and 2014.

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 December 31, 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 year ended December 31, 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 December 31, 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 had agreed to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. Qiagen had 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 year ended December 31, 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 made a final payment of $1,099 to Qiagen. Accordingly, there are no future financial obligations by the Company or Qiagen under the project work plan. The Company recorded research and development expense of $1,099 during the year ended December 31, 2016 related to this final payment to Qiagen.

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 December 31, 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. A lead plaintiff has yet to be appointed.

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 "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 February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.

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. A prospective lead plaintiff has filed a motion to consolidate the Doshi and Garbowski Actions for all purposes. A lead plaintiff has yet to be appointed.

On December 5, 2016, a putative securities class action was filed in the Business Litigation Session of the Superior Court Department of the Suffolk County Trial Court, Massachusetts ("Massachusetts State Court") 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 IPO, entitled Wu v. Tokai Pharmaceuticals, Inc., et al., 16-3725 BLS ("Wu Action"). The lawsuit alleges that the Company's IPO registration statement made false and misleading statements and omissions about the Company's clinical trials for galeterone, in violation of the Securities Act. The plaintiff seeks to represent a class of purchasers of Company common stock in or traceable to the Company's IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On December 19, 2016, defendants removed the Wu Action to the U.S. District Court for the District of Massachusetts, where it was captioned Wu v. Tokai Pharmaceuticals, Inc., et al., 16-cv-12550, and assigned to the same judge presiding over the Doshi and Garbowski Actions. On December 22, 2016, defendants filed a motion to consolidate the Wu Action with the Doshi and Garbowski Actions. On January 6, 2017, plaintiff filed a motion to remand the Wu Action to Massachusetts State Court.

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.

10. Income Taxes

During the years ended December 31, 2016, 2015 and 2014, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2016	2015	2014
Federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
Federal research and development tax credit	(0.6)	(0.5)	(0.9)
State taxes, net of federal benefit	(5.2)	(5.3)	(4.5)
Stock-based compensation expense	1.3	0.4	1.1
Other	—	0.1	0.2
Increase in deferred tax asset valuation allowance	38.5	39.3	38.1
Effective income tax rate	0.0%	0.0%	0.0%

Net deferred tax assets as of December 31, 2016 and 2015 consisted of the following:

	December 31,	
	2016	2015
Deferred tax assets:		
Capitalized research and development expenses	$ 47,594	$ 37,765
Net operating loss carryforwards	14,252	10,224
Stock-based compensation	1,956	1,371
Research and development tax credit carryforwards	1,590	1,273
Accrued expenses	207	339
Other	44	56
Total gross deferred tax assets	65,643	51,028
Valuation allowance	(65,643)	(51,028)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2016, 2015 and 2014 related primarily to the increase in capitalized research and development expenses, net operating loss carryforwards and stock-based compensation and were as follows:

	Year Ended December 31,		
	2016	2015	2014
Valuation allowance as of beginning of year	$51,028	$33,272	$24,402
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	14,615	17,756	8,870
Valuation allowance as of end of year	$65,643	$51,028	$33,272

As of December 31, 2016, the Company had net operating loss carryforwards for federal and state income tax purposes of $38,200 and $34,300, respectively, which begin to expire in 2024 and 2030, respectively. As of December 31, 2016, the federal and state net operating loss carryforwards include $1,400 of deductions for stock option compensation for which the associated tax benefit will be credited to additional paid-in capital when realized. This amount is accounted for separately and is not included in the Company's deferred tax assets. As of December 31, 2016, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $1,279 and $471, respectively, which begin to expire in 2025 and 2028, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Code, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since

inception and its lack of commercialization of any products since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2016 and 2015. Management reevaluates the positive and negative evidence at each reporting period.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2016 or 2015.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2013 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

11. 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 year ended December 31, 2016, the Company made matching contributions of $127.

12. Related Party Transactions

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.

The Company had an outstanding loan to a former advisor comprised of unpaid principal and interest in the amount of $220 that was deemed uncollectable and as a result, was fully reserved for in 2007. In 2014, the Company started to receive repayment of this note. This loan was fully repaid in April 2015. The Company recorded $49 and $158 for the years ended December 31, 2015 and 2014, respectively, in interest and other income, net, representing cash collected during those periods.

13. Share Purchase Agreement

On December 21, 2016, the Company entered into the Share Purchase Agreement with Otic and the Selling Shareholders pursuant to which, among other things, each Selling Shareholder agreed to sell to the Company, and the Company agreed to purchase from each Selling Shareholder, all of the Otic Shares owned by such Selling Shareholder. Immediately following the closing of the Otic Transaction, the Selling Shareholders are expected to own approximately 60% of the Company's outstanding common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing). Consummation of the Otic Transaction is subject to certain closing conditions, including, among other things, approval by the Company's stockholders. The Share Purchase Agreement contains certain termination rights for both the Company and Otic, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, the Company may be required to pay Otic a termination fee of $1,000, or Otic may be required to pay the Company a termination fee of $1,500. Upon consummation of the Otic Transaction, the Company will owe its strategic advisor $1,000. There can be no

assurances that the Otic Transaction will be consummated. The Company amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of the Company's common stock among the Selling Shareholders and to extend to May 31, 2017, the date after which the Company or Otic may terminate the Share Purchase Agreement.

In addition, the Company has entered into a commitment letter with Otic and certain purchasers set forth therein under which the purchasers have agreed to invest up to $7,000 of new capital in Otic and/or Tokai prior to or upon the closing of the Otic Transaction. Pursuant to this commitment letter, on January 31, 2017, the Company entered into a stock purchase agreement with the parties to the commitment letter under which such parties agreed to purchase 3,603,601 shares of the Company's common stock at a price of $1.11 per share. The purchase and sale of the Company's common stock pursuant to this stock purchase agreement will occur at the time of the closing of the Otic Transaction. The remaining $3,000 will be invested in Otic prior to the closing of the Otic Transaction through the exercise of outstanding warrants.

14. Selected Quarterly Financial Data (Unaudited)

	Three Months Ended							
	Dec. 31, 2016 (1)	Sept. 30, 2016 (1)	June 30, 2016	March 31, 2016	Dec. 31, 2015	Sept. 30, 2015	June 30, 2015	March 31, 2015
Statements of Operations Data:								
Revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Loss from operations	(3,760)	(9,308)	(13,575)	(11,480)	(11,072)	(11,907)	(8,982)	(13,300)
Net loss	(3,737)	(9,270)	(13,526)	(11,426)	(11,017)	(11,853)	(8,957)	(13,260)
Basic and diluted net loss per share	$ (0.17)	$ (0.41)	$ (0.60)	$ (0.51)	$ (0.49)	$ (0.53)	$ (0.40)	$ (0.59)

(1) In July 2016, the Company announced its plan to discontinue the ARMOR3-SV Phase 3 clinical trial and reduced its workforce by approximately 60%.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *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 December 31, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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 December 31, 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.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 *Internal Control—Integrated Framework.* Based on this assessment, our management has concluded that as of December 31, 2016, our internal control over financial reporting is effective.

As an emerging growth company, as defined under the terms of the Jobs Act of 2012, the Company's independent registered accounting firm is not required to issue an attestation report on the internal control over financial reporting.

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.

ITEM 9B. ***OTHER INFORMATION***

Pursuant to Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012, which added Section 13(r) of the Exchange Act, we hereby incorporate by reference herein Exhibit 99.1 of this report, which includes disclosures publicly filed by Novartis AG, of which Novartis BioVentures Ltd., which we consider to be our affiliate due to its stock ownership of our company, is an indirect wholly-owned subsidiary.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required by this Item 10 will be included in an amendment to this Annual Report on Form 10-K or in our definitive proxy statement to be filed with the SEC with respect to our 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the text of our Code of Business Conduct and Ethics under the "Investors & Media—Corporate Governance" section of our website, *www.tokaipharmaceuticals.com*. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this Item 11 will be included in an amendment to this Annual Report on Form 10-K or in our definitive proxy statement to be filed with the SEC with respect to our 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

The information required by this Item 12 will be included in an amendment to this Annual Report on Form 10-K or in our definitive proxy statement to be filed with the SEC with respect to our 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this Item 13 will be included in an amendment to this Annual Report on Form 10-K or in our definitive proxy statement to be filed with the SEC with respect to our 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this Item 14 will be included in an amendment to this Annual Report on Form 10-K or in our definitive proxy statement to be filed with the SEC with respect to our 2017 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) *Financial Statements*

For a list of the financial statements included herein, see Index to the Financial Statements on page 85 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(b) *Exhibits*

The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding such Exhibits, which Exhibit Index is incorporated herein by reference.

(c) *Financial Statement Schedules*

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the financial statements or the notes thereto.

ITEM 16. *FORM 10-K SUMMARY*

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 3, 2017

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jodie P. Morrison Jodie P. Morrison	President, Chief Executive Officer and Director (Principal Executive Officer)	March 3, 2017
/s/ John S. McBride John S. McBride	Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)	March 3, 2017
/s/ Seth L. Harrison Seth L. Harrison	Chairman of the Board	March 3, 2017
/s/ Stephen Buckley, Jr. Stephen Buckley, Jr.	Director	March 3, 2017
/s/ Cheryl L. Cohen Cheryl L. Cohen	Director	March 3, 2017
/s/ David A. Kessler David A. Kessler	Director	March 3, 2017
/s/ Joseph A. Yanchik III Joseph A. Yanchik III	Director	March 3, 2017

EXHIBIT INDEX

Exhibit Number	Description
2.1*	Amended and Restated Share Purchase Agreement dated as of March 2, 2017 by and among the Registrant, Otic Pharma, Ltd. and shareholders of Otic Pharma, Ltd. named therein. (All Schedules to the Share Purchase Agreement have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any schedules to the Securities and Exchange Commission upon request.)
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)
4.1	Specimen certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.1	Fifth Amended and Restated Investor Rights Agreement, dated as of May 13, 2013, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.2+	2007 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.3+	Form of Incentive Stock Option Agreement under 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.4+	Form of Nonstatutory Stock Option Agreement under 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.5+	2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.6+	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.7+	Form of Nonstatutory Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.8+	2014 Employee Stock Purchase Plan to (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.9+	Amended and Restated Employment Agreement, dated as of July 16, 2014, between the Registrant and Jodie P. Morrison (incorporated by reference to Exhibit 10.8 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.10+	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Jodie P. Morrison (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 26, 2015)

Exhibit Number	Description
10.11+	Employment Agreement, dated as of January 30, 2014, between the Registrant and John S. McBride (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.12+	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and John S. McBride (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 26, 2015)
10.13+	Employment Agreement, dated as of April 7, 2014, between the Registrant and Karen J. Ferrante, M.D. (incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.14+	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Karen J. Ferrante (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 26, 2015)
10. 15+†	Employment Letter, dated as of April 7, 2015, between the Registrant and Gerald E. Quirk. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on August 12, 2015)
10.16+	Consulting Agreement dated August 31, 2016 between the Registrant and Lee H. Kalowski (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on November 3, 2016)
10.17+	Consulting Agreement dated August 31, 2016 between the Registrant and Karen J. Ferrante (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on November 3, 2016)
10.18	Consulting Agreement dated September 21, 2016 between the Registrant and Apple Tree Life Sciences, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on November 3, 2016)
10.19+	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.20	Sublease Agreement, dated as of February 27, 2015, between the Registrant and Boston Private Wealth LLC (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 26, 2015)
10.21	Lease, executed on June 9, 2015, between the Registrant and 255 State Street LLC. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on August 12, 2015)
10.22†	Master License Agreement, dated as of May 19, 2006, between the Registrant and the University of Maryland, Baltimore, as amended by First Amendment, dated as of March 3, 2009, Second Amendment, dated as of April 10, 2012, and Third Amendment, dated as of October 28, 2013 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 (File No. 333-198052) filed on August 11, 2014)
10.23†	License Agreement, dated as of January 9, 2015, between the Registrant and The Johns Hopkins University (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 26, 2015)
10.24†	Master Collaboration Agreement, dated January 12, 2015, between the Registrant and Qiagen Manchester Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on May 12, 2015)

Exhibit Number	Description
10.25†	Fourth Amendment to Master License Agreement, dated March 15, 2016, between the Registrant and the University of Maryland, Baltimore(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36620) filed on May 10, 2016)
10.26	Support Agreement, dated as of December 21, 2016,by and among the Registrant, Otic Pharma, Ltd. and certain stockholders of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on December 22, 2016)
10.27	Stock Purchase Agreement, dated as of January 31, 2017, by and among the Registrant and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on February 3, 2017)
12.1*	Calculation of Ratios of Earnings to Fixed Charges and Ratios of Earnings to Combined Fixed Charges and Preferred Stock Dividends
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
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.
99.1*	Section 13(r) Disclosure
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.

† Confidential treatment has been granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

\+ Indicates management contract or plan.

\# 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.

Exhibit 2.1

AMENDED AND RESTATED SHARE PURCHASE AGREEMENT

by and among

TOKAI PHARMACEUTICALS, INC.,

OTIC PHARMA, LTD.

and

SHAREHOLDERS OF OTIC PHARMA, LTD.

Dated as of March 2, 2017

Effective as of December 21, 2016

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TABLE OF DEFINED TERMS

Terms	Cross Reference in Agreement
102 Plan	Section 3.8(k)
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AMENDED AND RESTATED SHARE PURCHASE AGREEMENT

THIS AMENDED AND RESTATED SHARE PURCHASE AGREEMENT (this "Agreement"), is entered into as of March 2, 2017, by and among Tokai Pharmaceuticals, Inc., a Delaware corporation ("Public Company"), Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic Pharma"), and the shareholders of Otic Pharma identified on the signature page hereto (the "Shareholders").

WHEREAS, on December 21, 2016 (the "Effective Date") the parties entered into that certain Share Purchase Agreement, dated as of the Effective Date (the "Original Agreement"), which may be amended pursuant to Section 8.4 thereof by an instrument in writing, signed on behalf of Public Company, Otic Pharma and the Shareholders holding a majority of the issued and outstanding shares of Otic Pharma Share Capital;

WHEREAS, this Agreement amends and restates the Original Agreement in its entirety for purposes of updating the allocation of the Aggregate Closing Consideration among the shareholders of Otic Pharma and the number of shares of Public Company Common Stock for which Otic Pharma Share Options and Otic Pharma Warrants will be exercisable, in each case without modifying the Maximum Consideration;

WHEREAS, the parties agree that references herein to the "date of this Agreement" and the "date hereof" shall be deemed to refer to the Effective Date;

WHEREAS, Shareholders own all of the issued and outstanding shares of Otic Pharma Share Capital;

WHEREAS, the parties desire to enter into this Agreement pursuant to which each Shareholder agrees to sell to Public Company and Public Company agrees to purchase from each Shareholder all of the shares of Otic Pharma Share Capital owned by such Shareholder (the "Transaction"), on the terms and subject to the conditions contained herein; and

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Shareholders' and Otic Pharma's willingness to enter into this Agreement, the stockholders of Public Company listed on Section A of the Public Company Disclosure Schedule have entered into Support Agreements, dated as of the date of this Agreement, in the form attached hereto as Exhibit A (the "Public Company Support Agreements"), pursuant to which such stockholders have, subject to the terms and conditions set forth therein, agreed to vote all of their shares of capital stock of Public Company in favor of the Transaction and against any competing proposals.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, Public Company, the Shareholders and Otic Pharma, intending to be legally bound, agree as follows:

ARTICLE I

THE SHARE PURCHASE

1.1 Share Purchase. Upon the terms and subject to the conditions set forth in this Agreement, on the Closing Date Public Company shall purchase from each Shareholder, and each Shareholder shall, severally and not jointly, sell, convey, assign, transfer and deliver to Public Company, all of the Otic Pharma Share Capital owned by such Shareholder, as set forth opposite such Shareholder's name on the Closing Date Allocation Schedule, free and clear of all Liens. Each Shareholder hereby waives any rights of pre-emption, rights of first refusal or other restrictions on transfer of the Otic Pharma Share Capital whether conferred by the Otic Pharma Organizational Documents or otherwise, in respect of the transfers contemplated by this Agreement.

1.2 Closing.

(a) Subject to the satisfaction or waiver (to the extent permitted by law) of the conditions set forth in Article VII, the closing of the Transaction (the "Closing") will take place at 10:00 a.m., Eastern time, on a date to be specified by Public Company and Otic Pharma (the "Closing Date"), which shall be no later than the second Business Day after satisfaction or waiver of the conditions set forth in Article VII (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the fulfillment or waiver of such conditions), at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, unless another date, place or time is agreed to in writing by Public Company and Otic Pharma. For the purposes of this Agreement, the term "Business Day" shall mean any day other than a Friday, Saturday, Sunday or other day on which commercial banking institutions in New York, New York or Tel Aviv, Israel are authorized or permitted by law to be closed.

(b) At the Closing:

(i) Otic Pharma and the Shareholders shall deliver to Public Company the various certificates, instruments and documents referred to in Section 7.2;

(ii) Public Company shall deliver to Otic Pharma the various certificates, instruments and documents referred to in Section 7.3;

(iii) Public Company shall deliver the consideration contemplated by Section 1.3(b); and

(iv) each Shareholder shall deliver or procure to be delivered to Public Company:

(A) duly executed share transfer deeds in favor of Public Company in respect of all shares of Otic Pharma Share Capital owned by such Shareholder, together with Certificates in respect of such shares, or if any Certificate shall have been lost, stolen, destroyed or never issued, an affidavit of that fact by the person claiming such Certificate to be lost, stolen, destroyed or never issued;

(B) a copy of any power of attorney under which this Agreement or any of the transactions, transfers or documents contemplated by this Agreement is effected and/or executed by the Shareholder, and evidence of the authority of any person signing on behalf of any Shareholder that is a corporate entity; and

(C) a power of attorney appointing Public Company as its attorney in its name and on its behalf to exercise any or all of the voting and other rights, powers and privileges (including the right to nominate proxies on its behalf) attached to the shares of Otic Pharma Share Capital registered in its name and under which such Shareholder undertakes to ratify everything done by Public Company, as its attorney, in pursuance of the power of attorney, and agrees that such power of attorney is executed to secure the interest of Public Company in the Otic Pharma Share Capital and shall accordingly be irrevocable.

1.3 Closing Date Deliverables; Certain Definitions.

(a) No later than three Business Days prior to the Closing Date, Otic Pharma shall deliver to Public Company the Closing Date Allocation Schedule.

(b) On the Closing Date, Public Company shall deliver to the Shareholders, in accordance with the Closing Date Allocation Schedule, certificates representing a number of shares of common stock, $0.001 par value per share, of Public Company ("Public Company Common Stock"), equal to the Aggregate Closing Consideration; provided, that payment hereunder in the form of shares of Public Company Common Stock shall be made only in whole shares, and any fractional shares shall be rounded down to the nearest whole share.

(c) For purposes of this Agreement, the following terms shall have the following meanings:

"102 Trustee" means Altshuler Shaham Benefits Ltd., appointed by Otic Pharma to serve as trustee pursuant to Section 102 of the Israeli Income Tax Ordinance and approved by the ITA.

"104H Trustee" means the trustee appointed by Otic Pharma in accordance with the provisions of Section 104H of the Israeli Income Tax Ordinance, and to be approved by the ITA in the 104H Ruling.

"Aggregate Closing Consideration" means the aggregate number of newly issued shares of Public Company Common Stock set forth in the Closing Date Allocation Schedule payable to the Shareholders at the Closing, which aggregate number shall in no event exceed the Maximum Consideration.

"Certificate" means a certificate which as of immediately prior to the Closing represented outstanding shares of Otic Pharma Share Capital.

"Closing Date Allocation Schedule" means a schedule, prepared by Otic Pharma in the format of the Preliminary Closing Date Allocation Schedule, dated as of the Closing Date and in form and substance reasonably acceptable to Public Company, setting forth, for each Shareholder: (a) such Shareholder's name and address; (b) the number of shares of each class of Otic Pharma Share Capital held as of the Closing Date by such Shareholder; (c) the portion of the Aggregate Closing Consideration payable to such Shareholder in accordance with the Otic Pharma Organizational Documents; and (d) such information that is required under Treasury Regulation Section 1.6045-1 for any share of Otic Pharma Share Capital that is a covered security as defined in Treasury Regulation Section 1.6045-1(a)(15); provided that item (c) of the Closing Date Allocation Schedule shall be calculated in compliance with the Otic Pharma Organizational Documents and the Otic Pharma Share Plan.

"Code" means the Internal Revenue Code of 1986, as amended.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended.

"ERISA Affiliate" means any entity that is, or at any applicable time was, a member of (1) a controlled group of corporations (as defined in Section 414(b) of the Code), (2) a group of trades or businesses under common control (as defined in Section 414(c) of the Code), or (3) an affiliated service group (as defined under Section 414(m) of the Code or the regulations under Section 414(o) of the Code), any of which includes or included the entity in question or any of its Subsidiaries.

"Exchange Ratio" means 4.255.

"Governmental Entity" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, Taxing or other governmental or quasi-governmental authority (including any governmental division, department, agency, commission, instrumentality, official, organization, unit, body or entity and any court or other tribunal).

"Israeli Income Tax Ordinance" means the Israeli Income Tax Ordinance (New Version) 1961 and the regulations and rules promulgated thereunder.

"ITA" means the Israeli Tax Authority.

"Maximum Consideration" means the aggregate number of shares of Public Company Common Stock equal to the product of (i) the total number of shares of Otic Pharma Share Capital issued and outstanding and shares of Otic Pharma Share Capital issuable upon exercise of outstanding Otic Pharma Share Options and Otic Pharma Warrants, as of immediately prior to the Closing and as calculated on an as-converted basis, and (ii) the Exchange Ratio, which aggregate number shall in no event exceed 36,911,631 shares of Public Company Common Stock (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar transactions affecting the Public Company Common Stock).

"Otic Pharma Board" means the Board of Directors of Otic Pharma.

"Otic Pharma Ordinary Shares" means Ordinary Shares, NIS 0.01 nominal value per share, of Otic Pharma.

"Otic Pharma Organizational Documents" means the Articles of Association of Otic Pharma.

"Otic Pharma Preferred Shares" means, collectively, the Series A Preferred Shares, Series B Preferred Shares and Series C Preferred Shares.

"Otic Pharma Share Capital" means Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares, collectively.

"Paying Agent" means the Public Company, or such other entity or Person as may be mutually agreed by the Public Company and Otic Pharma.

"Preliminary Closing Date Allocation Schedule" means the schedule attached hereto as Exhibit B and dated as of March 2, 2017, setting forth, for each Shareholder: (a) such Shareholder's name and address; (b) the number of shares of each class of Otic Pharma Share Capital expected to be held as of the Closing Date by such Shareholder; (c) the portion of the Aggregate Closing Consideration payable to such Shareholder in accordance with the Otic Pharma Organizational Documents; (d) such information that is required under Treasury Regulation Section 1.6045-1 for any share of Otic Pharma Share Capital that is a covered security as defined in Treasury Regulation Section 1.6045-1(a)(15).

"Public Company Board" means the Board of Directors of Public Company.

"Representatives" means, with respect to any entity, the directors, officers, employees, financial advisors, attorneys, accountants, consultants, agents and other authorized representatives of such entity, acting in such capacity.

"Series A Preferred Shares" means the Series A Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

"Series B Preferred Shares" means the Series B Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

"Series C Preferred Shares" means the Series C Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

1.4 [Intentionally omitted]

1.5 Treatment of Otic Pharma Share Options and Otic Pharma Warrants.

(a) At the Closing, each outstanding option to purchase Otic Pharma Ordinary Shares (each, a "Otic Pharma Share Option" and collectively, the "Otic Pharma Share Options"), whether vested or unvested, and the Otic Pharma Ltd. Global Share Incentive Plan (2012) (the "Otic Pharma Share Plan") itself, insofar as it relates to outstanding Otic Pharma Share Options, shall be assumed by Public Company and shall become an option to acquire, on the same terms and conditions as were applicable under such Otic Pharma Share Option immediately prior to the Closing, such number of shares of Public Company Common Stock as is set forth in Exhibit D attached hereto, subject to the unexercised portion of such Otic Pharma Share Option immediately prior to the Closing, at an exercise price per share as is set forth in Exhibit D attached hereto; provided that Exhibit D may be updated prior to the Closing upon delivery by Otic Pharma to Public Company of an updated Exhibit D at least three Business Days prior to the Closing solely to the extent necessary to reflect corresponding changes to the Closing Date Allocation Schedule; provided further that the assumption of each Otic Pharma Share Option pursuant to this Section 2.3(a) shall comply with all requirements of Sections 424 and 409A of the Code and the Treasury regulations issued thereunder, as applicable, and of the Israeli Options Tax Ruling. Such Otic Pharma Share Options shall continue in effect on the same terms and conditions to which they are currently subject (subject to the adjustments required by this Section 1.5 after giving effect to the Transaction). Otic Pharma shall, prior to the Closing, take all actions necessary or desirable in connection with the treatment of Otic Pharma Share Options contemplated by this Section 1.5(a), including obtaining the consent from each holder of any Otic Pharma Share Options (unless such consent is not required under the terms of the applicable agreement, instrument or plan).

(b) As soon as practicable after the Closing, Public Company shall deliver to the participants in the Otic Pharma Share Plan appropriate notice setting forth such participants' rights pursuant to Otic Pharma Share Options, as provided in this Section 1.5.

(c) Public Company shall take all corporate action necessary to reserve for issuance a sufficient number of shares of Public Company Common Stock for delivery upon exercise of Otic Pharma Share Options assumed in accordance with this Section 1.5. As promptly as practicable after the Closing, Public Company shall file a registration statement on Form S-8 (or any successor form) or another appropriate form with respect to the shares of Public Company Common Stock subject to such options and shall use commercially reasonable efforts to maintain the effectiveness of such registration statement or registration statements (and maintain the current status of the prospectus or prospectuses contained therein) for so long as such options remain outstanding.

(d) Otic Pharma shall terminate any employee share purchase plans in accordance with their terms as of or prior to the Closing.

(e) At the Closing, by virtue of the Transaction, each Otic Pharma Warrant outstanding immediately prior to the Closing shall be automatically assumed by Public Company and shall become a warrant to acquire, on the same terms and conditions as were applicable under such Otic Pharma Warrant, such number of shares of Public Company Common Stock as is set forth in Exhibit D attached hereto, subject to the unexercised portion of such Otic Pharma Warrant immediately prior to the Closing, at an exercise price per share as is set forth in Exhibit D attached hereto (each warrant, as so converted, an "Adjusted Warrant"). Otic Pharma shall, prior to the Closing, take all actions necessary or desirable in connection with the treatment of Otic Pharma Warrants contemplated by this Section 2.3(e). Public Company shall take all corporate actions necessary to reserve for issuance of shares of Public Company Common Stock that will be subject to the Adjusted Warrants.

(f) Notwithstanding the foregoing, in no event shall the aggregate number of shares of Public Company Common Stock issuable upon exercise of Otic Pharma Share Options and Adjusted Warrants and as set forth on Exhibit D, together with the Aggregate Closing Consideration, exceed the Maximum Consideration.

1.6 Allocation Schedules.

(a) The Preliminary Closing Date Allocation Schedule sets forth a good faith estimate as of the date of this Agreement of the amounts payable to the Shareholders pursuant to this Agreement. Otic Pharma shall deliver to Public Company, at least three Business Days prior to the Closing, the Closing Date Allocation Schedule. Public Company shall be entitled to rely conclusively on the Closing Date Allocation Schedule, and, as between the Shareholders, on the one hand, and Public Company, on the other hand, any amounts delivered by the Public Company to any Shareholder in accordance with the Closing Date Allocation Schedule shall be deemed for all purposes to have been delivered to the applicable Shareholder in full satisfaction of the obligations of the Public Company under this Article I.

(b) Public Company shall pay the portion of the Aggregate Closing Consideration payable in respect of the Otic Pharma Share Capital to the applicable Shareholders in accordance with the Closing Date Allocation Schedule.

1.7 Withholding Rights. Subject to the provisions of Section 1.8, each of Otic Pharma, Public Company, the Paying Agent and the 102 Trustee (each, a "Payor") will be entitled to deduct and withhold from the amounts otherwise payable by it pursuant to this Agreement to any person such amounts as it reasonably determines that it is required to deduct and withhold with respect to the making of such payment under the Israeli Income Tax Ordinance, the Code, or any other applicable law, including the Israeli Income Tax Ordinance and to collect any necessary Tax forms, including Forms W-8 or W-9, as applicable, or any similar information, from Shareholders and any other recipients of payments hereunder. In the event that any amount is so deducted and withheld, and properly remitted to the applicable Tax authority, such amount will be treated for all purposes of this Agreement as having been paid to the person to whom the payment from which such amount was withheld was made. The Public Company undertakes to promptly provide each of the Shareholders from whom Tax was so withheld with sufficient evidence regarding the amounts that were paid and withheld with respect to such Shareholders.

1.8 Additional Withholding Matters.

(a) Notwithstanding Section 1.7 above, with respect to Israeli Tax, no amount payable to a Shareholder or to a holder of Otic Pharma Share Options (each a "Payee") under this Agreement at the Closing shall be subject to withhold of Israeli Tax if the 104H Ruling has been received.

(b) To the extent not previously filed, Otic Pharma shall cause its Israeli counsel in full coordination with Public Company and its Israeli counsel, to prepare and file with the ITA an application for the following rulings:

(i) A ruling in relation to the Otic Pharma Share Capital subject to the provisions of Section 102(b)(2) of the Israeli Income Tax Ordinance ("Section 102(b)(2)") and Otic Pharma Share Options subject to the provisions of Section 102(b)(2) or Section 3(i) of the Israeli Income Tax Ordinance ("Section 3(i)"), as applicable, confirming, among others, that: (i) the assumption of the Otic Share Option Plan, and of the Otic Pharma Share Capital and Otic Pharma Share Options, which remain subject to the statutory minimum trust period under such Section 102 of the Israeli Income Tax Ordinance, will not constitute a violation of the requirements of Section 102 of the Israeli Income Tax Ordinance; and (ii) Public Company and anyone acting on its behalf, including the Paying Agent, shall be exempt from withholding Tax in relation to any payments or consideration transferred to the 102 Trustee in relation to Otic Pharma Share Capital subject to Section 102(b)(2) or Otic Pharma Share Options subject to Section 102(b)(2) or Section 3(i), as applicable; which ruling may be subject to customary conditions regularly associated with such a ruling (the "Israeli Options Tax Ruling"). If the Israeli Options Tax Ruling is not granted prior to the Closing, Otic Pharma shall seek to receive prior to the Closing an interim tax ruling confirming among others that Public Company and anyone acting on its behalf (including the Paying Agent) shall be exempt from Israeli withholding Tax in relation to any payments made to the 102 Trustee with respect to Otic Pharma Share Capital subject to Section 102(b)(2) or Otic Pharma Share Options subject to Section 102(b)(2) or Section 3(i) (which interim tax ruling may be subject to customary conditions regularly associated with such an interim tax ruling) (the "Interim Options Tax Ruling"); and

(ii) A ruling confirming that the provisions of Section 104H apply to the Transaction and that the applicable Israeli Tax with respect to the Transaction shall be deferred in accordance with the provisions of Section 104H (the "104H Ruling" and together with the Interim Options Tax Ruling and the Israeli Options Tax Rulings, the "Israeli Tax Rulings").

(c) The parties will cause their respective Israeli counsel, advisors and accountants to coordinate and cooperate and provide all information required with respect to Otic Pharma's preparation and filing of such application and in the preparation of any written or oral submissions that may be necessary, proper or advisable to obtain the Israeli Tax Rulings. Subject to the terms and conditions hereof, Otic Pharma shall use commercially reasonable efforts to promptly take, or cause to be taken, all reasonable action and to do, or cause to be done, all reasonable things necessary, proper or advisable to obtain the Israeli Tax Rulings as promptly as practicable; provided, however, that if none of such Israeli Tax Rulings is obtained for any reason whatsoever by the Closing Date, the Closing shall be delayed or postponed. For the avoidance of doubt, it is clarified that the language of the Israeli Tax Rulings (as applicable) shall be subject to the prior written approval of Public Company and its Israeli counsel, which shall not be unreasonably withheld or delayed. Otic Pharma will inform Public Company and its Israeli counsel in advance of any meeting or other discussion with the ITA with respect to any of the Israeli Tax Rulings and allow Public Company's counsel to attend such meeting and participate in such discussions. Should Public Company's counsel not attend any such meeting or discussion with the ITA, the counsel of Otic Pharma shall provide such counsel with an update of such meeting or discussion within one (1) Business Day of such meeting or discussion.

ARTICLE II

REPRESENTATIONS AND WARRANTIES OF SHAREHOLDERS

Each Shareholder, severally and not jointly, represents and warrants to Public Company that the statements contained in this Article II are true and correct.

2.1 Organization, Standing. To the extent such Shareholder is an entity, (a) the Shareholder is a corporation or other entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation and (b) the Shareholder is not in default under or in violation of any provision of its organizational documents. The Shareholder has all requisite power and authority to carry on the businesses in which it is engaged and to own and use the properties owned and used by it.

2.2 Authority, Power; No Conflict; Required Filings and Consents.

(a) Except as set forth in Section 2.2(a) of the Otic Pharma Disclosure Schedule, the Shareholder has all requisite power and authority and capacity (in the case of individuals) to execute and deliver this Agreement and the other agreements contemplated hereby to which the Shareholder is a party and to perform the Shareholder's obligations hereunder and thereunder. The execution and delivery by the Shareholder of this Agreement and the other agreements contemplated hereby to which the Shareholder is a party and the performance by the Shareholder of this Agreement and the consummation by the Shareholder of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate and other action on the part of the Shareholder. This Agreement and all other agreements contemplated hereby to which the Shareholder is a party have been or will be as of the Closing Date duly and validly executed and delivered by the Shareholder and, assuming the due authorization, execution and delivery by Public Company, Otic Pharma, the other Shareholders, and any other party thereto, constitutes or will constitute a valid and binding obligation of the Shareholder, enforceable against the Shareholder in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles (the "Bankruptcy and Equity Exception").

(b) The execution and delivery of this Agreement by the Shareholder does not, and the consummation by the Shareholder of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws (or similar organizational documents) of Shareholder (to the extent Shareholder is an entity), (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any

mortgage, security interest, pledge, lien, charge or encumbrance of any nature ("Liens") on assets under any of the terms, conditions or provisions of any note, bond, mortgage, indenture, lease, license, contract or other agreement, instrument or obligation to which the Shareholder is a party or by which any of its properties or assets may be bound, or (iii) conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to the Shareholder or any of its properties or assets, except in the case of clauses (ii) and (iii) of this Section 2.2(b), for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate, are not reasonably likely to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder. Section 2.2(b) of the Otic Pharma Disclosure Schedule lists all consents, waivers and approvals (if any) under any of the Shareholder's agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would reasonably be expected to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder.

(c) No consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to the Shareholder in connection with the execution and delivery of this Agreement by the Shareholder or the consummation by the Shareholder of the transactions contemplated by this Agreement, except for such consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would reasonably be expected to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder.

2.3 Ownership of Otic Pharma Share Capital. The Shareholder holds legally, beneficially and of record all of the Shareholder's Otic Pharma Share Capital set forth on Section 3.2(b) of the Otic Pharma Disclosure Schedule, free and clear of any Liens (other than restrictions on transfer arising under applicable securities laws). Except as set forth in Section 2.3 and Section 3.2(e) of the Otic Pharma Disclosure Schedule, the Shareholder is not a party to any voting trust, proxy, or other agreement or understanding with respect to the voting or transfer of any Shares. Upon consummation of the purchase contemplated hereby, Public Company will acquire from the Shareholder good and marketable title to all Shares owned by the Shareholder, free and clear of all Liens (other than restrictions on transfer arising under applicable securities laws).

2.4 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or has been threatened in writing against the Shareholder that questions the validity of this Agreement or any action taken or to be taken by the Shareholder in connection herewith or that would reasonably be expected to prohibit or materially delay the Shareholder's ability to consummate the transactions contemplated by this Agreement. The Shareholder does not have any claim of any kind against Otic Pharma.

2.5 Brokers. The Shareholder has no liability or obligation to pay any fees or commissions to any broker, finder or agent with respect to the transactions contemplated by this Agreement.

2.6 Purchase for Own Account; Sophistication. The Shareholder acknowledges and agrees that shares of Public Company Common Stock to be acquired by the Shareholder pursuant to this Agreement will be acquired for investment for the Shareholder's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Shareholder has no present intention of selling, granting any participation in, or otherwise distributing the same. The Shareholder acknowledges and agrees that the Shareholder does not presently have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third party, with respect to any of the shares of Public Company Common Stock to be received by it pursuant to this Agreement. The Shareholder represents and warrants that it has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of owning the shares of Public Company Common Stock to be received by it pursuant to this Agreement. The Shareholder has the ability to bear the economic risk of the investment in shares of Public Company Common Stock, including complete loss of such investment.

2.7 Access to Information. The Shareholder acknowledges that (a) it has been afforded (i) access to information about each of Otic Pharma and Public Company, respectively, and their respective financial conditions, results of operations, businesses, properties and prospects sufficient to enable the Shareholder to evaluate its investment in Public Company Common Stock; and (ii) the opportunity to obtain such additional information that the other party possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment in Public Company Common Stock and any such additional information has been provided to the Shareholder's reasonable satisfaction, and (b) it has sought such professional advice as it has considered necessary to make an informed decision with respect to its acquisition of the Public Company Common Stock. Except to the extent expressly provided for in this Agreement, the Shareholder hereby agrees that neither Public Company nor any of its Affiliates will have or be subject to any liability or indemnification obligation to the Shareholder or to any other person resulting from the issuance of shares of Public Company Common Stock to the Shareholders.

2.8 Restricted Securities; Legends.

(a) The Shareholder understands that the shares of Public Company Common Stock to be received by it in connection with the Transaction have not been, and will not be, registered under the Securities Act of 1933, as amended (the "Securities Act"), by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Shareholder's representations and warranties as expressed herein. The Shareholder understands that such shares of Public Company Common Stock will be "restricted securities" under applicable securities laws and that, pursuant to these laws, the Shareholder must hold such shares indefinitely unless they are registered with the Securities and Exchange Commission (the "SEC") and qualified by state authorities, or an exemption from such registration and qualification requirements is available.

(b) The Shareholder understands that the shares of Public Company Common Stock to be received by it in connection with the Transaction may be notated with one or more of the following legends:

(i) "THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933."

(ii) Any legend required by applicable securities laws to the extent such laws are applicable to the Shares represented by the certificate, instrument, or book entry so legended.

2.9 Accredited Investor; Regulation S. Except as set forth on Schedule 2.9 to this Agreement, the Shareholder either is (a) an "accredited investor" (as defined in Regulation D promulgated under the Securities Act) or (b) not a "U.S. person" within the meaning of Rule 902 of Regulation S of the Securities Act and is not acquiring Public Company Common Stock pursuant to this Agreement for the account or benefit of any U.S. person within the meaning of Rule 902 of Regulation S of the Securities Act (each such Shareholder, a "Regulation S Shareholder").

2.10 No Other Representations or Warranties. The Shareholder hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Public Company nor any other person on behalf of Public Company makes any express or implied representation or warranty with respect to Public Company or with respect to any other information provided to Otic Pharma, any Shareholder or any of their Affiliates in connection with the transactions contemplated hereby, and (subject to the express representations and warranties of Public Company set forth in Article IV (in each case as qualified and limited by the Public Company Disclosure Schedule)) no Shareholder nor any of their respective Affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF OTIC PHARMA

Otic Pharma represents and warrants to Public Company that the statements contained in this Article III are true and correct, except as expressly set forth herein or in the disclosure schedule delivered by Otic Pharma to Public Company on the date of this Agreement (the "Otic Pharma Disclosure Schedule"). For purposes hereof, the phrase "to the knowledge of Otic Pharma" and similar expressions mean the actual knowledge of the persons identified on Section K of the Otic Pharma Disclosure Schedule for this purpose, and such knowledge as such persons would reasonably be expected to have obtained in the course of their performance of their positions at Otic Pharma (but without any special investigation).

3.1 Organization, Standing and Power. Otic Pharma is a private limited company duly organized and validly existing under the laws of the State of Israel and is not a "breaching company" in the records of the Israeli Registrar of Companies. Otic Pharma has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction listed on Section 3.1 of the Otic Pharma Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. For purposes of this Agreement, the term "Otic Pharma Material Adverse Effect" means any material adverse change, effect, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, condition (financial or other), or results of operations of Otic Pharma and its Subsidiaries, taken as a whole; provided, however, that none of the following, to the extent arising after the date of this Agreement, shall be deemed to be a Otic Pharma Material Adverse Effect: any change or event caused by or resulting from (A) changes in prevailing economic or market conditions in the United States or any other jurisdiction in which such entity has substantial business operations (except to the extent those changes have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate in the relevant jurisdiction), (B) changes or events affecting the industry or industries in which Otic Pharma and its Subsidiaries operate generally (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (C) changes in generally accepted accounting principles or requirements applicable to Otic Pharma and its Subsidiaries (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (D) changes in laws, rules or regulations of general applicability or interpretations thereof by any Governmental Entity (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (E) any natural disaster or any outbreak of major hostilities in which the United States or Israel is involved or any act of terrorism within the United States or Israel or directed against their facilities or citizens wherever located (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), or (F) any failure by Otic Pharma to meet any internal guidance, budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations (but not, in the case of this clause (F), the underlying cause of such changes or failures, unless such changes or failures would otherwise be excepted from this definition). For

the avoidance of doubt, the parties agree that the terms "material," "materially" and "materiality" as used in this Agreement with an initial lower case "m" shall have their respective customary and ordinary meanings, without regard to the meanings ascribed to Otic Pharma Material Adverse Effect or Public Company Material Adverse Effect, in each case as defined in this Agreement. Otic Pharma has made available to Public Company complete and accurate copies of the Otic Pharma Organizational Documents and is not in material default under or in material violation of any provision of such documents.

3.2 Capitalization.

(a) The authorized share capital of Otic Pharma consists of 9,207,060 Ordinary Shares, of which 740,215 were issued and outstanding, and 5,958,682 Preferred Shares, of which: (i) 691,000 shares are designated as Series A Preferred Shares, of which 493,551 were issued and outstanding, (ii) 4,327,590 shares are designated as Series B Preferred Shares, of which 2,640,711 were issued and outstanding, and (iii) 1,546,950 shares are designated as Series C Preferred Shares, of which 940,092 were issued and outstanding. The rights and privileges of each class and series of Otic Pharma's share capital are as set forth in Otic Pharma's articles of association. As of the date of this Agreement, no shares were held in the treasury of Otic Pharma or by Subsidiaries of Otic Pharma.

(b) Section 3.2(b) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list, as of the date of this Agreement, of the holders of Otic Pharma Share Capital, showing the number of shares, and the class or series of such shares, held by each shareholder and (for shares other than Otic Pharma Ordinary Shares) the number of shares of Otic Pharma Ordinary Shares (if any) into which such shares are convertible. Section 3.2(b) of the Otic Pharma Disclosure Schedule also sets forth a complete and accurate list of all issued and outstanding shares of Otic Pharma Ordinary Shares that constitute restricted stock or that are otherwise subject to a repurchase or redemption right or right of first refusal in favor of Otic Pharma, indicating the name of the applicable shareholder, the vesting schedule for any such shares, including the extent to which any such repurchase or redemption right or right of first refusal has lapsed as of the date of this Agreement, whether (and to what extent) the vesting will be accelerated in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the transactions contemplated by this Agreement, and whether to the knowledge of Otic Pharma such holder has the sole power to vote and dispose of such shares.

(c) The Otic Pharma Ltd. Global Share Initiative Plan (2012) is the sole Otic Pharma Share Plan that Otic has ever had. Section 3.2(c) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list, as of the date of this Agreement, of: (i) the number of shares of Otic Pharma Ordinary Shares issued to date under such plan, the number of shares of Otic Pharma Ordinary Shares subject to outstanding options under such Plan and the number of shares of Otic Pharma Ordinary Shares reserved for future issuance under such Plan; and (ii) all outstanding Otic Pharma Share Options, indicating with respect to each such Otic Pharma Share Option the name of the holder thereof, the number of shares of Otic Pharma Ordinary Shares subject to such Otic Pharma Share Option, the exercise price, the date of grant and the vesting schedule, including whether (and to what extent) the vesting will be accelerated

in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the Transaction, whether such Otic Pharma Share Option is intended to be an incentive stock option, whether each such Otic Pharma Share Option was granted and is subject to Tax pursuant to Section 3(i) of the Israeli Income Tax Ordinance or Section 102 of the Israeli Income Tax Ordinance and the applicable sub-section of Section 102 of the Israeli Income Tax Ordinance, and for Otic Pharma Share Options subject to Section 102(b)(2) of the Israeli Income Tax Ordinance the date of deposit of such Otic Pharma Share Option with the 102 Trustee, including also full details of the grant and the date of deposit of the respective option agreement with the 102 Trustee. Otic Pharma has made available to Public Company complete and accurate copies of the Otic Pharma Share Plan and the form of share option agreements evidencing Otic Pharma Share Options.

(d) Section 3.2(d) of the Otic Pharma Disclosure Schedule sets forth the number of shares of Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares reserved for future issuance pursuant to warrants or other outstanding rights (other than Otic Pharma Share Options) to purchase shares of Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares outstanding as of the date of this Agreement (such outstanding warrants or other rights, the "Otic Pharma Warrants") and the agreement or other document under which such Otic Pharma Warrants were granted and sets forth a complete and accurate list of all holders of Otic Pharma Warrants indicating the number and type of shares of Otic Pharma Share Capital subject to each Otic Pharma Warrant, and the exercise price, the date of grant and the expiration date thereof. Otic Pharma has made available to Public Company complete and accurate copies of the forms of agreements evidencing all Otic Pharma Warrants.

(e) Except (i) as set forth in this Section 3.2 and (ii) as reserved for future grants under Otic Pharma Share Plan, (A) there are no equity securities of any class of Otic Pharma, or any security exchangeable into or exercisable for such equity securities, issued, reserved for issuance or outstanding and (B) there are no options, warrants, equity securities, calls, rights, commitments or agreements of any character to which Otic Pharma is a party or by which Otic Pharma or any of its Subsidiaries is bound obligating Otic Pharma or any of its Subsidiaries to issue, exchange, transfer, deliver or sell, or cause to be issued, exchanged, transferred, delivered or sold, additional shares of capital stock or other equity interests of Otic Pharma or any security or rights convertible into or exchangeable or exercisable for any such shares or other equity interests, or obligating Otic Pharma or any of its Subsidiaries to grant, extend, accelerate the vesting of, otherwise modify or amend or enter into any such option, warrant, equity security, call, right, commitment or agreement. Otic Pharma does not have any outstanding stock appreciation rights, phantom stock, performance based rights or similar rights or obligations. Other than Otic Pharma's articles of association, neither Otic Pharma nor any of its Affiliates is a party to or is bound by any, and to the knowledge of Otic Pharma, there are no, agreements or understandings with respect to the voting (including voting trusts and proxies) or sale or transfer (including agreements imposing transfer restrictions) of any shares or other equity interests of Otic Pharma. For purposes of this Agreement, the term "Affiliate" when used with respect to any party shall mean any person who is an "affiliate" of that party within the meaning of Rule 405 promulgated under the Securities Act. Except as contemplated by this Agreement or described in this Section 3.2(e), there are no registration rights to which Otic Pharma or any of its Subsidiaries is a party or by which it or they are bound with respect to any equity security of any class of Otic Pharma.

(f) All outstanding Otic Pharma Share Capital is, and all shares of Otic Pharma Ordinary Shares subject to issuance as specified in Sections 3.2(c), 3.2(d), and 3.2(e) upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, will be, duly authorized, validly issued, fully paid and nonassessable and not subject to or issued in violation of any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any provision of applicable law, the Otic Pharma Organizational Documents or any agreement to which Otic Pharma is a party or is otherwise bound. There are no obligations, contingent or otherwise, of Otic Pharma or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of Otic Pharma Share Capital. All outstanding shares of Otic Pharma Share Capital have been offered, issued and sold by Otic Pharma in compliance with all applicable securities laws.

(g) No consent of the holders of Otic Pharma Share Options or Otic Pharma Warrants, apart from consents previously obtained, is required in connection with the actions contemplated by Section 1.5.

3.3 Subsidiaries.

(a) Section 3.3(a) of the Otic Pharma Disclosure Schedule sets forth, for each Subsidiary of Otic Pharma: (i) its name; (ii) the number and type of outstanding equity securities and a list of the holders thereof; and (iii) the jurisdiction of organization. For purposes of this Agreement, the term "Subsidiary" means, with respect to any party, any corporation, partnership, trust, limited liability company or other non-corporate business enterprise in which such party (or another Subsidiary of such party) owns or controls, directly or indirectly, securities or other ownership interests representing (A) more that 50% of the voting power of all outstanding stock or ownership interests of such entity or (B) the right to receive more than 50% of the net assets of such entity available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution of such entity.

(b) Each Subsidiary of Otic Pharma is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation (to the extent such concepts are applicable in such jurisdiction), has all requisite corporate (or similar, in the case of a non-corporate entity) power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted and as currently proposed to be conducted, and is duly qualified to do business and is in good standing as a foreign corporation (to the extent such concepts are applicable) in each jurisdiction where the character of its properties owned, operated or leased or the nature of its activities makes such qualification necessary, except for such failures to be so organized, qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. All of the outstanding shares of capital stock and other equity securities or interests of each Subsidiary of Otic Pharma are duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights and all such shares (other than directors' qualifying shares in the case of non-U.S. Subsidiaries, all of which Otic Pharma has the power to

cause to be transferred for no or nominal consideration to Otic Pharma or Otic Pharma's designee) are owned, of record and beneficially, by Otic Pharma or another of its Subsidiaries free and clear of all Liens, claims, agreements or limitations in Otic Pharma's voting rights. There are no outstanding or authorized options, warrants, rights, agreements or commitments to which Otic Pharma or any of its Subsidiaries is a party or which are binding on any of them providing for the issuance, disposition or acquisition of any capital stock of any Subsidiary of Otic Pharma. There are no outstanding stock appreciation, phantom stock or similar rights with respect to any Subsidiary of Otic Pharma. There are no voting trusts, proxies or other agreements or understandings with respect to the voting of any capital stock of any Subsidiary of Otic Pharma.

(c) Otic Pharma has made available to Public Company complete and accurate copies of the charter, bylaws or other organizational documents of each Subsidiary of Otic Pharma.

(d) Otic Pharma does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity which is not a Subsidiary of Otic Pharma. There are no obligations, contingent or otherwise, of Otic Pharma or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of capital stock of any Subsidiary of Otic Pharma or to provide funds to or make any investment (in the form of a loan, capital contribution or otherwise) in any Subsidiary of Otic Pharma or any other entity, other than guarantees of bank obligations of Subsidiaries of Otic Pharma entered into in the ordinary course of business consistent in all material respects with past practice (as applicable to a party, the "Ordinary Course of Business").

3.4 Authority; No Conflict; Required Filings and Consents.

(a) Otic Pharma has all requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement by Otic Pharma have been duly authorized by all necessary corporate action on the part of Otic Pharma. This Agreement has been duly executed and delivered by Otic Pharma and constitutes the valid and binding obligation of Otic Pharma, enforceable against Otic Pharma in accordance with its terms, subject to the Bankruptcy and Equity Exception.

(b) The execution and delivery of this Agreement by Otic Pharma does not, and the consummation by Otic Pharma of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws of Otic Pharma or of the charter, bylaws or other organizational document of any Subsidiary of Otic Pharma, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any Liens on Otic Pharma's or any of its Subsidiaries' assets under

any of the terms, conditions or provisions of any Contract required to be disclosed in Section 3.11(d) of the Otic Pharma Disclosure Schedules, or (iii) conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to Otic Pharma or any of its Subsidiaries or any of its or their properties or assets, except in the case of clauses (ii) and (iii) of this Section 3.4(b) for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate, have not had, and are not reasonably likely to result in, the loss of a material benefit to, or in the creation of any material liability for, Otic Pharma. Section 3.4(b) of the Otic Pharma Disclosure Schedule lists all consents, waivers and approvals under any of Otic Pharma's or any of its Subsidiaries' agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would result in a loss of a material benefit to, or the creation of any material liability for, Otic Pharma or Public Company as a result of the Transaction.

(c) Except as set forth in Section 3.14(c) of the Otic Pharma Disclosure Schedule, no consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to Otic Pharma or any of its Subsidiaries in connection with the execution and delivery of this Agreement by Otic Pharma or the consummation by Otic Pharma of the Transaction, except for such consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would not result in a loss of a material benefit to, or the creation of any material liability for, Otic Pharma or Public Company as a result of the Transaction. No publication of a prospectus in Israel is required by or with respect to Otic Pharma or any of its Subsidiaries in connection with the execution and delivery of this Agreement by Otic Pharma or the consummation by Otic Pharma of the Transaction.

3.5 Financial Statements; Information Provided.

(a) Otic Pharma has made available to Public Company correct and complete copies of the Financial Statements. The Financial Statements (i) comply as to form in all material respects with all applicable accounting requirements, (ii) were prepared in accordance with United States generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods covered thereby (except as may be indicated in the notes to such financial statements) and (iii) fairly present in all material respects the consolidated financial position of Otic Pharma and its Subsidiaries as of the dates thereof and the consolidated assets, liabilities, business, financial condition, results of its operations and cash flows for the periods indicated, consistent with the books and records of Otic Pharma and its Subsidiaries, except that the unaudited interim financial statements are subject to normal and recurring year-end adjustments, which will not be material in amount or effect and which do not contain footnotes otherwise required by GAAP. For purposes of this Agreement, "Financial Statements" means (i) the audited consolidated balance sheets and statements of income, changes in shareholders' equity and cash flows of Otic Pharma as of the end of and for each of the last three fiscal years, and (ii) the unaudited consolidated balance sheet of Otic Pharma (the "Otic Pharma Balance Sheet") as of September 30, 2016 (the "Most Recent Balance Sheet Date") and the unaudited consolidated statements of income, changes in shareholders' equity and cash flows for the nine months ended as of the Most Recent Balance Sheet Date.

(b) Deloitte, Brightman Almagor Zohar & Co., Otic Pharma's current auditor, is and to the knowledge of Otic Pharma has been at all times since its engagement by Otic Pharma been, (x) "independent" with respect to Otic Pharma and its Subsidiaries within the meaning of Regulation S-X and (y) in compliance with subsections (g) through (l) of Section 10A of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (to the extent applicable), and the related rules of the SEC and Public Company Accounting Oversight Board.

(c) The information to be supplied by or on behalf of Otic Pharma for inclusion in a definitive proxy statement on Schedule 14A seeking stockholder approval of the Public Company Voting Proposal (the "Proxy Statement") to be sent to the stockholders of Public Company in connection with the meeting of Public Company's stockholders (the "Public Company Meeting") to consider the issuance of shares of Public Company Common Stock in the Transaction (the "Public Company Voting Proposal") under the rules of The NASDAQ Stock Market, Inc. ("NASDAQ") and the General Corporation Law of the State of Delaware (the "DGCL") (the "Public Company Stockholder Approval"), which information shall be deemed to include all information about or relating to Otic Pharma and its Subsidiaries shall not, on the date the Proxy Statement is first mailed to stockholders of Public Company, or at the time of the Public Company Meeting, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading; or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Public Company Meeting that has become false or misleading.

3.6 No Undisclosed Liabilities. Otic Pharma does not have any liability that is required to be set forth on a balance sheet of Otic Pharma in accordance with GAAP, except for (a) liabilities shown on the Most Recent Balance Sheet, (b) liabilities that have arisen since the Most Recent Balance Sheet Date in the Ordinary Course of Business, (c) liabilities for transaction expenses incurred in connection with the transactions contemplated by this Agreement and (d) contractual and other liabilities incurred in the Ordinary Course of Business that are not required by GAAP to be reflected on a balance sheet.

3.7 Absence of Certain Changes or Events. During the period beginning on the Most Recent Balance Sheet Date and ending on the date hereof, Otic Pharma and its Subsidiaries have conducted their respective businesses only in the Ordinary Course of Business and, since such date, there has not been (i) any change, event, circumstance, development or effect that, individually or in the aggregate, has had, or is reasonably likely to have, a Otic Pharma Material Adverse Effect; or (ii) any other action that would have required consent of Public Company pursuant to Section 5.1 (other than clause (A) of paragraph (j) or paragraphs (k) or (l) thereof) had such action or event occurred after the date of this Agreement.

3.8 Taxes.

(a) Each of Otic Pharma and its Subsidiaries has properly filed on a timely basis all income and other material Tax Returns that it was required to file, and all such Tax Returns were true, correct and complete in all material respects. Each of Otic Pharma and its Subsidiaries has paid on a timely basis all Taxes that were due and payable. The unpaid Taxes of Otic Pharma and each of its Subsidiaries for Tax periods through the date of the Otic Pharma Balance Sheet do not exceed the accruals and reserves for Taxes (excluding accruals and reserves for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the Otic Pharma Balance Sheet and all unpaid Taxes of Otic Pharma and each of its Subsidiaries for all Tax periods commencing after the date of the Otic Pharma Balance Sheet arose in the Ordinary Course of Business. Neither Otic Pharma nor any of its Subsidiaries is or has ever been a member of an affiliated group with which it has filed (or been required to file) consolidated, combined, unitary or similar Tax Returns, other than a group of which the common parent is Otic Pharma. With the exception of customary commercial leases or contracts that are not primarily related to Taxes entered into in the Ordinary Course of Business and liabilities thereunder, neither Otic Pharma nor any of its Subsidiaries (i) has any actual or potential liability under Treasury Regulations Section 1.1502-6 (or any comparable or similar provision of federal, state, local or foreign law), as a transferee or successor, pursuant to any contractual obligation, or otherwise for any Taxes of any person other than Otic Pharma or any of its Subsidiaries, or (ii) is a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement. All material Taxes that Otic Pharma or any of its Subsidiaries was required by law to withhold or collect have been duly withheld or collected and, to the extent required, have been properly paid to the appropriate Governmental Entity, and each of Otic Pharma and its Subsidiaries has complied with all material information reporting and backup withholding requirements, including the maintenance of required records with respect thereto, in connection with amounts paid to any employee, independent contractor, creditor, or other third party. For purposes of this Agreement, (i) "Taxes" shall mean any and all taxes, charges, fees, duties, contributions, levies or other similar assessments or liabilities in the nature of a tax, including, without limitation, income, gross receipts, corporation, ad valorem, premium, value-added, net worth, capital stock, capital gains, documentary, recapture, alternative or add-on minimum, disability, estimated, registration, recording, excise, real property, personal property, sales, use, license, lease, service, service use, transfer, withholding, employment, unemployment, insurance, social security, national insurance, health tax, business license, business organization, environmental, workers compensation, payroll, profits, severance, stamp, occupation, windfall profits, customs duties, franchise and other taxes of any kind whatsoever imposed by the United States of America or any state, local or foreign government, or any agency or political subdivision thereof, and any interest, fines, penalties, assessments or additions to tax imposed with respect to such items, and (ii) "Tax Returns" shall mean any and all reports, returns (including information returns), declarations, or statements relating to Taxes, including any schedule or attachment thereto and any amendment thereof, filed with or submitted to a Governmental Entity in connection with the determination, assessment, collection or payment of Taxes or in connection with the administration, implementation or enforcement of or compliance with any legal requirement relating to any Tax.

(b) Otic Pharma has delivered or made available to Public Company (i) complete and correct copies of all Tax Returns of Otic Pharma and any of its Subsidiaries relating to Taxes for all taxable periods for which the applicable statute of limitations has not yet expired, (ii) complete and correct copies of all private letter rulings, revenue agent reports, information document requests, notices of proposed deficiencies, deficiency notices, protests, petitions, closing agreements, settlement agreements, pending ruling requests and any similar documents submitted by, received by, or agreed to by or on behalf of Otic Pharma or any of its Subsidiaries relating to Taxes for all taxable periods for which the statute of limitations has not yet expired, and (iii) complete and correct copies of all material agreements, rulings, settlements or other Tax documents with or from any Governmental Entity relating to Tax incentives of Otic Pharma or any of its Subsidiaries. No examination or audit of any Tax Return of Otic Pharma or any of its Subsidiaries by any Governmental Entity is currently in progress or, to the knowledge of Otic Pharma, threatened or contemplated. Neither Otic Pharma nor any of its Subsidiaries has been informed in writing by any jurisdiction in which Otic Pharma or any Subsidiary does not file a Tax Return that the jurisdiction believes that Otic Pharma or any of its Subsidiaries was required to file any Tax Return that was not filed or is subject to Tax in such jurisdiction. Neither Otic Pharma nor any of its Subsidiaries has (i) waived any statute of limitations with respect to Taxes or agreed to extend the period for assessment or collection of any Taxes, which waiver or extension is still in effect, (ii) requested any extension of time within which to file any Tax Return, other than routine extensions available as a matter of right which Tax Return has not yet been filed, or (iii) executed or filed any power of attorney with any taxing authority, which is still in effect.

(c) Neither Otic Pharma nor any of its Subsidiaries has made any payment, is obligated to make any payment, or is a party to any agreement that could obligate it to make any payment that may be treated as an "excess parachute payment" under Section 280G of the Code (without regard to Sections 280G(b)(4) and 280G(b)(5) of the Code).

(d) Neither Otic Pharma nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(l)(A)(ii) of the Code.

(e) Neither Otic Pharma nor any of its Subsidiaries has distributed to its shareholders or security holders stock or securities of a controlled corporation, nor has stock or securities of Otic Pharma or any of its Subsidiaries been distributed, in a transaction to which Section 355 of the Code applies (i) in the two years prior to the date of this Agreement or (ii) in a distribution that could otherwise constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) that includes the transactions contemplated by this Agreement.

(f) There are no Liens with respect to Taxes upon any of the assets or properties of Otic Pharma or any of its Subsidiaries, other than with respect to Taxes not yet due and payable.

(g) Neither Otic Pharma nor any of its Subsidiaries will be required to include any item of income in, or exclude any item of deduction from, taxable income for any period (or any portion thereof) ending after the Closing Date as a result of any (i) adjustments under Section 481 of the Code (or any similar adjustments under any provision of the Code or the

corresponding foreign, state or local Tax laws), (ii) deferred intercompany gain or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding provision of state, local or foreign Tax law), (iii) closing agreement as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax law) executed on or prior to the Closing Date, (iv) installment sale or other open transaction disposition made on or prior to the Closing Date, (v) prepaid amount received on or prior to the Closing Date, or (vi) any election made pursuant to Section 108(i) of the Code on or prior to the Closing Date.

(h) Neither Otic Pharma nor any of its Subsidiaries has participated in any "reportable transaction" as defined in section 1.6011-4(b) of the Treasury Regulations or any analogous provision of state or local law.

(i) Neither Otic Pharma nor any Subsidiary (i) is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal income Tax purposes, (ii) has made an entity classification ("check-the-box") election under Section 7701 of the Code, (iii) is, or has been, a shareholder of a "controlled foreign corporation" as defined in Section 957 of the Code (or any similar provision of state, local or foreign law), or (iv) is, or has been, a shareholder in a "passive foreign investment company" within the meaning of Section 1297 of the Code.

(j) Neither Otic Pharma nor any Subsidiary (A) has or has had a permanent establishment in any country (other than its country of incorporation) as defined in any applicable Tax treaty or convention between such foreign country and Otic Pharma's or its Subsidiary's country of incorporation or (B) has or has had operations constituting doing business for Tax purposes in any country (other than its country of incorporation).

(k) The Otic Pharma Share Plan is intended to qualify as a capital gains track plan under Section 102 of the Israeli Income Tax Ordinance (a "102 Plan"), and has received a favorable determination or approval letter from, or is otherwise approved by, or deemed approved by passage of time without objection by, the ITA. Otic Pharma Share Capital and Otic Pharma Share Options which are subject to Tax under Section 102 of the Israeli Income Tax Ordinance and which were issued under any 102 Plan have been granted and issued, as applicable, in compliance with the applicable requirements of Section 102 of the Israeli Income Tax Ordinance (including the relevant sub-sections of Section 102) and the written requirements and guidance of the ITA, including the filing of the necessary documents with the ITA, the appointment of an authorized trustee to hold the Otic Pharma Share Capital and Otic Pharma Share Options, and the due deposit of such Otic Pharma Share Capital and Otic Pharma Share Options with such trustee pursuant to the terms of Section 102 of the Israeli Income Tax Ordinance and the guidance published by the ITA on July 24, 2012 and clarification dated November 6, 2012.

(l) All related party transactions involving Otic Pharma or any of its Subsidiaries have been conducted at arm's length in compliance with Section 482 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law. Each of Otic Pharma and its Subsidiaries has maintained documentation

(including any applicable transfer pricing studies) in connection with such related party transactions in accordance with Sections 482 and 6662 of the Code and the Treasury Regulations promulgated thereunder or the comparable provisions of any other foreign Tax law, as applicable, including Section 85A of the Israeli Income Tax Ordinance and the regulations promulgated thereunder.

(m) Otic Pharma and its Subsidiaries have complied in all material respects with all applicable laws relating to the payment and withholding of Taxes, including from payments made or deemed made to employees, suppliers, lenders and other third parties, from payments made or deemed made to any Person and have duly and timely withheld and paid over to the appropriate taxing authority all amounts required to be so withheld and paid under all applicable laws. Otic Pharma and its Subsidiaries are materially in compliance with, and its records contain all information and documents necessary to comply with, all applicable information reporting and withholding requirements under all applicable Tax laws.

(n) Otic Pharma is duly registered for the purposes of Israeli value added tax and has complied in all material respects with the requirements concerning value added Taxes ("VAT"). Otic Pharma (i) has not made any exempt transactions (as defined in the Israel Value Added Tax Law of 1975) and, to the knowledge of Otic Pharma, there are no circumstances by reason of which there might not be an entitlement to full credit of all VAT chargeable or paid on inputs, supplies, and other transactions and imports made by it, (ii) has collected and timely remitted to the relevant taxing authority the output VAT which it is required to collect and remit under any applicable law; and (iii) has not received a refund for input VAT for which it is not entitled under applicable law.

(o) Otic Pharma is not subject to any restrictions or limitations pursuant to Part E2 of the Israeli Income Tax Ordinance or pursuant to any Tax ruling made with reference to the provisions of Part E2 of the Israeli Income Tax Ordinance.

(p) Otic Pharma does not and has never participated or engaged in any transaction listed in Section 131(g) of the Israeli Income Tax Ordinance and the Israeli Income Tax Regulations (Reportable Tax Planning), 5767-2006 promulgated thereunder.

(q) Otic Pharma is not and has never been a real property corporation (*Igud Mekarke'in*) within the meaning of this term under Section 1 of the Israeli Land Taxation Law (Appreciation and Acquisition), 5723-1963.

(r) Each of Otic Pharma and each Subsidiary is a resident for Tax purposes solely in its country of incorporation, and, neither the Company nor its Subsidiary is subject to Tax in any jurisdiction other than its country of incorporation whether by virtue of having employees, or any other place of business in such jurisdiction or by virtue of exercising management and control in such jurisdiction.

(s) Neither Otic Pharma nor any of its Subsidiaries has made a valid election to be treated as a "Privileged Enterprise" (*Mifaal Muadaf*) under the Law for Encouragement of Capital Investments, 1959.

(t) Otic Pharma has provided to Public Company all material documentation relating to any applicable Tax holidays or incentives (other than incentives generally available by operation of law without application to or action by any Governmental Entity). Otic Pharma and its Subsidiaries are in compliance with the requirements of all such Tax holidays and incentives and none of the Tax holidays or incentives will be jeopardized by the consummation of the Transaction.

(u) Otic Pharma does not own any interest in any controlled foreign corporation pursuant to Section 75B of the Israel Income Tax Ordinance, or other entity the income of which is required to be included in the income of Otic Pharma.

3.9 Owned and Leased Real Properties.

(a) Neither Otic Pharma nor any of its Subsidiaries owns or has ever owned any real property.

(b) Section 3.9(b) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all real property leased, subleased or licensed by Otic Pharma or any of its Subsidiaries as of the date of this Agreement (collectively, the "Otic Pharma Leases") and the location of the premises. Neither Otic Pharma nor any of its Subsidiaries nor, to the knowledge of Otic Pharma, any other party is in breach or default and no event has occurred, is pending or, to the knowledge of Otic Pharma, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute any such breach or default under any of Otic Pharma Leases, except where the existence of such breaches or defaults, individually or in the aggregate, has not had, and is not reasonably likely to result in, the loss of a material right or in a material liability of Otic Pharma or any of its Subsidiaries. Neither Otic Pharma nor any of its Subsidiaries leases, subleases or licenses any real property to any person other than Otic Pharma and its Subsidiaries. Otic Pharma has made available to Public Company complete and accurate copies of all Otic Pharma Leases.

3.10 Intellectual Property.

(a) To the knowledge of Otic Pharma, Otic Pharma and its Subsidiaries own, license or otherwise possess legally enforceable rights, free and clear of any Liens, to use all material Intellectual Property used or necessary to conduct the business of Otic Pharma and its Subsidiaries as currently conducted, or that would be used or necessary as such business is currently proposed to be conducted (excluding generally commercially available software programs).

(b) The execution and delivery of this Agreement and consummation of the Transaction will not result in the breach of, or create on behalf of any third party the right to terminate or modify, (i) any license, sublicense or other agreement relating to any Intellectual Property owned by Otic Pharma or any of its Subsidiaries that is material to the business of Otic Pharma and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Otic Pharma or any of its Subsidiaries, but excluding generally commercially available software

programs (such Intellectual Property, the "Otic Pharma Intellectual Property") or (ii) any license, sublicense and other agreement as to which Otic Pharma or any of its Subsidiaries is a party and pursuant to which Otic Pharma or any of its Subsidiaries is authorized to use any third party Intellectual Property that is material to the business of Otic Pharma and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Otic Pharma or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the "Otic Pharma Third Party Intellectual Property"). Section 3.10(b)(i) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all Patent Rights and registrations and applications for Trademarks and copyrights included in Otic Pharma Intellectual Property and Section 3.10(b)(ii) sets forth a complete and accurate list of all agreements under which Otic Pharma or any of its Subsidiaries has in-licensed any Otic Pharma Third Party Intellectual Property.

(c) To the knowledge of Otic Pharma, all issued patents and registrations for Trademarks, service marks and copyrights which are owned by or licensed to Otic Pharma or any of its Subsidiaries and that are material to the business of Otic Pharma and its Subsidiaries, taken as a whole, are valid and subsisting and all payments due and all registration and renewal formalities relating to Otic Pharma Intellectual Property are up to date, complete and correct. Otic Pharma and its Subsidiaries have taken reasonable measures to protect the proprietary nature of the Otic Pharma Intellectual Property. To the knowledge of Otic Pharma, as of the date of this Agreement (i) no other person or entity is infringing, violating or misappropriating any of the Otic Pharma Intellectual Property or Otic Pharma Third Party Intellectual Property and (ii) no claim or demand has been made in writing and no proceeding has been filed or is threatened in writing asserting that such Intellectual Property is invalid or unenforceable.

(d) To the knowledge of Otic Pharma, none of the (i) products previously or currently sold by Otic Pharma or any of its Subsidiaries or (ii) business or activities previously or currently conducted by Otic Pharma or any of its Subsidiaries infringes, violates or constitutes a misappropriation of, any Intellectual Property of any third party. As of the date of this Agreement, neither Otic Pharma nor any of its Subsidiaries has received any written complaint, claim or notice alleging any such infringement, violation or misappropriation.

(e) For purposes of this Agreement, the following terms shall have the following meanings:

(i) "Intellectual Property" means the following subsisting throughout the world:

(A) Patent Rights;

(B) Trademarks and all goodwill in the Trademarks;

(C) copyrights, designs, data and database rights and registrations and applications for registration thereof, including moral rights of authors;

(D) mask works and registrations and applications for registration thereof under the laws of any jurisdiction;

(E) inventions, invention disclosures, statutory invention registrations, trade secrets and confidential business information, know-how, manufacturing and product processes and techniques, research and development information, financial, marketing and business data, pricing and cost information, business and marketing plans and customer and supplier lists and information, whether patentable or nonpatentable, whether copyrightable or non-copyrightable and whether or not reduced to practice; and

(F) other proprietary rights relating to any of the foregoing (including remedies against infringement thereof and rights of protection of interest therein under the laws of all jurisdictions).

(ii) "Patent Rights" means all patents, patent applications, utility models, and design registrations (including all related continuations, continuations-in-part, divisionals, reissues and reexaminations).

(iii) "Trademarks" means all registered trademarks and service marks, logos, Internet domain names, corporate names and doing business designations and all registrations and applications for registration of the foregoing, common law trademarks and service marks and trade dress.

3.11 Contracts.

(a) As of the date of this Agreement, there are no Contracts that are material contracts (as defined in Item 601(b)(10) of Regulation S-K) with respect to Otic Pharma (assuming Otic Pharma was subject to the requirements of the Exchange Act), other than those Contracts identified in Section 3.11(a) of the Otic Pharma Disclosure Schedule.

(b) Neither Otic Pharma nor any of its Subsidiaries has entered into any transaction that would be subject to proxy statement disclosure pursuant to Item 404 of Regulation S-K (assuming Otic Pharma was subject to the requirements of the Exchange Act), other than as disclosed in Section 3.11(b) of the Otic Pharma Disclosure Schedule.

(c) Neither Otic Pharma nor any of its Subsidiaries is a party to any agreement under which a third party would be entitled to receive a license or any other right to Otic Pharma Intellectual Property as a result of the transactions contemplated by this Agreement.

(d) Section 3.11(d) of the Otic Pharma Disclosure Schedule lists the following Contracts of Otic Pharma in effect as of the date of this Agreement:

(i) any Contract (or group of related Contracts) for the purchase or sale of products or for the furnishing or receipt of services (A) which calls for performance over a period of more than 180 days from the date of this Agreement, (B) which involves an aggregate of more than $150,000 or (C) in which Otic Pharma or any of its Subsidiaries has granted manufacturing rights, "most favored nation" pricing provisions or marketing or distribution rights relating to any products or territory or has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a particular party;

(ii) any Contract under which the consequences of a default or termination would reasonably be likely to have a Otic Pharma Material Adverse Effect;

(iii) any Contract that could reasonably be expected to have the effect of prohibiting or impairing the conduct of the business of Otic Pharma or any of its Subsidiaries or Public Company or any of its Subsidiaries as currently conducted and as currently proposed to be conducted;

(iv) any Contract under which Otic Pharma or any of its Subsidiaries is restricted from selling, licensing or otherwise distributing any of its technology or products, or providing services to, customers or potential customers or any class of customers, in any geographic area, during any period of time or any segment of the market or line of business;

(v) any dealer, distribution, joint marketing, joint venture, joint development, partnership, strategic alliance, collaboration, development agreement or outsourcing arrangement;

(vi) any Contract for the conduct of research studies, pre-clinical or clinical studies, manufacturing, distribution, supply, marketing or co-promotion of any products in development by or which has been or which is being marketed, distributed, supported, sold or licensed out, in each case by or on behalf of Otic Pharma or any of its Subsidiaries; and

(vii) any Contract that would entitle any third party to receive a license or any other right to intellectual property of Public Company or any of Public Company's Affiliates following the Closing.

(e) Otic Pharma has made available to Public Company a complete and accurate copy of each Contract listed in Sections 3.10(b)(i), 3.10(b)(ii), 3.11(a), 3.11(b) and 3.11(d) of the Otic Pharma Disclosure Schedule. With respect to each Contract so listed: (i) the Contract is legal, valid, binding and enforceable and in full force and effect against Otic Pharma and/or its Subsidiaries party thereto, as applicable, and, to the knowledge of Otic Pharma, against each other party thereto, as applicable, subject to the Bankruptcy and Equity Exception; (ii) the Contract will continue to be legal, valid, binding and enforceable and in full force and effect against Otic Pharma and/or its Subsidiaries party thereto, as applicable, and, to the knowledge of Otic Pharma, against each other party thereto, immediately following the Closing in accordance with the terms thereof as in effect immediately prior to the Closing (other than any such Contracts that expire or terminate before such time in accordance with their terms and not as a result of a breach or default by Otic Pharma or its Subsidiaries), in each such case subject to the Bankruptcy and Equity Exception; and (iii) none of Otic Pharma, its Subsidiaries nor, to the knowledge of Otic Pharma, any other party, is in breach or violation of, or default under, any such Contract, and no event has occurred, is pending or, to the knowledge of Otic Pharma, is threatened, which, with or without notice or lapse of time, or both, would constitute a breach or default by Otic Pharma, its Subsidiaries or, to the knowledge of Otic Pharma, any other party under such Contract, except for such breaches, violations or defaults that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect.

(f) For purposes of this Agreement, the term "Contract" shall mean, with respect to any person, any written, oral or other agreement, contract, subcontract, lease (whether for real or personal property), mortgage, understanding, arrangement, instrument, note, option, warranty, license, sublicense, insurance policy, benefit plan or commitment or undertaking of any nature to which such person is a party or by which such person or any of its assets are bound under applicable law.

3.12 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or threatened in writing against Otic Pharma or any of its Subsidiaries that (a) seeks either damages in excess of $100,000 or equitable relief or (b) in any manner challenges or seeks to prevent, enjoin, alter or delay the transactions contemplated by this Agreement, except for such actions, suits, proceedings, claims, arbitrations or investigations first arising after the date of this Agreement that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. There are no material judgments, orders or decrees outstanding against Otic Pharma or any of its Subsidiaries.

3.13 Environmental Matters.

(a) Except for such matters that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect:

(i) Otic Pharma and its Subsidiaries have complied with all applicable Environmental Laws;

(ii) the properties currently owned, leased or operated by Otic Pharma and its Subsidiaries (including soils, groundwater, surface water, buildings or other structures) are not contaminated with any Hazardous Substances;

(iii) the properties formerly owned, leased or operated by Otic Pharma or any of its Subsidiaries were not contaminated with Hazardous Substances during the period of ownership, use or operation by Otic Pharma or any of its Subsidiaries;

(iv) neither Otic Pharma nor any of its Subsidiaries are subject to liability for any Hazardous Substance disposal or contamination on the property of any third party; and

(v) neither Otic Pharma nor any of its Subsidiaries have released any Hazardous Substance into the environment.

(b) As of the date of this Agreement, neither Otic Pharma nor any of its Subsidiaries has received any written notice, demand, letter, claim or request for information alleging that Otic Pharma or any of its Subsidiaries may be in violation of, liable under or have obligations under, any Environmental Law.

(c) Neither Otic Pharma nor any of its Subsidiaries is subject to any orders, decrees, injunctions or other arrangements with any Governmental Entity or is subject to any indemnity or other agreement with any third party relating to liability under any Environmental Law or relating to Hazardous Substances.

(d) For purposes of this Agreement, the term "Environmental Law" means any law, regulation, order, decree, permit, authorization, opinion, common law or agency requirement of any jurisdiction relating to: (i) the protection, investigation or restoration of the environment, human health and safety or natural resources, (ii) the handling, use, storage, treatment, presence, disposal, release or threatened release of any Hazardous Substance or (iii) noise, odor, wetlands, pollution, contamination or any injury or threat of injury to persons or property.

(e) For purposes of this Agreement, the term "Hazardous Substance" means any substance that is: (i) listed, classified, regulated or which falls within the definition of a "hazardous substance," "hazardous waste" or "hazardous material" pursuant to any Environmental Law; (ii) any petroleum product or by-product, asbestos-containing material, lead-containing paint or plumbing, polychlorinated biphenyls, radioactive materials or radon; or (iii) any other substance that is the subject of regulatory action by any Governmental Entity pursuant to any Environmental Law.

3.14 Employee Benefit Plans.

(a) Section 3.14(a) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all Employee Benefit Plans maintained, or contributed to, by Otic Pharma or any of its Subsidiaries or any of their respective ERISA Affiliates for the benefit of, or relating to, any current or former employee or other service provider of Otic Pharma or any of its Subsidiaries (collectively, the "Otic Pharma Employee Plans"). Except as set forth in Section 3.14(a) of the Otic Pharma Disclosure Schedule, no Otic Pharma Employee Plan is subject to ERISA or covers any person providing services in the United States.

(b) With respect to each Otic Pharma Employee Plan, Otic Pharma has made available to Public Company, a complete and accurate copy of (i) such plan (or a written summary of any unwritten plan), (ii) each trust agreement, group annuity contract and summary plan description, if any, relating to such Otic Pharma Employee Plan, (iii) the three (3) most recent financial statements for each Otic Pharma Employee Plan that is funded, (iv) all personnel, payroll and employment manuals and policies, (v) all employee handbooks, (vi) all regulatory or other filings or submissions to any Governmental Entity with respect to each Otic Pharma Employee Plan, if any, (vii) all material correspondence to or from any Governmental Entity received in the last three years with respect to each Otic Pharma Employee Plan, if any.

(c) Each Otic Pharma Employee Plan has been administered in all respects in accordance with applicable laws and the regulations thereunder and in accordance with its terms and each of Otic Pharma and its Subsidiaries and their respective ERISA Affiliates has in all respects met its obligations with respect to such Otic Pharma Employee Plan and has made all required contributions thereto (or reserved such contributions on the Otic Pharma Balance Sheet). Otic Pharma and its Subsidiaries and each of their respective ERISA Affiliates and each Otic Pharma Employee Plan are in compliance in all respects with the currently applicable law. All filings and reports as to each Otic Pharma Employee Plan required to have been submitted under applicable law have been timely submitted. There is no audit, investigation or other proceeding (including any voluntary correction application) pending against or involving any Otic Pharma Employee Plan. There have been no events with respect to any Otic Pharma Employee Plan that could result in payment or assessment by or against Otic Pharma or any of its Subsidiaries of any Taxes. With respect to Otic Pharma Employee Plans, no event has occurred, and to the knowledge of Otic Pharma, there exists no condition or set of circumstances in connection with which Otic Pharma or any of its Subsidiaries could be subject to any liability that is reasonably likely, individually or in the aggregate, to have a Otic Pharma Material Adverse Effect under applicable law.

(d) There are no legal proceedings (except claims for benefits payable in the normal operation of the Otic Pharma Employee Plan) against or involving any Otic Pharma Employee Plan or asserting any rights or claims to benefits under any Otic Pharma Employee Plan. Neither Otic Pharma nor any of its Subsidiaries has received any written notice of any audit or examination of any Otic Pharma Employee Plan by any Governmental Entity.

(e) With respect to Otic Pharma Employee Plans, there are no benefit obligations for which contributions have not been made or properly accrued and there are no benefit obligations that have not been accounted for by reserves, or otherwise properly footnoted in accordance with GAAP, on the financial statements of Otic Pharma, which obligations are reasonably likely, individually or in the aggregate, to have a Otic Pharma Material Adverse Effect. The assets of each Otic Pharma Employee Plan that is funded are reported at their fair market value on the books and records of such Otic Pharma Employee Plan.

(f) All Otic Pharma Employee Plans (if any) that are intended to be qualified under Section 401(a) of the Code have received determination letters from the Internal Revenue Service (the "IRS") to the effect that such Otic Pharma Employee Plans are qualified and the plans and trusts related thereto are exempt from federal income taxes under Sections 401(a) and 501(a), respectively, of the Code, no such determination letter has been revoked and revocation has not been threatened, and no such Otic Pharma Employee Plan has been amended or operated since the date of its most recent determination letter or application therefor in any respect, and no act or omission has occurred, that would adversely affect its qualification or materially increase its cost. Each Otic Pharma Employee Plan that is required to satisfy Section 401(k)(3) or Section 401(m)(2) of the Code has been tested for compliance with, and satisfies the requirements of, Section 401(k)(3) and Section 401(m)(2) of the Code, as the case may be, for each plan year ending prior to the Closing Date.

(g) Neither Otic Pharma nor any of its Subsidiaries nor any of their respective ERISA Affiliates has (i) ever maintained an Employee Benefit Plan that was ever subject to Section 412 of the Code or Title IV of ERISA or (ii) ever been obligated to contribute to a

"multiemployer plan" (as defined in Section 4001(a)(3) of ERISA). No Otic Pharma Employee Plan is funded by, associated with or related to a "voluntary employees' beneficiary association" within the meaning of Section 501(c)(9) of the Code. No Otic Pharma Employee Plan holds securities issued by Otic Pharma or any of its Subsidiaries or any of their respective ERISA Affiliates.

(h) Each Otic Pharma Employee Plan is amendable and terminable unilaterally by Otic Pharma and any of Otic Pharma's Subsidiaries and their respective ERISA Affiliates that are a party thereto or covered thereby at any time without liability to Otic Pharma or any of its Subsidiaries or their respective ERISA Affiliates as a result thereof (other than for benefits accrued through the date of termination or amendment and reasonable administrative expenses related thereto), and no Otic Pharma Employee Plan, plan documentation or agreement, summary plan description or other written communication distributed generally to employees by its terms prohibits Otic Pharma or any of its Subsidiaries or their respective ERISA Affiliates from amending or terminating any such Otic Pharma Employee Plan. The investment vehicles used to fund Otic Pharma Employee Plans may be changed at any time without incurring a sales charge, surrender fee or other similar expense.

(i) Neither Otic Pharma nor any of its Subsidiaries nor any of their respective ERISA Affiliates is a party to any oral or written (i) agreement with any shareholders, director, executive officer or other key employee of Otic Pharma or any of its Subsidiaries (A) the benefits of which are contingent, or the terms of which are altered, upon the occurrence of a transaction involving Otic Pharma or any of its Subsidiaries of the nature of any of the transactions contemplated by this Agreement, (B) providing any term of employment or compensation guarantee or (C) providing severance benefits or other benefits after the termination of employment of such director, executive officer or key employee; (ii) agreement, plan or arrangement under which any person may receive payments from Otic Pharma or any of its Subsidiaries or any of its ERISA Affiliates that may be subject to the tax imposed by Section 4999 of the Code or included in the determination of such person's "parachute payment" under Section 280G of the Code, without regard to Section 280G(b)(4) of the Code; (iii) agreement providing any person providing for "tax gross up" or tax indemnifications related to Sections 280G or 409A of the Code or otherwise; or (iv) agreement or plan binding Otic Pharma or any of its Subsidiaries or any of its ERISA Affiliates, including any stock option plan, stock appreciation right plan, restricted stock plan, stock purchase plan or severance benefit plan, any of the benefits of which shall be increased, or the vesting of the benefits of which shall be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which shall be calculated on the basis of any of the transactions contemplated by this Agreement. There are no loans or extensions of credit by Otic Pharma, any of its Subsidiaries or any of their respective ERISA Affiliate to any employee or any other service provider to Otic Pharma or any of its Subsidiaries.

(j) None of the Otic Pharma Employee Plans promises or provides post-termination medical or other post-termination welfare benefits to any person, except as required by applicable law and at the sole expense of the participant

(k) Otic Pharma and its Subsidiaries are in material compliance with all applicable provisions of the Affordable Care Act, including reporting requirements, and there has been no change in health plan terms or coverage that would reasonably be expected to attract an excise tax under Section 4980H of the Code for the current year.

(l) Each Otic Pharma Employee Plan that is a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code) complies in form and operation with Section 409A of the Code and all IRS regulations and other guidance promulgated thereunder. No event has occurred that would be treated by Section 409A(b) of the Code as a transfer of property for purposes of Section 83 of the Code. No stock option or equity unit option granted under any Otic Pharma Employee Plan has an exercise price that has been or may be less than the fair market value of the underlying stock or equity units (as the case may be) as of the date such option was granted or has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option. No nonqualified deferred compensation plan has been administered in a manner that would cause an excise tax to apply to payments to plan participants.

(m) Section 3.14(m) of the Otic Pharma Disclosure Schedule sets forth the policy of Otic Pharma and each of its Subsidiaries with respect to accrued vacation, accrued sick time and earned time off and the amount of such liabilities as of September 30, 2016.

(n) For purposes of this Agreement, the following terms shall have the following meanings:

(i) "Employee Benefit Plan" means any "employee pension benefit plan" (including as defined in Section 3(2) of ERISA), any "employee welfare benefit plan" (as defined in Section 3(1) of ERISA) and any other written or oral plan, agreement or arrangement involving direct or indirect compensation, including insurance coverage, severance benefits, disability benefits, fringe benefits, perquisites, change in control benefits, deferred compensation, bonuses, stock options, stock purchase, phantom stock, stock appreciation or other forms of incentive compensation or post-retirement compensation and all unexpired severance agreements, written or otherwise.

3.15 Compliance With Laws. Otic Pharma and each of its Subsidiaries has complied in all material respects with, is not in material violation of, and, as of the date of this Agreement, has not received any notice alleging any material violation with respect to, any applicable provisions of any statute, law or regulation with respect to the conduct of its business, or the ownership or operation of its properties or assets.

3.16 Permits and Regulatory Matters.

(a) Otic Pharma and each of its Subsidiaries have all permits, licenses, registrations, authorizations, certificates, orders, approvals, franchises, variances and other similar rights issued by or obtained from any Governmental Entities (collectively, "Permits") that are material to the conduct of its business as currently conducted, including a business permit and all such Permits required by the U.S. Food and Drug Administration (the "FDA") and any other federal, state or foreign agencies or bodies (together with the FDA, the "Regulating Authority") engaged in the regulation of pharmaceuticals or biohazardous materials.

(b) All Permits that are necessary for the conduct of the business of Otic Pharma and each of its Subsidiaries as currently conducted ("Otic Pharma Authorizations") are in full force and effect, and to the knowledge of Otic Pharma, no violations or notices of failure to comply have been issued or recorded in respect of any such Otic Pharma Authorization. No such Otic Pharma Authorization shall cease to be effective as a result of the consummation of the transactions contemplated by this Agreement. Otic Pharma and each of its Subsidiaries is in compliance in all material respects under any of such Otic Pharma Authorizations. All applications, reports, notices and other documents required to be filed by Otic Pharma and its Subsidiaries with all Governmental Entities under the Otic Pharma Authorizations have been timely filed and are complete and correct in all material respects as filed or as amended prior to the date of this Agreement. None of Otic Pharma, any Subsidiary of Otic Pharma, and to Otic Pharma's knowledge, any officer, employee or agent of Otic Pharma or any of its Subsidiaries has been convicted of any crime or engaged in any conduct that has previously caused or would reasonably be expected to result in (A) disqualification or debarment by the FDA under 21 U.S.C. Sections 335(a) or (b), or any similar law, rule or regulation of any other Governmental Entity, or (B) exclusion under 42 U.S.C. Section 1320a-7 or any similar law, rule or regulation of any Governmental Entity.

(c) Otic Pharma and each of its Subsidiaries: (i) is and at all times has been in material compliance, to the extent applicable, with all statutes, rules, regulations, and with all orders and guidance administered or issued by the FDA or any other Governmental Entity exercising comparable authority, applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product tested, developed, promoted, marketed, manufactured or distributed by Otic Pharma and each of its Subsidiaries; (ii) has not received any notice or correspondence from any Governmental Entity alleging or asserting any noncompliance with any Otic Pharma Authorizations; and (iii) has not received notice that any Governmental Entity has taken or is intending to take action to limit, suspend, modify or revoke any Otic Pharma Authorizations and, to the knowledge of Otic Pharma, there is no action or proceeding pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that such Governmental Entity is considering such action. Neither Otic Pharma nor any of its Subsidiaries nor any of their respective officers, employees or agents have made an untrue statement of a material fact or fraudulent statement to any Governmental Entity relating to the Otic Pharma Authorizations or failed to disclose a material fact required to be disclosed to any Governmental Entity relating to the Otic Pharma Authorizations.

(d) There are no seizures, recalls, market withdrawals, field notifications or corrective actions, notifications of misbranding or adulteration, destruction orders, safety alerts or similar actions relating to the safety or efficacy of any products marketed or sold by Otic Pharma or any of its Subsidiaries being conducted, requested in writing or, to the knowledge of Otic Pharma, threatened by the FDA or any other Governmental Entity. Otic Pharma has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated, conducted or issued any recall, market withdrawal, safety alert or other similar notice or action relating to the alleged lack of safety or efficacy of any products marketed or sold by Otic Pharma or any of its Subsidiaries.

(e) The studies, tests and preclinical and clinical trials, if any, conducted by or on behalf of Otic Pharma or any of its Subsidiaries are being conducted or have been conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by Otic Pharma or its Subsidiaries and all applicable laws and regulations. The descriptions of, protocols for, and data and other results of, any such studies, tests and/or trials that have been furnished or made available to Public Company are accurate and complete in all material respects. Otic Pharma is not aware of any studies, test or trials the results of which reasonably call into question the results of the studies, tests and trials conducted by or on behalf of Otic Pharma or any of its Subsidiaries, and neither Otic Pharma nor any of its Subsidiaries has received any notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority or any institutional review board or comparable authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of Otic Pharma or any of its Subsidiaries.

3.17 Employees.

(a) All current and past employees, founders and current and former independent contractors of Otic Pharma or any of its Subsidiaries have entered into confidentiality and assignment of inventions agreements (which include a waiver of moral rights) with Otic Pharma or such Subsidiary, a copy or form of which has previously been made available to Public Company. All former and current employees have executed a waiver of the right to claim royalties in Service Inventions as defined in Section 132 of the Israel Patents Law, 1967 (the "Patents Law"). The Intellectual Property owned by Otic Pharma was developed and created solely by either (i) employees of Otic Pharma or its Subsidiaries acting within the scope of their employment or (ii) by third parties who have validly and irrevocably assigned all of their rights therein to Otic Pharma or its Subsidiaries, and no third party owns or has any claim, right or interest in or to any of the Intellectual Property owned by Otic Pharma.

(b) To the knowledge of Otic Pharma, no Otic Pharma personnel who was involved in, or who contributed to, the creation or development of any Intellectual Property owned by Otic Pharma, has performed services for any Governmental Entity, university, college or other educational institution or research center with respect to technology or inventions that have been or may be incorporated into a product of Otic Pharma or related to Intellectual Property owned by Otic Pharma, during a period of time during which such Otic Pharma personnel was also performing services for Otic Pharma or any of its Subsidiaries. Otic Pharma and its Subsidiaries are not subject to any order of any Governmental Entity that restricts or impairs the use, transfer or licensing of any portion of Intellectual Property owned by Otic Pharma.

(c) To the knowledge of Otic Pharma, as of the date of this Agreement, no employee of Otic Pharma or any Subsidiary of Otic Pharma is in violation of any term of any patent disclosure agreement, non-competition agreement, or any restrictive covenant to a former employer relating to the right of any such employee to be employed by Otic Pharma or any of its Subsidiaries because of the nature of the business currently conducted by Otic Pharma or any of its Subsidiaries or to the use of trade secrets or proprietary information of others. To the knowledge of Otic Pharma, as of the date of this Agreement, no key employee or group of key employees has any plans to terminate employment with Otic Pharma or its Subsidiaries.

(d) Neither Otic Pharma nor any of its Subsidiaries is a party to or otherwise bound by any collective bargaining agreement, contract or other agreement or understanding with a labor union or labor organization. Neither Otic Pharma nor any of its Subsidiaries is the subject of any proceeding asserting that Otic Pharma or any of its Subsidiaries has committed an unfair labor practice or is seeking to compel it to bargain with any labor union or labor organization, nor is there pending or, to the knowledge of Otic Pharma, threatened, any labor strike, dispute, walkout, work stoppage, slow-down or lockout involving Otic Pharma or any of its Subsidiaries.

(e) Section 3.17(e) of the Otic Pharma Disclosure Schedule contains a list of all employees of Otic Pharma and its Subsidiaries along with the position, the annual rate of salary of each such employee, whether such employee is full time or part time, is exempt or non-exempt from overtime compensation laws, is on leave and if so, the type of leave and expected date of return, visa status (as applicable), date of hire, any incentive payment paid or payable in calendar year 2016 (and whether such incentive is cash or, if not, what other property is due), short-term or temporary basis, vacation entitlement and accrued vacation or paid time-off balance, car entitlement, sick leave entitlement and accrual (if any), and recuperation pay entitlement and accrual, pension entitlements and provident funds (including manager's insurance, pension fund, education fund and health fund), their respective contribution rates for each component (e.g., severance component, pension savings and disability insurance) and the salary basis for such contributions, severance entitlements (including whether such employee, to the extent employed in the State of Israel, is subject to a Section 14 arrangement under the Severance Pay Law, 5723 1963 (the "Israeli Severance Pay Law" and "Section 14 Arrangement")), and, to the extent such employee is subject to such a Section 14 Arrangement, an indication of whether such arrangement (or other applicable pension arrangement) has been applied to such person from the commencement date of their employment and on the basis of their entire salary including other compensation (e.g., commission), main work location, notice period entitlement, and any other material compensation payable to such employee. Neither Otic Pharma nor its Subsidiaries is delinquent in payments to any employees for wages, salaries, commissions or bonuses for services performed as of the date of this Agreement or amounts required by applicable law to be reimbursed to such employees. The consummation of the Transaction will not give rise to any liability of Otic Pharma or any of its Subsidiaries for payments related to severance, termination, bonus, accrued vacation or personal time, accrued days of sick pay or any similar payment.

(f) Otic Pharma and its Subsidiaries are, and at all times within applicable statutes of limitations have been, in material compliance with all applicable laws respecting labor, employment, hiring and termination, fair employment practices, terms and conditions of employment, occupational health and safety and wage and hour laws, including the Advance Notice for Dismissal and Resignation Law, 5761-2001, the Notification to an Employee (Terms of Employment) Law, 5762-2002, the Wage Protection Law 5718-1958, Prior Notice to the Employee Law, 5762-2002, the Prevention of Sexual Harassment Law, 5758-1998, the Hours of Work and Rest Law, 5711-1951, the Annual Leave Law, 5711-1951, the Employment by Human Resource Contractors Law, 5756-1996 and the Increased Enforcement of Labor Laws-2012. During the past three (3) years, each current and former employee of each of Otic Pharma and its Subsidiaries has been properly categorized as exempt or non-exempt from applicable laws pertaining to payment of minimum wage and overtime compensation and has been paid overtime wages to the extent required by applicable law. Each individual who has rendered services to Otic Pharma or any of its Subsidiaries and has been classified as an independent contractor or other non-employee status for any purpose (including for purposes of Taxes and Tax reporting and under Otic Pharma Employee Plans) has been properly so classified. During the past three (3) years, there has not been and there is no pending or, to the knowledge of Otic Pharma, threatened, any material claim, charge, grievance or Legal Proceeding against Otic Pharma or any of its Subsidiaries brought by or on behalf of any current or former applicant, employee, independent contractor, subcontractor, leased employee, volunteer, or temporary employee of Otic Pharma or its Subsidiaries, alleging violation of any applicable employment law, agreement or any other claim arising out of such Person's employment, application for employment or termination of employment, consulting or other relationship with Otic Pharma or any of its Subsidiaries.

(g) Otic Pharma and its Subsidiaries have withheld, paid and reported all amounts required by the Israeli Tax Ordinance, the National Insurance Law (Consolidated Version), 5755 1995, the National Health Insurance Law, 5754-1994 or any other law or by contract to be withheld, paid and reported with respect to compensation, wages, salaries, payments to the National Insurance Institute, employees' pension or managers insurance funds, disability insurance, continuing education fund or other similar funds and other payments to employees or consultants of Otic Pharma and its Subsidiaries. Neither Otic Pharma nor any of its Subsidiaries is required to make payments for overtime hours above the global overtime compensation paid by it.

(h) At all times since January 1, 2014, Otic Pharma and its Subsidiaries have never engaged any employees whose employment would require special licenses or permits by Otic Pharma or its Subsidiaries. Otic Pharma and its Subsidiaries have not engaged, and do not currently engage, any contractors or contractors' employees who, according to Israeli law, would reasonably be expected to be entitled to the rights of an employee vis-à-vis Otic Pharma or its Subsidiaries, including rights to severance pay, vacation, recuperation pay (*dmei havraa*) and other employee-related statutory and contractual benefits.

(i) Otic Pharma's and (if applicable) its Subsidiaries' obligations to provide statutory severance pay to its Israeli employees pursuant to the Israeli Severance Pay Law are fully funded in accordance with Section 14 under the Israeli Severance Pay Law and it is and was implemented properly, from the commencement date of the employee's employment and on the basis of the employee's entire salary. Upon the termination of employment of Israeli employees, Otic Pharma will not have to make any payment under the Israeli Severance Pay Law, except for release of the funds accumulated in accordance with Section 14.

(j) Otic Pharma and its Subsidiaries are not required (under any law, contract or otherwise) to provide benefits or working conditions beyond the minimum benefits and working conditions required by law to be provided pursuant to rules and regulations of the Israeli Histadrut (General Federation of Labor), the Israeli Coordinating Bureau of Economic Organization and the Israeli Industrialists' Association. Otic Pharma and its Subsidiaries have not and are not subject to, and no employee or consultant of them benefits from, any extension order (*tzavei harchave*) or any general contract or arrangement with respect to employment or termination of employment, except those extension orders that apply to all Israeli companies generally, and there are no unwritten Otic Pharma policies or customs which, by extension, could entitle Israeli employees to any benefits in addition to what they are entitled by applicable law, agreement or any written policy.

(k) Section 3.17(k) of the Otic Pharma Disclosure Schedule contains a list of all employees of each of Otic Pharma and its Subsidiaries who are a party to a non-competition agreement with Otic Pharma; copies of such agreements have previously been delivered, or made available, to Public Company. Section 3.17(k) of the Otic Pharma Disclosure Schedule also contains a list of all employees of each of Otic Pharma and its Subsidiaries who are not citizens or lawful permanent residents of the jurisdiction in which they are working, and for each, the basis of his or her employment authorization in such jurisdiction and the expiration of such authorization.

3.18 Insurance. Otic Pharma and its Subsidiaries maintain insurance policies (the "Otic Pharma Insurance Policies"), including insurance covering directors and officers for securities law and other customary liabilities, with reputable insurance carriers against all risks of a character and in such amounts as are usually insured against by similarly situated companies in the same or similar businesses. Each Otic Pharma Insurance Policy is in full force and effect. None of the Otic Pharma Insurance Policies shall terminate or lapse (or be affected in any other adverse manner) by reason of any of the transactions contemplated by this Agreement. Otic Pharma and each of its Subsidiaries have complied in all material respects with the provisions of each Otic Pharma Insurance Policy under which it is the insured party. No insurer under any Otic Pharma Insurance Policy has cancelled or generally disclaimed liability under any such policy or indicated any intent to do so or not to renew any such policy. All claims under the Otic Pharma Insurance Policies have been filed in a timely fashion.

3.19 No Fairness Opinion. Otic Pharma has not received, and, as of the date hereof, does not intend to obtain, an opinion from any financial advisor, investment banker or other firm or person performing a similar function, with respect to the fairness of the Transaction, including the fairness of the consideration to be received by holders of Otic Pharma Share Capital in connection with the Transaction.

3.20 Brokers; Fees and Expenses. No agent, broker, investment banker, financial advisor or other firm or person is or shall be entitled, as a result of any action, agreement or commitment of Otic Pharma or any of its Affiliates, to any broker's, finder's, financial advisor's or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, except Piper Jaffray & Co ("Piper") whose fees and expenses shall be paid by Otic Pharma immediately prior to the Closing. Otic Pharma has made available to Public Company a complete and accurate copy of all agreements pursuant to which Piper is entitled to any fees and expenses in connection with any of the transactions contemplated by this Agreement. Otic Pharma is not a party to any agreements with any agent, broker, investment banker, financial advisor or other similar firm or person that have not been made available to Public Company and which grant to such person rights after the Closing, other than agreement that have been made available to the Public Company.

3.21 Certain Business Relationships With Affiliates. Other than as set forth in Section 3.21 of the Otic Pharma Disclosure Schedules, no Affiliate of Otic Pharma or of any of its Subsidiaries (a) owns any property or right, tangible or intangible, which is used in the business of Otic Pharma or any of its Subsidiaries, (b) has any claim or cause of action against Otic Pharma or any of its Subsidiaries or (c) owes any money to, or is owed any money by, Otic Pharma or any of its Subsidiaries. Section 3.21 of the Otic Pharma Disclosure Schedule describes any material Contracts between Otic Pharma and any Affiliate thereof which were entered into or have been in effect at any time since September 30, 2014, other than (i) any employment Contracts, invention assignment agreements and other Contracts entered into in the Ordinary Course of Business relating to employment, or (ii) Contracts relating to stock purchases and awards, stock options and other equity arrangements, in each case relating to compensation.

3.22 Controls and Procedures, Certifications and Other Matters.

(a) Otic Pharma and each of its Subsidiaries maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal control over financial reporting that provide assurance that (i) transactions are executed with management's authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements of Otic Pharma and to maintain accountability for Otic Pharma's consolidated assets, (iii) access to assets of Otic Pharma and its Subsidiaries is permitted only in accordance with management's authorization, (iv) the reporting of assets of Otic Pharma and its Subsidiaries is compared with existing assets at regular intervals and (v) accounts, notes and other receivables and inventory were recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis.

(b) Otic Pharma maintains disclosure controls and procedures as would be required by Rules 13a-15 or 15d-15 under the Exchange Act if Otic Pharma were registered under Section 12 of the Exchange Act, and such controls and procedures are effective to ensure that all material information concerning Otic Pharma and its Subsidiaries is made known on a timely basis to the individuals responsible for the preparation of Otic Pharma's filings with the SEC and other public disclosure documents. Section 3.22(b) of the Otic Pharma Disclosure Schedule lists, and Otic Pharma has made available to Public Company copies of, all written descriptions of, and all policies, manuals and other documents promulgating, such disclosure controls and procedures.

(c) Neither Otic Pharma nor any of its Subsidiaries has extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any director or executive officer of Otic Pharma. Section 3.22(c) of the Otic Pharma Disclosure Schedule identifies any loan or extension of credit maintained by Otic Pharma to which the second sentence of Section 13(k)(1) of the Exchange Act applies.

(d) Otic Pharma either (i) satisfies the conditions to qualification as a "smaller reporting company" set forth in 17 C.F.R. 229.10(f)(1), or (ii) if shares of Otic Pharma Ordinary Shares were traded on any regulated market or stock exchange, would qualify as a "smaller reporting company," as defined by 17 C.F.R. 229.10(f)(1).

3.23 Books and Records. The minute books and other similar records of Otic Pharma and each of its Subsidiaries contain complete and accurate records of all material actions taken at any meetings of Otic Pharma's or such Subsidiary's shareholders, Board of Directors or any committee thereof and of all written consents executed in lieu of the holding of any such meeting. The books and records of Otic Pharma and each of its Subsidiaries accurately reflect in all material respects the assets, liabilities, business, financial condition and results of operations of Otic Pharma or such Subsidiary and have been maintained in accordance with good business and bookkeeping practices.

3.24 Ownership of Public Company Common Stock. None of Otic Pharma nor any of Otic Pharma's "Affiliates" or "Associates" directly or indirectly "owns," beneficially or otherwise, and at all times during the three-year period prior to the date of this Agreement, none of Otic Pharma's "Affiliates" or "Associates" directly or indirectly has "owned," beneficially or otherwise, any of the outstanding Public Company Common Stock, as those terms are defined in Section 203 of the DGCL.

3.25 Privacy and Data Security.

(a) Otic Pharma and each of its Subsidiaries, the products and all internet websites owned, maintained or operated by or on behalf of Otic Pharma or any of its Subsidiaries (the "Otic Pharma Sites"), and all third parties, solely in connection with their performance of activities on Otic Pharma's or any of Otic Pharma's Subsidiaries' behalf or in connection with their use of Personal Information collected by or on behalf of Otic Pharma or any of its Subsidiaries, comply, and have at all times complied with all applicable data security, and Privacy Laws. Copies of all current internal and public-facing privacy policies of Otic Pharma, if any, that apply to the Otic Pharma Sites and products have been made available to the Public Company, and none of the disclosures in such policies have been in violation of any Privacy Laws. Any consents required under applicable laws for the collection, processing, transfer and other use of Personal Information by Otic Pharma or any of its Subsidiaries for the conduct of the business of Otic Pharma or any of its Subsidiaries have been obtained. There is no complaint to, or any proceeding, or to the knowledge of Otic Pharma, an investigation (formal or informal) or claim or audit currently pending against, Otic Pharma or any of Otic Pharma's Subsidiaries by any Person with respect to Personal Information and, to the knowledge of Otic Pharma, there is no threatened complaint, proceeding, investigation (formal or informal) or claim against Otic

Pharma or any of its Subsidiaries with respect thereto. With respect to all Personal Information collected, stored, used, or maintained by or for Otic Pharma or any of its Subsidiaries, Otic Pharma and its Subsidiaries have at all times implemented reasonable security measures aiming to ensure that such Personal Information is protected against loss and against unauthorized access, use, modification and disclosure. To the knowledge of Otic Pharma, there has been no loss, unauthorized access to or other misuse of such Personal Information. All databases owned, controlled, held or used by Otic Pharma or any of its Subsidiaries and required to be registered under applicable laws have been properly registered, and the data therein has been used by Otic Pharma or any of its Subsidiaries solely as permitted pursuant to such registrations. The consummation of the contemplated transactions shall not violate Otic Pharma's internal and public-facing privacy policies as they currently exist or any applicable law.

(b) For the purposes of this Agreement:

"Privacy Laws" shall mean all applicable laws regarding the collection, use and protection of Personal Information (including the Protection of Privacy Law 1981 and related regulations, directives and orders of any Governmental Entity of the State of Israel).

"Personal Information" shall mean individually identifiable information from or about an individual, including an individual's: (a) personally identifiable information (e.g., name, address, telephone number, email address, financial account number, government-issued identifier, details of a person's personality, personal status, intimate affairs, state of health, economic status, professional training, opinions or beliefs and any other data used or intended to be used to identify, contact or precisely locate a person), (b) Internet Protocol address or other persistent identifier; and (c) "information" as defined by the Israeli Protection of Privacy Law, 1981 and applicable Israeli judicial precedents defining that term and the corresponding laws of other jurisdictions.

3.26 Government Funding. Otic Pharma is subject to the provisions of the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744 1984, or the "Innovation Law" (formerly known as the Israeli Encouragement of Industrial Research and Development Law 5744-1984), as amended from time to time and/or such other law as will be legislated in lieu thereof, including the regulations, directives, procedures and rules that have been or will be promulgated thereunder and/or by virtue thereof. Section 3.26 of the Otic Pharma Disclosure Schedule provides a true, complete and correct list all pending and outstanding grants, incentives and subsidies from the Government of the State of Israel or any agency thereof, or from any Governmental Entity, granted to Otic Pharma and any of its Subsidiaries, including grants from the OCS (collectively, "Government Grants"). Otic Pharma has made available to Public Company true, complete and correct copies of all documents evidencing Government Grants submitted by Otic Pharma and any its Subsidiaries (or transferred or assigned or purchased by Otic Pharma and any of its Subsidiaries) and of all letters of approval, certificates of completion, and supplements and amendments thereto, granted to Otic Pharma and any of its Subsidiaries, and all material correspondence related thereto. Section 3.26 of the Otic Pharma Disclosure Schedule sets forth: (a) the aggregate amount of each Government Grant; (b) the aggregate outstanding obligations, if any, of Otic Pharma and each of its

Subsidiaries under each Government Grant with respect to royalties or other payments; and (c) the outstanding amounts to be paid by the OCS to Otic Pharma and any of its Subsidiaries under the Government Grants, if any. Otic Pharma and each of its Subsidiaries are in compliance with the terms and conditions of all Government Grants and the laws applicable thereto (including the provisions of the Innovation Law and relevant regulations promulgated pursuant thereto), which have been approved, and have duly fulfilled all the undertakings required thereby to be fulfilled. To the knowledge of Otic Pharma, there is no event or other set of circumstances which would reasonably be expected to lead to the revocation or material modification of any of the Government Grants that have been approved. Otic Pharma represents that no OCS funded Intellectual Property is incorporated into Otic Pharma's "Surfactant Platform" products, which are based on intellectual property licensed from Otodyne Inc., and that no OCS funded Intellectual Property is related to Otic Pharma's current and/or anticipated business with respect to the Surfactant Platform. For the purposes of this Agreement "OCS" shall mean the Israel Innovation Authority (formerly known as the Office of the Chief Scientist) of the Israeli Ministry of Economy and Industry.

3.27 Export Control Laws.

(a) Otic Pharma and its Subsidiaries have at all times conducted their export and re-export transactions in accordance with all applicable import/export controls in countries in which Otic Pharma and its Subsidiaries conducts business. Without limiting the foregoing, Otic Pharma and its Subsidiaries have obtained all applicable export and import licenses, approvals and filings with any Governmental Entity required for its export, import and re-export of products, services, software and technologies ("Export Approvals"). Otic Pharma and its Subsidiaries are in compliance with the terms of all applicable Export Approvals. There are no pending legal proceedings or threatened claims against Otic Pharma and its Subsidiaries with respect to such Export Approvals or export or re-export transactions. There are no actions, conditions or circumstances pertaining to Otic Pharma's export transactions that would reasonably be expected to give rise to any future claims; and

(b) Otic Pharma's and its Subsidiaries' business, as currently conducted, does not involve the use or development of, or engaging in, encryption technology, or other technology whose development, commercialization or export is restricted under Israeli or other applicable foreign law, and Otic Pharma's and its Subsidiaries' business, as currently conducted, does not require Otic Pharma or its Subsidiaries to obtain a license from the Israeli Ministry of Defense or an authorized body thereof pursuant to the Control of Products and Services Declaration (Engagement in Encryption), 1974, as amended, or other applicable laws regulating the development, commercialization or export of technology.

3.28 No Other Representations or Warranties. Otic Pharma hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Public Company, nor any other person on behalf of Public Company makes any express or implied representation or warranty with respect to Public Company, or with respect to any other information provided to Otic Pharma or any of its Affiliates in connection with the transactions

contemplated hereby, and (subject to the express representations and warranties of Public Company set forth in Article IV (in each case as qualified and limited by the Public Company Disclosure Schedule)) none of Otic Pharma or any of its Affiliates, shareholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF PUBLIC COMPANY

Public Company represents and warrants to Otic Pharma that the statements contained in this Article IV are true and correct, except: (a) as disclosed in the Public Company SEC Reports filed or furnished prior to the date of this Agreement, or (b) as expressly set forth herein or in the disclosure schedule delivered by Public Company to Otic Pharma on the date of this Agreement (the "Public Company Disclosure Schedule"). For purposes hereof, the phrase "to the knowledge of Public Company" and similar expressions mean the actual knowledge of the persons identified on Section K of the Public Company Disclosure Schedule for this purpose, and such knowledge as such persons would reasonably be expected to have obtained in the course of their performance of their positions at the Public Company (but without any special investigation).

4.1 Organization, Standing and Power. Public Company is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction listed on Section 4.1 of the Public Company Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. For purposes of this Agreement, the term "Public Company Material Adverse Effect" means any material adverse change, effect, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, condition (financial or other), or results of operations of Public Company and its Subsidiaries, taken as a whole; provided, however, that none of the following, to the extent arising after the date of this Agreement, shall be deemed to be a Public Company Material Adverse Effect: any change or event caused by or resulting from (A) changes in prevailing economic or market conditions in the United States or any other jurisdiction in which such entity has substantial business operations (except to the extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (B) changes or events affecting the industry or industries in which Public Company and its Subsidiaries operate generally (except to the extent those changes or events have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (C) changes in generally accepted accounting principles or requirements applicable to Public Company and its Subsidiaries (except

to the extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (D) changes in laws, rules or regulations of general applicability or interpretations thereof by any Governmental Entity (except to the extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (E) any natural disaster or any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against its facilities or citizens wherever located (except to the extent those changes or events have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate); (F) a change in the public trading price of Public Company Common Stock or the implications thereof, (G) a change in the trading volume of Public Company Common Stock, (H) any failure by Public Company to meet any public estimates or expectations of Public Company's revenue, earnings or other financial performance or results of operations for any period, or (I) any failure by Public Company to meet any guidance, budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations (but not, in the case of (F) through (I), the underlying cause of such changes or failures, unless such changes or failures would otherwise be excepted from this definition). For the avoidance of doubt, the parties agree that the terms "material," "materially" and "materiality" as used in this Agreement with an initial lower case "m" shall have their respective customary and ordinary meanings, without regard to the meanings ascribed to Public Company Material Adverse Effect or Otic Pharma Material Adverse Effect, in each case as defined in this Agreement. Public Company has made available to Otic Pharma complete and accurate copies of its certificate of incorporation and bylaws and is not in material default under or in material violation of any provision of any such documents.

4.2 Capitalization.

(a) The authorized capital stock of Public Company consists of 200,000,000 shares of Public Company Common Stock and 5,000,000 shares of preferred stock, $0.001 par value per share ("Public Company Preferred Stock"). The rights and privileges of each class of Public Company's capital stock are as set forth in Public Company's certificate of incorporation. As of the close of business on the Business Day prior to the date of this Agreement, (i) 22,641,651 shares of Public Company Common Stock were issued or outstanding, (ii) no shares of Public Company Common Stock were held in the treasury of Public Company or by Subsidiaries of Public Company, and (iii) no shares of Public Company Preferred Stock were issued or outstanding.

(b) Section 4.2(b) of the Public Company Disclosure Schedule sets forth a complete and accurate list of the number of shares of Public Company Common Stock reserved for future issuance pursuant to stock options granted and outstanding as of the close of business on the Business Day prior to the date of this Agreement, the plans under which such options were granted (collectively, "Public Company Stock Plans") and the total number of outstanding options to purchase shares of Public Company Common Stock (such outstanding options, "Public Company Stock Options") under the Public Company Stock Plans as of the close of business on the Business Day prior to the date of this Agreement, indicating, as of the date of this

Agreement, with respect to each such Public Company Stock Option the name of the holder thereof, the Public Company Stock Plan under which it was granted, the number of shares of Public Company Common Stock subject to such Public Company Stock Option, the exercise price, the date of grant and the vesting schedule, including whether (and to what extent) the vesting will be accelerated in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the Transaction, and whether such Public Company Stock Option is intended to be an incentive stock option. As of the close of business on the Business Day prior to the date of this Agreement, Public Company has reserved 250,000 shares of Public Company Common Stock for issuance to employees pursuant to Public Company's 2014 Employee Stock Purchase Plan (the "Public Company ESPP"), of which 250,000 shares remain available for issuance thereunder as of the date hereof. Public Company has not granted, issued or authorized the grant or issuance of any Public Company Stock Options on the Business Day prior to the date of this Agreement or on the date of this Agreement. Public Company has made available to Otic Pharma accurate and complete copies of all Public Company Stock Plans and the forms of all stock option agreements evidencing Public Company Stock Options.

(c) Section 4.2(c) of the Public Company Disclosure Schedule lists the number of shares of Public Company Common Stock reserved for future issuance pursuant to warrants or other outstanding rights (other than Public Company Stock Options) to purchase shares of Public Company Common Stock outstanding as of the close of business on the Business Day prior to the date of this Agreement (such outstanding warrants or other rights, the "Public Company Warrants") and the agreement or other document under which such Public Company Warrants were granted, and the exercise price, the date of grant and the expiration date thereof. Public Company has made available to Otic Pharma accurate and complete copies of the forms of agreements evidencing all Public Company Warrants.

(d) Except (i) as set forth in this Section 4.2 or in Article II, (ii) as reserved for future grants under Public Company Stock Plans, outstanding as of the close of business on the Business Day prior to the date of this Agreement and (iii) for the rights to acquire shares pursuant to the Public Company ESPP, (A) there are no equity securities of any class of Public Company, or any security exchangeable into or exercisable for such equity securities, issued, reserved for issuance or outstanding and (B) there are no options, warrants, equity securities, calls, rights, commitments or agreements of any character to which Public Company or any of its Subsidiaries is a party or by which Public Company or any of its Subsidiaries is bound obligating Public Company or any of its Subsidiaries to issue, exchange, transfer, deliver or sell, or cause to be issued, exchanged, transferred, delivered or sold, additional shares of capital stock or other equity interests of Public Company or any security or rights convertible into or exchangeable or exercisable for any such shares or other equity interests, or obligating Public Company or any of its Subsidiaries to grant, extend, accelerate the vesting of, otherwise modify or amend or enter into any such option, warrant, equity security, call, right, commitment or agreement. Public Company does not have any outstanding stock appreciation rights, phantom stock, performance based rights or similar rights or obligations. Other than the Public Company Support Agreement, neither Public Company nor any of its Affiliates is a party to or is bound by any, and to the knowledge of Public Company, there are no, agreements or understandings with respect to the voting (including voting trusts and proxies) or sale or transfer (including agreements imposing

transfer restrictions) of any shares of capital stock or other equity interests of Public Company. Except as contemplated by this Agreement or described in this Section 4.2(d), there are no registration rights to which Public Company or any of its Subsidiaries is a party or by which it or they are bound with respect to any equity security of any class of Public Company. Stockholders of Public Company are not entitled to dissenters' or appraisal rights under applicable state law in connection with the Transaction.

(e) All outstanding shares of Public Company Common Stock are, and all shares of Public Company Common Stock subject to issuance as specified in Sections 4.2(b) and 4.2(c) or pursuant to Article II, upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, will be, duly authorized, validly issued, fully paid and nonassessable and not subject to or issued in violation of any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any provision of the DGCL, Public Company's certificate of incorporation or bylaws or any agreement to which Public Company is a party or is otherwise bound.

4.3 Subsidiaries.

(a) Section 4.3(a) of the Public Company Disclosure Schedule sets forth, for each Subsidiary of Public Company: (i) its name; (ii) the number and type of outstanding equity securities and a list of the holders thereof; and (iii) the jurisdiction of organization.

(b) Each Subsidiary of Public Company is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction where the character of its properties owned, operated or leased or the nature of its activities makes such qualification necessary, except for such failures to be so organized, qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. All of the outstanding shares of capital stock and other equity securities or interests of each Subsidiary of Public Company are duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights and all such shares (other than directors' qualifying shares in the case of non-U.S. Subsidiaries, all of which Public Company has the power to cause to be transferred for no or nominal consideration to Public Company or Public Company's designee) are owned, of record and beneficially, by Public Company or another of its Subsidiaries free and clear of all Liens, claims, pledges, agreements or limitations in Public Company's voting rights. There are no outstanding or authorized options, warrants, rights, agreements or commitments to which Public Company or any of its Subsidiaries is a party or which are binding on any of them providing for the issuance, disposition or acquisition of any capital stock of any Subsidiary of Public Company. There are no outstanding stock appreciation, phantom stock or similar rights with respect to any Subsidiary of Public Company. There are no voting trusts, proxies or other agreements or understandings with respect to the voting of any capital stock of any Subsidiary of Public Company.

(c) Public Company has made available to Otic Pharma complete and accurate copies of the charter, bylaws or other organizational documents of each Subsidiary of Public Company.

(d) Public Company does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity which is not a Subsidiary of Public Company. There are no obligations, contingent or otherwise, of Public Company or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of capital stock of any Subsidiary of Public Company or to provide funds to or make any material investment (in the form of a loan, capital contribution or otherwise) in any Subsidiary of Public Company or any other entity, other than guarantees of bank obligations of Subsidiaries of Public Company entered into in the Ordinary Course of Business.

4.4 Authority; No Conflict; Required Filings and Consents.

(a) Public Company has all requisite corporate power and authority to enter into this Agreement and, subject only to the Public Company Stockholder Approval, to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement by Public Company has been duly authorized by all necessary corporate action on the part of Public Company, subject only to the Public Company Stockholder Approval. This Agreement has been duly executed and delivered by Public Company and constitutes the valid and binding obligation of Public Company, enforceable against Public Company in accordance with its terms, subject to the Bankruptcy and Equity Exception.

(b) The execution and delivery of this Agreement by Public Company does not, and the consummation by Public Company of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws of Public Company or of the charter, bylaws or other organizational document of any other Subsidiary of Public Company, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any Lien on Public Company's or any of its Subsidiaries' assets under any of the terms, conditions or provisions of any Contract required to be disclosed in Section 4.11(d) of the Public Company Disclosure Schedule, or (iii) subject to obtaining the Public Company Stockholder Approval and compliance with the requirements specified in clauses (i) through (vii) of Section 4.4(c), conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to Public Company or any of its Subsidiaries or any of its or their properties or assets, except in the case of clauses (ii) and (iii) of this Section 4.4(b), for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate have not had, and are not reasonably likely to result in, the loss of a material benefit to, or in the creation of a material liability for, Public Company. Section 4.4(b) of the Public Company Disclosure Schedule lists all consents, waivers and approvals

under any of Public Company's or any of its Subsidiaries' agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would result in a loss of a material benefit to, or the creation of any material liability for, Public Company or Otic Pharma as a result of the Transaction.

(c) No consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity or any stock market or stock exchange on which shares of Public Company Common Stock are listed for trading is required by or with respect to Public Company or any of its Subsidiaries in connection with the execution and delivery of this Agreement or the consummation by Public Company of the transactions contemplated by this Agreement, except for (i) the filing of the Proxy Statement with the SEC in accordance with the Exchange Act, (ii) the filing of such reports, schedules or materials under Section 13 of or Rule 14a-12 under the Exchange Act as may be required in connection with this Agreement and the transactions contemplated hereby and thereby, (iii) such consents, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable state securities laws and the laws of any foreign country, (iv) a NASDAQ Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of Public Company Common Stock to be issued pursuant to this Agreement (the "NASDAQ Listing Application") and (v) such other consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would not result in a loss of a material benefit to, or the creation of any material liability for, Public Company or Otic Pharma as a result of the Transaction.

(d) The affirmative vote in favor of the issuance of shares of Public Company Common Stock in the Transaction by the holders of a majority of the shares of Public Company Common Stock present or represented by proxy and voting at the Public Company Meeting is the only vote of the holders of any class or series of Public Company's capital stock or other securities of Public Company necessary to approve the Public Company Voting Proposal. There are no bonds, debentures, notes or other indebtedness of Public Company having the right to vote (or convertible into, or exchangeable for, securities having the right to vote) on any matters on which stockholders of Public Company may vote.

4.5 SEC Filings; Financial Statements; Information Provided.

(a) Public Company has filed all registration statements, forms, reports, certifications and other documents required to be filed by Public Company with the SEC since September 18, 2014. All such registration statements, forms, reports and other documents (including those that Public Company may file after the date hereof until the Closing) are referred to herein as the "Public Company SEC Reports." All of the Public Company SEC Reports (A) were or will be filed on a timely basis, (B) at the time filed, complied, or will comply when filed, as to form in all material respects with the requirements of the Securities Act and the Exchange Act applicable to such Public Company SEC Reports and (C) did not or will not at the time they were or are filed contain any untrue statement of a material fact or omit to state a material fact required to be stated in such Public Company SEC Reports or necessary in order to make the statements in such Public Company SEC Reports, in the light of the circumstances under which they were made, not misleading, in any material respect.

(b) Each of the consolidated financial statements (including, in each case, any related notes and schedules) contained or to be contained in the Public Company SEC Reports at the time filed (i) complied or will comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, (ii) were or will be prepared in accordance with GAAP applied on a consistent basis throughout the periods involved and at the dates involved (except as may be indicated in the notes to such financial statements or, in the case of unaudited interim financial statements, as permitted by the SEC on Form 10-Q under the Exchange Act) and (iii) fairly presented or will fairly present in all material respects the consolidated financial position of Public Company and its Subsidiaries as of the dates indicated and the consolidated results of its operations and cash flows for the periods indicated, except that the unaudited interim financial statements were or are subject to normal and recurring year-end adjustments. The consolidated balance sheet of Public Company as of September 30, 2016 is referred to herein as the "Public Company Balance Sheet."

(c) PricewaterhouseCoopers LLP, Public Company's current auditors, is and has been at all times since its engagement by Public Company (i) "independent" with respect to Public Company within the meaning of Regulation S-X and (ii) in compliance with subsections (g) through (l) of Section 10A of the Exchange Act (to the extent applicable) and the related rules of the SEC and the Public Company Accounting Oversight Board.

(d) The information to be supplied by or on behalf of Public Company for inclusion, or filed by the Public Company and incorporated by reference, in the Proxy Statement to be sent to the stockholders of Public Company in connection with the Public Company Meeting, which information shall be deemed to include all information about or relating to Public Company, the Public Company Voting Proposal or the Public Company Meeting, shall not, on the date the Proxy Statement is first mailed to stockholders of Public Company, or at the time of the Public Company Meeting, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading; or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Public Company Meeting that has become false or misleading.

(e) Public Company does not have and never has had any sales in or revenues from the State of Israel.

4.6 No Undisclosed Liabilities. Public Company does not have any liability that is required to be set forth on a balance sheet of Public Company in accordance with GAAP, except for (a) liabilities shown on the Public Company Balance Sheet, (b) liabilities that have arisen since the date of the Public Company Balance Sheet in the Ordinary Course of Business, (c) liabilities for transaction expenses incurred in connection with the transactions contemplated by this Agreement and alternatives to such transactions, and (d) contractual and other liabilities incurred in the Ordinary Course of Business that are not required by GAAP to be reflected on a balance sheet.

4.7 Absence of Certain Changes or Events. During the period beginning on the date of the Public Company Balance Sheet and ending on the date hereof, Public Company and its Subsidiaries have conducted their respective businesses only in the Ordinary Course of Business and, since such date, there has not been (i) any change, event, circumstance, development or effect that, individually or in the aggregate, has had, or is reasonably likely to have, a Public Company Material Adverse Effect or (ii) any other action or event that would have required the consent of Otic Pharma pursuant to Section 5.2 (other than clause (A) of paragraph (j) or paragraphs (k) or (l) thereof) had such action or event occurred after the date of this Agreement.

4.8 Taxes.

(a) Each of Public Company and its Subsidiaries has properly filed on a timely basis all income and other material Tax Returns that it was required to file, and all such Tax Returns were true, correct and complete in all material respects. Each of Public Company and its Subsidiaries has paid on a timely basis all Taxes that were due and payable. The unpaid Taxes of Public Company and each of its Subsidiaries for Tax periods through the date of the Public Company Balance Sheet do not exceed the accruals and reserves for Taxes (excluding accruals and reserves for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the Public Company Balance Sheet, and all unpaid Taxes of Public Company and each of its Subsidiaries for all Tax periods commencing after the date of the Public Company Balance Sheet arose in the Ordinary Course of Business. Neither Public Company nor any of its Subsidiaries is or has ever been a member of an affiliated group with which it has filed (or been required to file) consolidated, combined, unitary or similar Tax Returns, other than a group of which the common parent is Public Company. With the exception of customary commercial leases or contracts that are not primarily related to Taxes entered into in the Ordinary Course of Business and liabilities thereunder, neither Public Company nor any of its Subsidiaries (i) has any actual or potential liability under Treasury Regulations Section 1.1502-6 (or any comparable or similar provision of federal, state, local or foreign law), as a transferee or successor, pursuant to any contractual obligation, or otherwise for any Taxes of any person other than Public Company or any of its Subsidiaries, or (ii) is a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement. All material Taxes that Public Company or any of its Subsidiaries was required by law to withhold or collect have been duly withheld or collected and, to the extent required, have been properly paid to the appropriate Governmental Entity, and each of Public Company and its Subsidiaries has complied with all material information reporting and backup withholding requirements, including the maintenance of required records with respect thereto, in connection with amounts paid to any employee, independent contractor, creditor, or other third party.

(b) Public Company has delivered or made available to Otic Pharma (i) complete and correct copies of all Tax Returns of Public Company and any of its Subsidiaries relating to Taxes for all taxable periods for which the applicable statute of limitations has not yet expired, (ii) complete and correct copies of all private letter rulings, revenue agent reports, information document requests, notices of proposed deficiencies, deficiency notices, protests,

petitions, closing agreements, settlement agreements, pending ruling requests and any similar documents submitted by, received by, or agreed to by or on behalf of Public Company or any of its Subsidiaries relating to Taxes for all taxable periods for which the statute of limitations has not yet expired, and (iii) complete and correct copies of all material agreements, rulings, settlements or other Tax documents with or from any Governmental Entity relating to Tax incentives of Otic Pharma or any of its Subsidiaries. No examination or audit of any Tax Return of Public Company or any of its Subsidiaries by any Governmental Entity is currently in progress or, to the knowledge of Public Company, threatened or contemplated. Neither Public Company nor any of its Subsidiaries has been informed in writing by any jurisdiction in which Public Company or any Subsidiary does not file a Tax Return that the jurisdiction believes that Public Company or any of its Subsidiaries was required to file any Tax Return that was not filed or is subject to Tax in such jurisdiction. Neither Public Company nor any of its Subsidiaries has (i) waived any statute of limitations with respect to Taxes or agreed to extend the period for assessment or collection of any Taxes, which waiver or extension is still in effect, (ii) requested any extension of time within which to file any Tax Return, other than routine extensions available as a matter of right which Tax Return has not yet been filed, or (iii) executed or filed any power of attorney with any taxing authority, which is still in effect.

(c) Neither Public Company nor any of its Subsidiaries has made any payment, is obligated to make any payment, or is a party to any agreement that could obligate it to make any payment that may be treated as an "excess parachute payment" under Section 280G of the Code (without regard to Sections 280G(b)(4) and 280G(b)(5) of the Code).

(d) Neither Public Company nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(l)(A)(ii) of the Code.

(e) Neither Public Company nor any of its Subsidiaries has distributed to its stockholders or security holders stock or securities of a controlled corporation, nor has stock or securities of Public Company or any of its Subsidiaries been distributed, in a transaction to which Section 355 of the Code applies (i) in the two years prior to the date of this Agreement or (ii) in a distribution that could otherwise constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) that includes the transactions contemplated by this Agreement.

(f) There are no Liens with respect to Taxes upon any of the assets or properties of Public Company or any of its Subsidiaries, other than with respect to Taxes not yet due and payable.

(g) Neither Public Company nor any of its Subsidiaries will be required to include any item of income in, or exclude any item of deduction from, taxable income for any period (or any portion thereof) ending after the Closing Date as a result of any (i) adjustments under Section 481 of the Code (or any similar adjustments under any provision of the Code or the corresponding foreign, state or local Tax laws), (ii) deferred intercompany gain or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding provision of state, local or foreign Tax law), (iii) closing agreement as described

in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax law) executed on or prior to the Closing Date, (iv) installment sale or other open transaction disposition made on or prior to the Closing Date, (v) prepaid amount received on or prior to the Closing Date, or (vi) any election made pursuant to Section 108(i) of the Code on or prior to the Closing Date.

(h) Neither Public Company nor any of its Subsidiaries has participated in any "reportable transaction" as defined in Section 1.6011-4(b) of the Treasury Regulations or any analogous provision of state or local law.

(i) Neither Public Company nor any Subsidiary (i) is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal income Tax purposes, (ii) has made an entity classification ("check-the-box") election under Section 7701 of the Code, (iii) is a stockholder of a "controlled foreign corporation" as defined in Section 957 of the Code (or any similar provision of state, local or foreign law), or (iv) is a stockholder in a "passive foreign investment company" within the meaning of Section 1297 of the Code.

(j) Neither Public Company nor any Subsidiary (A) has or has had a permanent establishment in any country (other than its country of incorporation) as defined in any applicable Tax treaty or convention between such country and Public Company or its Subsidiary's country of incorporation or (B) has or has had operations constituting doing business for Tax purposes in any country (other than its country of incorporation).

(k) All related party transactions involving Public Company or any of its Subsidiaries have been conducted at arm's length in compliance with Section 482 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law. Each of Public Company and its Subsidiaries has maintained documentation (including any applicable transfer pricing studies) in connection with such related party transactions in accordance with Sections 482 and 6662 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law.

4.9 Owned and Leased Real Properties.

(a) Neither Public Company nor any of its Subsidiaries owns or has ever owned any real property.

(b) Section 4.9(b) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all real property leased, subleased or licensed by Public Company or any of its Subsidiaries as of the date of this Agreement (collectively, the "Public Company Leases") and the location of the premises. Neither Public Company nor any of its Subsidiaries nor, to the knowledge of Public Company, any other party is in breach or default and no event has occurred, is pending or, to the knowledge of Public Company, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute any such breach or default under any of under any of the Public Company Leases, except where the existence of such defaults, individually or in the aggregate, has not had, and is not reasonably likely to result in, the loss of a material right or in a material liability of Public Company or any of its Subsidiaries. Neither Public Company nor any of its Subsidiaries leases, subleases or licenses any real property to any person other than Public Company and its Subsidiaries. Public Company has made available to Otic Pharma complete and accurate copies of all Public Company Leases.

4.10 Intellectual Property.

(a) To the knowledge of Public Company, Public Company and its Subsidiaries own, license or otherwise possess legally enforceable rights, free and clear of any Liens, to use all material Intellectual Property used or necessary to conduct the business of Public Company and its Subsidiaries as currently conducted, or that would be used or necessary as such business is currently proposed to be conducted (excluding generally commercially available software programs).

(b) The execution and delivery of this Agreement and consummation of the Transaction will not result in the breach of, or create on behalf of any third party the right to terminate or modify, (i) any license, sublicense or other agreement relating to any Intellectual Property owned by Public Company or any of its Subsidiaries that is material to the business of Public Company and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Public Company or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the "Public Company Intellectual Property") or (ii) any license, sublicense and other agreement as to which Public Company or any of its Subsidiaries is a party and pursuant to which Public Company or any of its Subsidiaries is authorized to use any third party Intellectual Property that is material to the business of Public Company and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Public Company or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the "Public Company Third Party Intellectual Property"). Section 4.10(b)(i) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all Patent Rights and registrations and applications for Trademarks and copyrights included in the Public Company Intellectual Property and Section 4.10(b)(ii) sets forth a complete and accurate list of all agreements under which the Public Company or any of its Subsidiaries have in-licensed any Public Company Third Party Intellectual Property.

(c) To the knowledge of Public Company, all issued patents and registrations for Trademarks, service marks and copyrights which are owned by or licensed to Public Company or any of its Subsidiaries and that are material to the business of Public Company and its Subsidiaries, taken as a whole, are valid and subsisting and all payments due and all registration and renewal formalities relating to the Public Company Intellectual Property are up to date, complete and correct. Public Company and its Subsidiaries have taken reasonable measures to protect the proprietary nature of the Public Company Intellectual Property. To the knowledge of Public Company, as of the date of this Agreement (i) no other person or entity is infringing, violating or misappropriating any of the Public Company Intellectual Property or Public Company Third Party Intellectual Property and (ii) no claim or demand has been made in writing and no proceeding has been filed or is threatened in writing asserting that such Intellectual Property is invalid or unenforceable.

(d) To the knowledge of Public Company, none of the (i) products previously or currently sold by Public Company or any of its Subsidiaries or (ii) business or activities previously or currently conducted by Public Company or any of its Subsidiaries infringes, violates or constitutes a misappropriation of, any Intellectual Property of any third party. As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written complaint, claim or notice alleging any such infringement, violation or misappropriation.

4.11 Contracts.

(a) As of the date of this Agreement, there are no Contracts that are material contracts (as defined in Item 601(b)(10) of Regulation S-K) with respect to Public Company, other than those Contracts identified or described in the Public Company SEC Reports filed prior to the date hereof.

(b) Public Company has not entered into any transaction that would be subject to proxy statement disclosure pursuant to Item 404 of Regulation S-K other than as disclosed in an SEC Report filed prior to the date hereof.

(c) Neither Public Company nor any of its Subsidiaries is a party to any agreement under which a third party would be entitled to receive a license or any other right to Public Company Intellectual Property as a result of the transactions contemplated by this Agreement.

(d) Section 4.11(d) of the Public Company Disclosure Schedule lists the following Contracts of Public Company and its Subsidiaries in effect as of the date of this Agreement:

(i) any Contract (or group of related Contracts) for the purchase or sale of products or for the furnishing or receipt of services (A) which calls for performance over a period of more than 180 days from the date of this Agreement, (B) which involves an aggregate of more than $150,000 or (C) in which Public Company or any of its Subsidiaries has granted manufacturing rights, "most favored nation" pricing provisions or marketing or distribution rights relating to any products or territory or has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a particular party;

(ii) any Contract under which the consequences of a default or termination would reasonably be likely to have a Public Company Material Adverse Effect;

(iii) any Contract that could reasonably be expected to have the effect of prohibiting or impairing the conduct of the business of Otic Pharma or any of its Subsidiaries or Public Company or any of its Subsidiaries as currently conducted and as currently proposed to be conducted;

(iv) any Contract under which Public Company or any of its Subsidiaries is restricted from selling, licensing or otherwise distributing any of its technology or products, or providing services to, customers or potential customers or any class of customers, in any geographic area, during any period of time or any segment of the market or line of business;

(v) any dealer, distribution, joint marketing, joint venture, joint development, partnership, strategic alliance, collaboration, development agreement or outsourcing arrangement;

(vi) any Contract for the conduct of research studies, pre-clinical or clinical studies, manufacturing, distribution, supply, marketing or co-promotion of any products in development by or which has been or which is being marketed, distributed, supported, sold or licensed out, in each case by or on behalf of Public Company or any of its Subsidiaries; and

(vii) any Contract that would entitle any third party to receive a license or any other right to intellectual property of Otic Pharma or any of Otic Pharma's Affiliates following the Closing.

(e) Public Company has made available to Otic Pharma a complete and accurate copy of each Contract listed in Sections 4.10(b)(i), 4.10(b)(ii) and 4.11(d) of the Public Company Disclosure Schedule. With respect to each Contract so listed and those Contracts identified or described in the Public Company SEC Reports filed prior to the date hereof: (i) the Contract is legal, valid, binding and enforceable and in full force and effect against Public Company and/or its Subsidiaries, as applicable, and, to the knowledge of Public Company, against each other party thereto, as applicable, subject to the Bankruptcy and Equity Exception; (ii) the Contract will continue to be legal, valid, binding and enforceable and in full force and effect against Public Company and/or its Subsidiaries, as applicable, and, to the knowledge of Public Company, against each other party thereto, immediately following the Closing in accordance with the terms thereof as in effect immediately prior to the Closing (other than any such Contracts that expire or terminate before such time in accordance with their terms and not as a result of a breach or default by Public Company or any of its Subsidiaries), in each case subject to the Bankruptcy and Equity Exception; and (iii) none of Public Company, its Subsidiaries nor, to the knowledge of Public Company, any other party, is in breach or violation of, or default under, any such Contract, and no event has occurred, is pending or, to the knowledge of Public Company, is threatened, which, with or without notice or lapse of time, or both, would constitute a breach or default by Public Company, its Subsidiaries or, to the knowledge of Public Company, any other party under such Contract, except for such breaches, violations or defaults that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect.

4.12 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or has been threatened in writing against Public Company or any of its Subsidiaries that (a) seeks either damages in excess of $100,000 or equitable relief or (b) in any manner seeks material injunctive or other non-monetary relief, including but not limited to a challenge or request to prevent, enjoin, alter or delay the transactions contemplated by this Agreement, except for such actions, suits,

proceedings, claims, arbitrations or investigations first arising after the date of this Agreement that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. There are no material judgments, orders or decrees outstanding against Public Company or any of its Subsidiaries.

4.13 Environmental Matters. Except for such matters that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect:

(i) Public Company and its Subsidiaries have complied with all applicable Environmental Laws;

(ii) the properties currently owned, leased or operated by Public Company and its Subsidiaries (including soils, groundwater, surface water, buildings or other structures) are not contaminated with any Hazardous Substances;

(iii) the properties formerly owned, leased or operated by Public Company or any of its Subsidiaries were not contaminated with Hazardous Substances during the period of ownership, use or operation by Public Company or any of its Subsidiaries;

(iv) neither Public Company nor any of its Subsidiaries are subject to liability for any Hazardous Substance disposal or contamination on the property of any third party; and

(v) neither Public Company nor any of its Subsidiaries have released any Hazardous Substance into the environment.

(b) As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notice, demand, letter, claim or request for information alleging that Public Company or any of its Subsidiaries may be in violation of, liable under or have obligations under, any Environmental Law.

(c) Neither Public Company nor any of its Subsidiaries is subject to any orders, decrees, injunctions or other arrangements with any Governmental Entity or is subject to any indemnity or other agreement with any third party relating to liability under any Environmental Law or relating to Hazardous Substances.

4.14 Employee Benefit Plans.

(a) Section 4.14(a) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all Employee Benefit Plans maintained, or contributed to, by Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates for the benefit of, or relating to, any current or former employee or other service provider of the Public Company or any of its Subsidiaries (together, the "Public Company Employee Plans").

(b) With respect to each Public Company Employee Plan, Public Company has made available to Otic Pharma, a complete and accurate copy of (i) such plan (or a written summary of any unwritten plan), (ii) the three (3) most recent annual reports (Form 5500) filed with the IRS, (iii) each trust agreement, group annuity contract and summary plan description, if any, relating to such Public Company Employee Plan, (iv) the three (3) most recent financial statements for each Public Company Employee Plan that is funded, (v) all personnel, payroll and employment manuals and policies, (vi) all employee handbook, (vii) all reports regarding the satisfaction of the nondiscrimination requirements of Sections 410(b), 401(k) and 401(m) of the Code and (viii) any non-routine correspondence to or from the IRS, Department of Labor or other regulator concerning any Public Company Employee Plan, including any voluntary corrections submissions.

(c) Each Public Company Employee Plan has been administered in all material respects in accordance with ERISA, the Code and all other applicable laws and the regulations thereunder and in accordance with its terms and each of Public Company and its Subsidiaries and their respective ERISA Affiliates has in all material respects met its obligations with respect to such Public Company Employee Plan and has made all required contributions thereto (or reserved such contributions on the Public Company Balance Sheet). Public Company and its Subsidiaries and each of their respective ERISA Affiliates and each Public Company Employee Plan are in compliance in all material respects with the currently applicable provisions of ERISA and the Code and the regulations thereunder (including Section 4980B of the Code, Subtitle K, Chapter 100 of the Code and Sections 601 through 608 and Section 701 et seq. of ERISA). All filings and reports as to each Public Company Employee Plan required to have been submitted to the IRS or to the United States Department of Labor have been timely submitted. There is no audit, investigation or other proceeding (including any voluntary correction application) pending against or involving any Public Company Employee Plan. There have been no events with respect to any Public Company Employee Plan that could result in payment or assessment by or against Public Company or any of its Subsidiaries of any Taxes, including (but without limitation) any excise Taxes under Sections 4972, 4975, 4976, 4977, 4979, 4980B, 4980D, 4980E, 4980H or 5000 of the Code. With respect to the Public Company Employee Plans, no event has occurred, and to the knowledge of Public Company, there exists no condition or set of circumstances in connection with which Public Company or any of its Subsidiaries could be subject to any liability that is reasonably likely, individually or in the aggregate, to have a Public Company Material Adverse Effect under ERISA, the Code or any other applicable law.

(d) With respect to the Public Company Employee Plans, there are no benefit obligations for which contributions have not been made or properly accrued and there are no benefit obligations that have not been accounted for by reserves, or otherwise properly footnoted in accordance with GAAP, on the financial statements of Public Company, which obligations are reasonably likely, individually or in the aggregate, to have a Public Company Material Adverse Effect. The assets of each Public Company Employee Plan that is funded are reported at their fair market value on the books and records of such Public Company Employee Plan.

(e) All Public Company Employee Plans that are intended to be qualified under Section 401(a) of the Code have received determination letters from the IRS to the effect that such Public Company Employee Plans are qualified and the plans and trusts related thereto are exempt from federal income taxes under Sections 401(a) and 501(a) of the Code,

respectively, of the Code, no such determination letter has been revoked and revocation has not been threatened, and no such Public Company Benefit Plan has been amended or operated since the date of its most recent determination letter or application therefor in any respect, and no act or omission has occurred, that would adversely affect its qualification or materially increase its cost. Each Public Company Employee Plan that is required to satisfy Section 401(k)(3) or Section 401(m)(2) of the Code had been tested for compliance with, and satisfies the requirements of, Section 401(k)(3) and Section 401(m)(2) of the Code, as the case may be, for each plan year ending prior to the Closing Date.

(f) Neither Public Company nor any of its Subsidiaries nor any of their respective ERISA Affiliates has (i) ever maintained a Public Company Employee Benefit Plan that was ever subject to Section 412 of the Code or Title IV of ERISA or (ii) ever been obligated to contribute to a "multiemployer plan" (as defined in Section 4001(a)(3) of ERISA). No Public Company Employee Plan is funded by, associated with or related to a "voluntary employees' beneficiary association" within the meaning of Section 501(c)(9) of the Code. No Public Company Employee Plan holds securities issued by Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates.

(g) Each Public Company Employee Plan is amendable and terminable unilaterally by Public Company and any of Public Company's Subsidiaries and their respective ERISA Affiliates that are a party thereto or covered thereby at any time without liability to Public Company or any of its Subsidiaries or their respective ERISA Affiliates as a result thereof (other than for benefits accrued through the date of termination or amendment and reasonable administrative expenses related thereto), and no Public Company Employee Plan, plan documentation or agreement, summary plan description or other written communication distributed generally to employees by its terms prohibits Public Company or any of its Subsidiaries or their respective ERISA Affiliates from amending or terminating any such Public Company Employee Plan. The investment vehicles used to fund the Public Company Employee Plans may be changed at any time without incurring a material sales charge, surrender fee or other similar expense.

(h) Neither Public Company nor any of its Subsidiaries nor any of their respective ERISA Affiliates is a party to any oral or written (i) agreement with any stockholders, director, executive officer or other key employee of Public Company or any of its Subsidiaries (A) the benefits of which are contingent, or the terms of which are materially altered, upon the occurrence of a transaction involving Public Company or any of its Subsidiaries of the nature of any of the transactions contemplated by this Agreement, (B) providing any term of employment or compensation guarantee or (C) providing severance benefits or other benefits after the termination of employment of such director, executive officer or key employee; (ii) agreement, plan or arrangement under which any person may receive payments from Public Company or any of its Subsidiaries or their respective ERISA Affiliates that may be subject to the tax imposed by Section 4999 of the Code or included in the determination of such person's "parachute payment" under Section 280G of the Code, without regard to Section 280G(b)(4); (iii) agreement providing any person providing for "tax gross up" or tax indemnifications related to Sections 280G or 409A of the Code or otherwise; or (iv) agreement or plan binding Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates, including any stock option plan, stock

appreciation right plan, restricted stock plan, stock purchase plan or severance benefit plan, any of the benefits of which shall be increased, or the vesting of the benefits of which shall be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which shall be calculated on the basis of any of the transactions contemplated by this Agreement. There are no loans or extensions of credit by Public Company, any of its Subsidiaries or any of their respective ERISA Affiliate to any employee or any other service provider to Public Company or any of its Subsidiaries.

(i) None of the Public Company Employee Plans promises or provides post-termination medical or other post-termination welfare benefits to any person, except as required by applicable law and at the sole expense of the participant.

(j) Public Company and its Subsidiaries are in material compliance with all applicable provisions of the Affordable Care Act, including reporting requirements, and there has been no change in health plan terms or coverage that would reasonably be expected to attract an excise tax under Section 4980H of the Code for the current year.

(k) Each Public Company Employee Plan that is a "nonqualified deferred compensation plan" (as defined in Section 409A(d)(1) of the Code) materially complies in form and operation with Section 409A of the Code and all IRS regulations and other guidance thereunder. No event has occurred that would be treated by Section 409A(b) of the Code as a transfer of property for purposes of Section 83 of the Code. Since January 1, 2005, no stock option or equity unit option granted under any Public Company Employee Plan has an exercise price that has been or may be less than the fair market value of the underlying stock or equity units (as the case may be) as of the date such option was granted or has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option. No nonqualified deferred compensation plan has been administered in a manner that would cause an excise tax to apply to payments to plan participants.

4.15 Compliance With Laws. Public Company and each of its Subsidiaries has complied in all material respects with, is not in material violation of, and, as of the date of this Agreement, has not received any notice alleging any material violation with respect to, any applicable provisions of any statute, law or regulation with respect to the conduct of its business, or the ownership or operation of its properties or assets.

4.16 Permits and Regulatory Matters.

(a) Public Company and each of its Subsidiaries have all material Permits required to conduct their businesses as currently conducted, including all such Permits required by the FDA or any other Governmental Entity exercising comparable authority (the "Public Company Authorizations").

(b) Public Company and its Subsidiaries are in compliance in all material respects with the terms of the Public Company Authorizations. No Public Company Authorization shall cease to be effective as a result of the consummation of the transactions contemplated by this Agreement.

(c) All manufacturing, processing, distribution, labeling, storage, testing, specifications, sampling, sale or marketing of products performed by or on behalf of Public Company or any of its Subsidiaries are in compliance in all material respects with all applicable laws, rules, regulations or orders administered or issued by the FDA or any other Governmental Entity exercising comparable authority. As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority, and to the knowledge of Public Company there is no action or proceeding pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that Public Company or any of its Subsidiaries is not currently in compliance with any and all applicable laws, regulations or orders implemented by the FDA or any other Governmental Entity exercising comparable authority.

(d) There are no seizures, recalls, market withdrawals, field notifications or corrective actions, notifications of misbranding or adulteration, destruction orders, safety alerts or similar actions relating to the safety or efficacy of any products marketed or sold by Public Company or any of its Subsidiaries being conducted, requested in writing or, to the knowledge of Public Company, threatened by the FDA or any other Governmental Entity exercising comparable authority. Public Company has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated, conducted or issued any recall, market withdrawal, safety alert or other similar notice or action relating to the alleged lack of safety or efficacy of any products marketed or sold by Public Company or any of its Subsidiaries.

(e) The studies, tests and preclinical and clinical trials conducted by or on behalf of Public Company or any of its Subsidiaries were and, if still pending, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards; and, as of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of Public Company or any of its Subsidiaries.

4.17 Employees.

(a) All current and past key employees of Public Company or any of its Subsidiaries have entered into confidentiality and assignment of inventions agreements with Public Company, a copy or form of which has previously been made available to Otic Pharma. To the knowledge of Public Company, as of the date of this Agreement, no employee of Public Company or any Subsidiary of Public Company is in violation of any term of any patent disclosure agreement, non-competition agreement, or any restrictive covenant to a former employer relating to the right of any such employee to be employed by Public Company or any of its Subsidiaries because of the nature of the business currently conducted by Public Company

or any of its Subsidiaries or to the use of trade secrets or proprietary information of others. To the knowledge of Public Company, as of the date of this Agreement, no key employee or group of employees has any plans to terminate employment with Public Company or its Subsidiaries.

(b) Neither Public Company nor any of its Subsidiaries is a party to or otherwise bound by any collective bargaining agreement, contract or other agreement or understanding with a labor union or labor organization. Neither Public Company nor any of its Subsidiaries is the subject of any proceeding asserting that Public Company or any of its Subsidiaries has committed an unfair labor practice or is seeking to compel it to bargain with any labor union or labor organization, nor is there pending or, to the knowledge of Public Company, threatened, any labor strike, dispute, walkout, work stoppage, slow-down or lockout involving Public Company or any of its Subsidiaries.

4.18 Insurance. Public Company and its Subsidiaries maintain those insurance policies listed on Section 4.18 of the Public Company Disclosure Schedule, setting forth the type of policy, the effective date, the expiration date, the policy limits and deductible or retention amounts for each such policy (the "Public Company Insurance Policies"). Each Public Company Insurance Policy is in full force and effect. None of the Public Company Insurance Policies shall terminate or lapse (or be affected in any other adverse manner) by reason of any of the transactions contemplated by this Agreement. Public Company and each of its Subsidiaries have complied in all material respects with the provisions of each Public Company Insurance Policy under which it is the insured party. No insurer under any Public Company Insurance Policy has cancelled or generally disclaimed liability under any such policy or indicated any intent to do so or not to renew any such policy. All claims under the Public Company Insurance Policies have been filed in a timely fashion. All material claims pending under the Public Company Insurance Policies as of the date of this Agreement are listed on Section 4.18 of the Public Company Disclosure Schedule (the "Pending Claims"), setting forth the general nature of such claims (including claimant(s) and damages sought), the date on which the claim(s) arose and the expenses incurred to date under the retention or deductible.

4.19 Opinion of Financial Advisor. The financial advisor of Public Company, Wedbush PacGrow (the "Public Company Financial Advisor"), has delivered to Public Company an opinion dated the date of this Agreement to the effect, as of such date, that the consideration to be paid by Public Company in connection with the Transaction is fair, from a financial point of view, to Public Company, a signed copy of which opinion will be delivered to Otic Pharma within one Business Day following the date of this Agreement.

4.20 Section 203 of the DGCL. Assuming the accuracy of the representations and warranties of Otic Pharma in Section 3.24, Public Company Board has taken all actions so that the restrictions contained in Section 203 of the DGCL applicable to a "business combination" (as defined in Section 203) shall not apply to the execution, delivery or performance of this Agreement, the Public Company Support Agreement or the consummation of the Transaction or the other transactions contemplated by this Agreement or the Public Company Support Agreement.

4.21 Brokers; Fees and Expenses. No agent, broker, investment banker, financial advisor or other firm or person is or shall be entitled, as a result of any action, agreement or commitment of Public Company or any of its Subsidiaries, to any broker's, finder's, financial advisor's or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, except the Public Company Financial Advisor. Public Company has made available to Otic Pharma a complete and accurate copy of all agreements pursuant to which the Public Company Financial Advisor is entitled to any fees and expenses in connection with any of the transactions contemplated by this Agreement. Public Company is not a party to any agreements with the Public Company Financial Advisor providing the Public Company Financial Advisor with any rights after the Closing that have not been made available to Otic Pharma.

4.22 Controls and Procedures, Certifications and Other Matters.

(a) Public Company and each of its Subsidiaries maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal control over financial reporting designed to provide assurance that (i) transactions are executed with management's authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements of Public Company and to maintain accountability for Public Company's consolidated assets, (iii) access to assets of Public Company and its Subsidiaries is permitted only in accordance with management's authorization, (iv) the reporting of assets of Public Company and its Subsidiaries is compared with existing assets at regular intervals and (v) accounts, notes and other receivables and inventory were recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis.

(b) Public Company maintains disclosure controls and procedures required by Rules 13a-15 or 15d-15 under the Exchange Act, and such controls and procedures are effective to ensure that all material information concerning Public Company and its Subsidiaries is made known on a timely basis to the individuals responsible for the preparation of Public Company's filings with the SEC and other public disclosure documents.

(c) Neither Public Company nor any of its Subsidiaries has, since Public Company became subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act, extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any director or executive officer of Public Company. Section 4.22(c) of the Public Company Disclosure Schedule identifies any loan or extension of credit maintained by Public Company to which the second sentence of Section 13(k)(1) of the Exchange Act applies.

4.23 Books and Records. The minute books and other similar records of Public Company contain complete and accurate records of all material actions taken at any meetings of Public Company's stockholders, Board of Directors or any committee thereof and of all written consents executed in lieu of the holding of any such meeting. The books and records of Public Company accurately reflect in all material respects the assets, liabilities, business, financial condition and results of operations of Public Company and have been maintained in accordance with good business and bookkeeping practices.

4.24 No Other Representations or Warranties. Public Company hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Otic Pharma nor any other person on behalf of Otic Pharma makes any express or implied representation or warranty with respect to Otic Pharma or with respect to any other information provided to Public Company or any of its Affiliates in connection with the transactions contemplated hereby, and (subject to the express representations and warranties of Otic Pharma set forth in Article III (in each case as qualified and limited by the Otic Pharma Disclosure Schedule)) none of Public Company or any of its Affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE V

CONDUCT OF BUSINESS

5.1 Covenants of Otic Pharma. Except as set forth in Section 5.1 of the Otic Pharma Disclosure Schedule or as expressly provided herein or as consented to in writing by Public Company (which consent shall not be unreasonably withheld, conditioned or delayed), from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Otic Pharma shall, and shall cause each of its Subsidiaries to, act and carry on its business in the Ordinary Course of Business, pay its debts and Taxes and perform its other obligations when due (subject to good faith disputes over such debts, Taxes or obligations), comply with applicable laws, rules and regulations, and use commercially reasonable efforts, consistent in all material respects with past practices, to maintain and preserve its and each of its Subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Without limiting the generality of the foregoing, except as set forth in Section 5.1 of the Otic Pharma Disclosure Schedule, from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Otic Pharma shall not, and shall not permit any of its Subsidiaries to, directly or indirectly, do any of the following without the prior written consent of Public Company (which consent shall not, in the case of the actions set forth in clauses (k) and (l) of this Section 5.1, be unreasonably withheld, conditioned or delayed):

(a) (i) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, securities or other property) in respect of, any of its capital stock (other than dividends and distributions by a direct or indirect wholly owned Subsidiary of Otic Pharma to its parent); (ii) split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or (iii) purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities, other than, in the case of this clause (iii), from former employees, directors and consultants in accordance with agreements in effect on the date of this Agreement providing for the repurchase of shares at no or nominal consideration in connection with any termination of services to Otic Pharma or any of its Subsidiaries;

(b) except as permitted by Section 5.1(l), issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (other than the issuance of shares of Otic Pharma Ordinary Shares upon the exercise of Otic Pharma Share Options or Otic Pharma Warrants outstanding on the date of this Agreement in accordance with their present terms (including cashless exercises) or Otic Pharma Share Options granted as contemplated by Section 5.1(l));

(c) amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

(d) except for purchases of inventory, raw materials and, to the extent the cost thereof is not in excess of $100,000 in the aggregate, equipment, in each case in the Ordinary Course of Business, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Otic Pharma and its Subsidiaries, taken as a whole;

(e) except in the Ordinary Course of Business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Otic Pharma or of any of its Subsidiaries;

(f) whether or not in the Ordinary Course of Business, sell, dispose of or otherwise transfer any assets material to Otic Pharma and its Subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its Subsidiaries, but excluding the sale or license of products in the Ordinary Course of Business);

(g) (i) incur or suffer to exist any indebtedness for borrowed money other than such indebtedness that existed as of the date of the Otic Pharma Balance Sheet to the extent reflected on the Otic Pharma Balance Sheet or guarantee any such indebtedness of another person, provided, however, that if the Closing does not occur on or prior to March 1, 2017, Otic Pharma shall have the right, in its sole discretion, to incur up to an aggregate of $3,000,000 of additional indebtedness from the Shareholders on the terms set forth in Section 5.1(g) of the Otic Pharma Disclosure Schedule, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Otic Pharma or any of its Subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Otic Pharma in the Ordinary Course of Business) or capital

contributions to, or investment in, any other person, other than Otic Pharma or any of its direct or indirect wholly owned Subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Otic Pharma or its Subsidiaries against fluctuations in commodities prices or exchange rates;

(h) make any capital expenditures or other expenditures with respect to property, plant or equipment, other than as set forth in Otic Pharma's budget for capital expenditures previously made available to Public Company or the specific capital expenditures disclosed and set forth in Section 5.1(h) of the Otic Pharma Disclosure Schedule;

(i) make any changes in accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

(j) except (i) in the Ordinary Course of Business or (ii) for terminations as a result of the expiration of any contract that expires in accordance with terms, (A) modify or amend in any material respect, or terminate, any material contract or agreement to which Otic Pharma or any of its Subsidiaries is party, or (B) knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Otic Pharma of any of its Subsidiaries);

(k) except in the Ordinary Course of Business, (i) enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Otic Pharma or any of its Subsidiaries or (ii) license any material intellectual property rights to or from any third party;

(l) except as required to comply with applicable law or agreements, plans or arrangements existing on the date hereof and either disclosed in the Otic Pharma Disclosure Schedules or not required by this Agreement to be so disclosed, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the Ordinary Course of Business), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of this Agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), or (vi) take any action other than in the Ordinary Course of Business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

(m) make or change any material Tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to Taxes, settle or compromise any material Tax liability, claim or assessment, surrender any right to claim a refund of material Taxes, or amend any income or other material Tax return;

(n) commence any offering of shares of Otic Pharma Ordinary Shares pursuant to any Employee Stock Purchase Plan;

(o) initiate, compromise or settle any material litigation or arbitration proceeding;

(p) open or close any facility or office;

(q) fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of this Agreement;

(r) fail to pay accounts payable and other obligations in the Ordinary Course of Business;

(s) suspend any clinical trials sponsored by Otic Pharma or involving any products marketed or in development by Otic Pharma;

(t) permit the exercise of any Otic Pharma Share Options or Otic Pharma Warrants by any Person who is not a signatory to this Agreement, unless such Person first executes a joinder agreement agreeing to be bound by the terms of this Agreement in form and substance reasonable acceptable to Public Company; or

(u) authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Otic Pharma in this Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of any conditions in Article VII hereof.

5.2 Covenants of Public Company. Except as set forth in Section 5.2 of the Public Company Disclosure Schedule or as expressly provided herein or as consented to in writing by Otic Pharma (which consent shall not be unreasonably withheld, conditioned or delayed), from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Public Company shall, and shall cause each of its Subsidiaries to, act and carry on its business in the Ordinary Course of Business, pay its debts and Taxes and perform its other obligations when due (subject to good faith disputes over such debts, Taxes or obligations), comply with applicable laws, rules and regulations, and, use commercially reasonable efforts, consistent in all material respects with past practices, to maintain and preserve its and each of its Subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Without limiting the generality of the foregoing, except as set forth on Section 5.2 of the Public Company Disclosure Schedule from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms

and the Closing, Public Company shall not, and shall not permit any of its Subsidiaries to, directly or indirectly, do any of the following without the prior written consent of Otic Pharma (which consent shall not, in the case of the actions set forth in clauses (k) and (l) of this Section 5.2, be unreasonably withheld, conditioned or delayed):

(a) (i) split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or (ii) purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities, other than, in the case of this clause (ii), from former employees, directors and consultants in accordance with agreements in effect on the date of this Agreement providing for the repurchase of shares at no or nominal consideration in connection with any termination of services to Public Company or any of its Subsidiaries;

(b) issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (in each case other than the issuance of shares of Public Company Common Stock upon the exercise of Public Company Stock Options or Public Company Warrants outstanding on the date of this Agreement in accordance with their present terms (including cashless exercises));

(c) amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

(d) except for purchases of inventory and raw materials in the Ordinary Course of Business, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Public Company and its Subsidiaries, taken as a whole;

(e) except in the Ordinary Course of Business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Public Company or of any of its Subsidiaries;

(f) whether or not in the Ordinary Course of Business, sell, dispose of or otherwise transfer any assets material to Public Company and its Subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its Subsidiaries, but excluding the sale or license of products in the Ordinary Course of Business);

(g) (i) incur or suffer to exist any indebtedness for borrowed money or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Public Company or any of its Subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other

agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Public Company in the Ordinary Course of Business) or capital contributions to, or investment in, any other person, other than Public Company or any of its direct or indirect wholly owned Subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Public Company or its Subsidiaries against fluctuations in commodities prices or exchange rates;

(h) make any capital expenditures or other expenditures, other than (i) those contemplated by the Public Company financial model provided to Otic Pharma on the date hereof; provided that variances in any line item in the financial model shall be permitted to the extent the aggregate expenditures do not exceed the amount shown in the model (except as provided in clauses (ii) and (iii), (ii) additional expenditures not exceeding 10% of the amount of aggregate expenditures shown in the model and (iii) expenditures incurred by the Public Company as a result of events or circumstances involving the Public Company's ongoing clinical trials that arise outside of the Public Company's control;

(i) make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

(j) except (i) in the Ordinary Course of Business or (ii) for terminations as a result of the expiration of any contract that expires in accordance with its terms, (A) modify or amend in any material respect, or terminate, any material contract or agreement to which Public Company or any of its Subsidiaries is party, or (B) knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Public Company of any of its Subsidiaries);

(k) except in the Ordinary Course of Business, (i) enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Public Company or any of its Subsidiaries or (ii) license any material intellectual property rights to or from any third party;

(l) except as required to comply with applicable law or agreements, plans or arrangements existing on the date hereof and either disclosed in the Public Company Disclosure Schedules, not required by this Agreement to be so disclosed or disclosed in the Public Company SEC Reports filed or furnished prior to the date of this Agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the Ordinary Course of Business), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of this Agreement under any

benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), (vi) hire any additional officers or other employees, or any consultants or independent contractors, in each case, other than as set forth on Section 5.2(l) of the Public Company Disclosure Schedules and employees, consultants or independent contractors hired to fill open position created as a result of the separation of service of an officer, employee, consultant or independent contractor, as applicable, after the date of this Agreement, or (vii) take any action other than in the Ordinary Course of Business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

(m) make or change any material Tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to Taxes, settle or compromise any material Tax liability, claim or assessment, surrender any right to claim a refund of material Taxes, or amend any income or other material Tax return;

(n) commence any offering of shares of Public Company Common Stock pursuant to any Employee Stock Purchase Plan;

(o) initiate, compromise or settle any material litigation or arbitration proceeding;

(p) open or close any facility or office;

(q) fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of this Agreement;

(r) fail to pay accounts payable and other obligations in the Ordinary Course of Business; or

(s) authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Public Company in this Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of any conditions in Article VII hereof.

5.3 Confidentiality. The parties acknowledge that Public Company and Otic Pharma have previously executed a mutual non-disclosure agreement, dated as of September 6, 2016 (the "Confidentiality Agreement"), which Confidentiality Agreement shall continue in full force and effect in accordance with its terms, except as expressly modified by this Agreement.

ARTICLE VI

ADDITIONAL AGREEMENTS

6.1 No Solicitation

(a) No Solicitation or Negotiation. Except as set forth in this Section 6.1, until the Specified Time, each of Otic Pharma, Public Company and their respective Subsidiaries shall not, and each of Otic Pharma and Public Company shall use commercially reasonable efforts to cause their respective Representatives not to, directly or indirectly:

(i) solicit, seek or initiate or knowingly take any action to facilitate or encourage any offers, inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any Acquisition Proposal;

(ii) enter into, continue or otherwise participate or engage in any discussions or negotiations regarding any Acquisition Proposal, or furnish to any person any non-public information or afford any person other than Public Company or Otic Pharma, as applicable, access to such party's property, books or records (except pursuant to a request by a Governmental Entity) in connection with any Acquisition Proposal; provided, however, that nothing in this Section 6.1 shall prevent a party or its Representatives from referring a person to this Section 6.1;

(iii) take any action to make the provisions of any takeover statute inapplicable to any transactions contemplated by an Acquisition Proposal; or

(iv) publicly propose to do any of the foregoing described in clauses (i) through (iii).

Notwithstanding the foregoing or anything to the contrary set forth in this Agreement, subject to compliance with Section 6.1(c), Public Company may (A) furnish non-public information with respect to Public Company and its Subsidiaries to any Qualified Person (and the Representatives of such Qualified Person), pursuant to a confidentiality agreement not materially less restrictive with respect to the confidentiality obligations of the Qualified Person than the Confidentiality Agreement, (B) engage in discussions or negotiations (including solicitation of revised Acquisition Proposals) with any Qualified Person (and the Representatives of such Qualified Person) regarding any such Acquisition Proposal or (C) amend, or grant a waiver or release under, any standstill or similar agreement with respect to any capital stock of such party with any Qualified Person. It is understood and agreed that any violation of the restrictions in this Section 6.1 (or action that, if taken by Public Company would constitute such a violation) by any Representatives of Public Company shall be deemed to be a breach of this Section 6.1 by Public Company.

(b) No Change in Recommendation or Alternative Acquisition Agreement.

Prior to the Specified Time:

(i) Public Company Board shall not, except as set forth in this Section 6.1, withhold, withdraw or modify, or publicly propose to withdraw or modify, its approval or recommendation with respect to the Public Company Voting Proposal (a "Public Company Board Recommendation Change");

(ii) each of Public Company and Otic Pharma shall not enter into any letter of intent, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement or similar agreement (an "Alternative Acquisition Agreement") providing for the consummation of a transaction contemplated by any Acquisition Proposal (other than a confidentiality agreement referred to in Section 6.1(a) entered into in the circumstances referred to in Section 6.1(a)); and

(iii) each of the Public Company Board and the Otic Pharma Board, and each committee thereof, shall not, except as set forth in this Section 6.1, adopt, approve or recommend, or publicly propose to adopt, approve or recommend, any Acquisition Proposal.

Notwithstanding the foregoing or anything to the contrary set forth in this Agreement (including the provisions of this Section 6.1), at any time prior to the approval of the Public Company Voting Proposal, the Public Company Board may effect a Public Company Board Recommendation Change if: (i) the Public Company Board shall have determined in good faith (after consultation with outside legal counsel) that the failure to effect a Public Company Board Recommendation Change could reasonably be expected to be inconsistent with its fiduciary obligations under applicable law; (ii) Public Company has provided at least four Business Days prior written notice to Otic Pharma that it intends to effect a Public Company Board Recommendation Change, including a description in reasonable detail of the reasons for such recommendation change, and written copies of any relevant proposed transactions agreements with any party making a potential Superior Proposal (a "Recommendation Change Notice") (it being understood that the Recommendation Change Notice shall not constitute a Public Company Board Recommendation Change for purposes of this Agreement); (iii) such party has complied in all material respects with the requirements of this Section 6.1 in connection with any potential Superior Proposal; and (iv) if the other party shall have delivered to such party a written, binding and irrevocable offer to alter the terms or conditions of this Agreement during the four Business Day period referred to in clause (ii) above, the Public Company Board of directors shall have determined in good faith (after consultation with outside legal counsel), after considering the terms of such offer by the other party, that the failure to effect a Public Company Board Recommendation Change could still reasonably be expected to be inconsistent with its fiduciary obligations under applicable law. In the event of any material amendment to any Superior Proposal (including any revision in the amount, form or mix of consideration Public Company's stockholders would receive as a result of such potential Superior Proposal), Public Company shall be required to provide the other party with notice of such material amendment and there shall be a new two Business Day period following such notification during which the parties shall comply again with the requirements of this Section 6.1(b) and the Public Company Board shall not make a Public Company Board Recommendation Change prior to the end of any such period as so extended.

(c) Notices of Proposals. Each party will as promptly as reasonably practicable (and in any event within twenty-four (24) hours after receipt) (i) notify the other party of its receipt of any Acquisition Proposal and (ii) provide to the other party a copy of such Acquisition Proposal (if written), or a summary of the material terms and conditions of such Acquisition Proposal (if oral), including the identity of the Person making such Acquisition Proposal, and copies of all written communications with such Person with respect to such actual

or potential Acquisition Proposal. Such party in receipt of an Acquisition Proposal shall notify the other party, in writing, of any decision of its board of directors as to whether to consider any Acquisition Proposal or to enter into discussions or negotiations concerning any Acquisition Proposal or to provide non-public information with respect to such to any person, which notice shall be given as promptly as practicable after such determination was reached (and in any event no later than one Business Day after such determination was reached). Such party in receipt of an Acquisition Proposal will (A) provide the other party with written notice setting forth such information as is reasonably necessary to keep the other party informed in all material respects of the status and material terms of any such Acquisition Proposal and of any material amendments or modifications thereto, (B) keep such other party informed as promptly as practicable with respect to any changes to the material terms of an Acquisition Proposal submitted to such party (and in any event within twenty-four (24) hours following any such changes), including by providing a copy of all written proposals and a summary of all oral proposals or material oral modifications to an earlier written proposal, in each case relating to any Acquisition Proposal, (C) prior to, or substantially concurrently with, the provision of any non-public information of such party to any such person, provide such information to the other party (including by posting such information to an electronic data room), to the extent such information has not previously been made available to the other party, and (D) promptly (and in any event within twenty-four (24) hours of such determination) notify the other party of any determination by such party's board of directors that such Acquisition Proposal constitutes a Superior Proposal.

(d) Certain Permitted Disclosure. Notwithstanding anything to the contrary in this Agreement, nothing contained in this Agreement shall prohibit the Public Company Board from (i) taking and disclosing to its stockholders a position with respect to a tender offer contemplated by Rule 14d-9 or Rule 14e-2 promulgated under the Exchange Act, or from issuing a "stop, look and listen" statement pending disclosure of its position thereunder (none of which, in and of itself, shall be deemed to constitute a Public Company Board Recommendation Change), or (ii) making any disclosure to its stockholders if, in the good faith judgment of its board of directors, after consultation with outside counsel, failure to so disclose could be inconsistent with its obligations under applicable law; provided, however, that notwithstanding clauses (i) and (ii) of this Section 6.1(d), in no event shall Public Company, the Public Company Board, or any committee of the Public Company Board, take, or agree or resolve to take, any action prohibited by Section 6.1(b), except as expressly permitted by Section 6.1(b).

(e) Cessation of Ongoing Discussions. Each of Public Company and Otic Pharma shall, and shall direct its Representatives to, cease immediately all discussions and negotiations that commenced prior to the date of this Agreement regarding any proposal that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal; provided, however, that the foregoing shall not in any way limit or modify the rights of any party hereto under the other provisions of this Section 6.1. Public Company and Otic Pharma will immediately revoke or withdraw access of any person (other than the Public Company, Otic Pharma and their respective Representatives) to any data room (virtual or actual) containing any non-public information with respect to Public Company and request from each third party (other than the Public Company, Otic Pharma and their Representatives) the prompt return or destruction of all non-public information with respect to Public Company or Otic Pharma, as applicable, previously provided to such person.

(f) Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

"Acquisition Proposal" means, with respect to Public Company or Otic Pharma, (a) any inquiry, proposal or offer for a merger, consolidation, dissolution, sale of substantial assets, recapitalization, share exchange, tender offer or other business combination involving such party and its Subsidiaries (other than mergers, consolidations, recapitalizations, share exchanges or other business combinations involving solely such party and/or one or more Subsidiaries of such party), (b) any proposal for the issuance by such party of 15% or more of its equity securities or (c) any proposal or offer to acquire in any manner, directly or indirectly, 15% or more of the equity securities or consolidated total assets of such party and its Subsidiaries, in each case other than the transactions contemplated by this Agreement.

"Qualified Person" means any person making an unsolicited Acquisition Proposal that the Public Company Board determines in good faith (after consultation with outside counsel and its financial advisors) is, or could reasonably be expected to lead to, a Superior Proposal, and such Acquisition Proposal has not resulted from a material breach by Public Company of its obligations under Section 6.1(a).

"Superior Proposal" means, with respect to Public Company, any *bona fide*, unsolicited written proposal made by a third party to acquire 50% or more of the equity securities or consolidated total assets of such party and its Subsidiaries, pursuant to a tender or exchange offer, a merger, a consolidation, business combination or recapitalization or a sale or exclusive license of its assets, (a) on terms which the board of directors of such party determines in its good faith judgment to be more favorable to the holders of such party's capital stock than the transactions contemplated by this Agreement (after consultation with its financial and legal advisors), taking into account all the terms and conditions of such proposal and this Agreement (including any termination or break-up fees and conditions to consummation, as well as any written, binding offer by the other party hereto to amend the terms of this Agreement, which offer is not revocable for at least three Business Days) that the board of directors of such party determines to be relevant and (b) which board of directors of such party has determined to be reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal that board of directors of such party determines to be relevant (including the likelihood and timing of consummation (as compared to the transactions contemplated hereby).

"Specified Time" means the earlier to occur of (a) the Closing, and (b) the time at which this Agreement is terminated in accordance with the terms hereof.

6.2 Proxy Statement.

(a) As promptly as practical after the execution of this Agreement, Public Company, with the cooperation of Otic Pharma, shall prepare and file with the SEC the Proxy Statement. Otic Pharma shall provide to Public Company as promptly as reasonably practical all information regarding Otic Pharma required to be included in the Proxy Statement. Public Company shall respond to any comments of the SEC on the preliminary filing(s) of the Proxy

Statement and shall use commercially reasonable efforts to file the definitive version of the Proxy Statement as promptly as practicable, and Public Company shall cause the Proxy Statement to be mailed to its stockholders at the earliest practicable time after the SEC has completed its review of the preliminary filing of the Proxy Statement (or once 10 days after the initial filing of the preliminary Proxy Statement, if the SEC will not review the Proxy Statement). Public Company shall notify Otic Pharma promptly upon the receipt of any comments from the SEC or its staff and of any request by the SEC or its staff for amendments to the Proxy Statement or any filing pursuant to Section 6.2(b) or for additional information and shall supply Otic Pharma with copies of all correspondence between Public Company or any of its representatives, on the one hand, and the SEC, or its staff, on the other hand, with respect to the Proxy Statement or any filing pursuant to Section 6.2(b). Public Company shall use commercially reasonable efforts to cause all documents that it is responsible for filing with the SEC under this Section 6.2 to comply in all material respects with all applicable requirements of law and the rules and regulations promulgated thereunder. Whenever either Public Company or Otic Pharma shall become aware of the occurrence of any event which is required to be set forth in an amendment or supplement to the Proxy Statement or any filing pursuant to Section 6.2(b), Public Company or Otic Pharma, as the case may be, shall promptly inform the other of such occurrence and cooperate in filing with the SEC or its staff, and/or mailing to stockholders of Public Company and Otic Pharma, such amendment or supplement.

(b) Public Company shall promptly make all necessary filings required of Public Company with respect to the Transaction under the Securities Act, the Exchange Act, applicable state blue sky laws and the rules and regulations thereunder.

6.3 NASDAQ Listing. Public Company agrees to use its commercially reasonable efforts to continue the listing of Public Company Common Stock on NASDAQ during the term of this Agreement and to cause the shares of Public Company Common Stock being issued in connection with the Transaction to be approved for listing (subject to notice of issuance) on NASDAQ at or prior to the Closing, including by filing the NASDAQ Listing Application. Otic Pharma will cooperate with Public Company to cause the NASDAQ Listing Application to be approved and shall promptly furnish to Public Company all information concerning Otic Pharma and its equity holders that may be required or reasonably requested in connection with any action contemplated by this Section 6.3. To the extent necessary in order to maintain the listing of the Public Company Common Stock on NASDAQ (e.g., in order to meet the NASDAQ minimum bid price requirement), the Public Company shall seek stockholder approval for a reverse stock split as part of the Proxy Statement (the "NASDAQ Proposal"), with the specific terms for such split to be proposed by Public Company and approved by Otic Pharma (such approval not to be unreasonably withheld, conditioned or delayed).

6.4 Access to Information. Subject to compliance with applicable confidentiality obligations owed to third parties in effect as of the date of this Agreement, each of Public Company and Otic Pharma shall (and shall cause each of its Subsidiaries to) afford to the other party's officers, employees, accountants, counsel and other representatives, reasonable access, during normal business hours during the period prior to the Closing, to all its properties, books, contracts, commitments, personnel and records and, during such period, each of Public Company and Otic Pharma shall (and shall cause each of its Subsidiaries to) furnish promptly to the other

party all information concerning its business, properties, assets and personnel as the other party may reasonably request. Each of Public Company and Otic Pharma will hold any such information which is nonpublic in confidence in accordance with the Confidentiality Agreement. No information or knowledge obtained in any investigation pursuant to this Section 6.4 or otherwise shall affect or be deemed to modify any representation or warranty contained in this Agreement or the conditions to the obligations of the parties to consummate the Transaction. Without limiting the generality of the foregoing, from the date of this Agreement until the Closing, each of Public Company and Otic Pharma shall promptly provide the other party with copies of: (a) unaudited monthly financial statements or management accounts, when available; (b) any written materials or communications sent by or on behalf of such party to its stockholders; (c) any notice, report or other document filed with or sent to, or received from, any Governmental Entity in connection with the Transaction or any of the other transactions contemplated by this Agreement; and (d) any material notice, report or other document received from any Governmental Entity.

6.5 Stockholder Approval.

(a) Public Company, acting through the Public Company Board, shall take all actions in accordance with applicable law, its certificate of incorporation and bylaws and NASDAQ rules to duly call, give notice of, convene and hold as promptly as practicable, after the declaration of effectiveness of the Registration Statement, the Public Company Stockholders Meeting for the purpose of considering and voting upon the Public Company Voting Proposal as well as the NASDAQ Proposal, if any. Subject to Section 6.1(b), the Public Company Board shall include in the Proxy Statement the recommendation of the Public Company Board in favor of approval of the Public Company Voting Proposal. Public Company shall take all action that is both reasonable and lawful to solicit from its stockholders proxies in favor of the Public Company Voting Proposal. Notwithstanding anything to the contrary contained in this Agreement, Public Company, after consultation with Otic Pharma, may adjourn or postpone Public Company Stockholders Meeting to the extent necessary to ensure that any required supplement or amendment to the Proxy Statement is provided to Public Company's stockholders or, if as of the time for which the Public Company Stockholders Meeting is originally scheduled (as set forth in the Proxy Statement), there are insufficient shares of Public Company Common Stock represented (either in person or by proxy) to constitute a quorum necessary to conduct the business of the Public Company Stockholders Meeting.

(b) Notwithstanding the foregoing, nothing herein shall limit a party's right to terminate this Agreement pursuant to Section 8.1.

6.6 Legal Conditions to Transaction.

(a) Subject to the terms hereof, including Section 6.6(b), Otic Pharma and Public Company shall each use commercially reasonable efforts to (i) take, or cause to be taken, all actions, and do, or cause to be done, and to assist and cooperate with the other parties in doing, all things necessary, proper or advisable to consummate and make effective the transactions contemplated hereby as promptly as practicable, (ii) as promptly as practicable, obtain from any Governmental Entity or any other third party any consents, licenses, permits,

waivers, approvals, authorizations, or orders required to be obtained or made by Otic Pharma or Public Company or any of their Subsidiaries in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, (iii) as promptly as practicable, make all necessary filings, and thereafter make any other required submissions, with respect to this Agreement and the Transaction required under (A) the Securities Act and the Exchange Act, and any other applicable securities laws, and (B) any other applicable law and (iv) execute or deliver any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purposes of, this Agreement. Otic Pharma and Public Company shall reasonably cooperate with each other in connection with the making of all such filings. Otic Pharma and Public Company shall use their respective commercially reasonable efforts to furnish to each other all information required for any application or other filing to be made pursuant to the rules and regulations of any applicable law (including all information required to be included in the Proxy Statement and the Registration Statement) in connection with the transactions contemplated by this Agreement.

(b) Each of Otic Pharma and Public Company shall give (or shall cause their respective Subsidiaries to give) any notices to third parties, and use, and cause their respective Subsidiaries to use, their commercially reasonable efforts to obtain any third party consents related to or required in connection with the Transaction that are (i) necessary to consummate the transactions contemplated hereby, (ii) disclosed or required to be disclosed in the Otic Pharma Disclosure Schedule or the Public Company Disclosure Schedule, as the case may be, or (iii) required to prevent the occurrence of an event that may have a Otic Pharma Material Adverse Effect or a Public Company Material Adverse Effect from occurring prior to or after the Closing.

6.7 Public Disclosure. Except as may be required by applicable law or stock market regulations, (i) the press release announcing the execution of this Agreement shall be issued only in such form as shall be mutually agreed upon by Public Company and Otic Pharma, (ii) Public Company shall use commercially reasonable efforts to consult with Otic Pharma before issuing any press release or otherwise making any public statement with respect to the Transaction or this Agreement and shall not issue any such press release or make any such public statement prior to using such efforts (provided, however, that these restrictions shall not apply to any communications by Public Company with respect to any Acquisition Proposal, Superior Proposal, Recommendation Change Notice or Public Company Board Recommendation Change) and (iii) Otic Pharma shall not issue any press release or otherwise make any public statement with respect to the Transaction or this Agreement without the prior written consent of Public Company.

6.8 Affiliate Legends. Section 6.8 of the Otic Pharma Disclosure Schedule sets forth a list of those persons who are, in Otic Pharma's reasonable judgment, "affiliates" of Otic Pharma within the meaning of Rule 145 promulgated under the Securities Act ("Rule 145 Affiliates"). Otic Pharma shall notify Public Company in writing regarding any change in the identity of its Rule 145 Affiliates prior to the Closing Date. Public Company shall be entitled to place appropriate legends on the certificates evidencing any shares of Public Company Common Stock to be received by Rule 145 Affiliates of Otic Pharma in the Transaction reflecting the restrictions set forth in Rule 145 promulgated under the Securities Act and to issue appropriate stop transfer instructions to the transfer agent for Public Company Common Stock.

6.9 Indemnification.

(a) From the Closing through the sixth anniversary of the Closing Date, Public Company shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Closing, a director or officer of Otic Pharma, Public Company or any of their respective Subsidiaries (the "Indemnified Persons"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the Indemnified Person is or was an officer, director, employee or agent of Otic Pharma, Public Company or any of their respective Subsidiaries, or, while a director or officer of Otic Pharma, Public Company or any of their respective Subsidiaries, is or was serving at the request of Otic Pharma, Public Company or any of their respective Subsidiaries as a director, officer, employee or agent of another person, whether asserted or claimed prior to, at or after the Closing, to the fullest extent permitted by applicable law. Each Indemnified Person will be entitled to advancement of expenses (including attorneys' fees) incurred in the defense of any such claim, action, suit, proceeding or investigation from Public Company following receipt by Public Company from the Indemnified Person of a request therefor; provided that any person to whom expenses are advanced provides an undertaking, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification. The certificate of incorporation and bylaws of the Public Company will contain provisions at least as favorable as the provisions relating to the indemnification, advance of expenses and elimination of liability for monetary damages set forth in the certificate of incorporation and bylaws of the Public Company on the date hereof.

(b) Public Company shall either (A) maintain in effect for six years after the Closing Date the Public Company's existing directors' and officers' insurance policies in place as of the date hereof, or (B) prior to the Closing, purchase a six-year "tail" policy under its own existing directors' and officers' liability insurance policy, with an effective date as of the Closing (provided that Public Company may substitute therefor a policy of at least the same coverage containing terms and conditions that are not less favorable in any material respect); provided, however, that in no event shall Public Company be required to expend pursuant to this Section 6.9(b) more than an amount equal to 200% of the current annual premiums paid by Public Company for such insurance; provided, further, that during the term of the "tail" policy, Public Company shall not take any action following the Closing to cause such "tail" policy to be cancelled or any provision therein to be amended or waived in any manner that would adversely affect in any material respect the rights of their former and current officers and directors.

(c) Public Company shall pay all expenses, including reasonable attorneys' fees, that may be incurred by a person in successfully enforcing such person's rights provided in this Section 6.9.

(d) Public Company and Otic Pharma agree that all rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the Closing, whether asserted or claimed prior to, at or after the Closing, now existing in favor of the current or former directors, officers or employees, as the case may be, of Public Company, Otic

Pharma or any of their respective Subsidiaries as provided in their respective certificates of incorporation or by-laws or other organization documents or in any agreement shall survive the Transaction and shall continue in full force and effect. The provisions of this Section 6.9 are intended to be in addition to the rights otherwise available to the current officers and directors of Public Company, Otic Pharma or any of their respective Subsidiaries by law, charter, statute, by-law or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the Indemnified Persons, their heirs and their representatives. The obligations set forth in this Section 6.9 shall not be terminated, amended or otherwise modified in any manner that adversely affects any Indemnified Person, or any person who is a beneficiary under the policies referred to in this Section 6.9 and their heirs and representatives, without the prior written consent of such affected Indemnified person or other person.

(e) If Public Company, Otic Pharma or any of their respective successors or assigns shall (i) consolidate with or merge into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfer all or substantially all of its properties and assets to any person, then, and in each such case, proper provisions shall be made so that the successors and assigns of such person shall assume all of the obligations of such person set forth in this Section 6.9.

(f) Nothing in this Agreement is intended to, shall be construed to or shall release, waive or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to Otic Pharma, Public Company or any of their respective Subsidiaries for any of their respective directors, officers or other employees, it being understood and agreed that the indemnification provided for in this Section 6.9 is not prior to or in substitution for any such claims under such policies.

6.10 Notification of Certain Matters. Public Company shall give prompt notice to Otic Pharma, and Otic Pharma shall give prompt notice to Public Company, upon becoming aware of the occurrence, or failure to occur, of any event, which occurrence or failure to occur would be reasonably likely to cause (a) (i) any representation or warranty of such party contained in this Agreement that is qualified as to materiality to be untrue or inaccurate in any respect or (ii) any other representation or warranty of such party contained in this Agreement to be untrue or inaccurate in any material respect, in each case, at any time from and after the date of this Agreement until the Closing, or (b) any material failure of Public Company or Otic Pharma, as the case may be, or of any officer, director, employee or agent thereof, to comply with or satisfy any covenant, condition or agreement to be complied with or satisfied by it under this Agreement.

6.11 Corporate Identity. Promptly after the Closing, Public Company shall take all action necessary to cause its certificate of incorporation to be amended to reflect a change in Public Company's name to OticPharma, Inc.

6.12 Succession. Promptly after the Closing, Public Company shall take all action necessary to cause the persons identified on Schedule 6.12 of the Public Company Disclosure Schedule to be appointed as executive officers of Public Company.

6.13 Board of Directors of Public Company. Promptly after the Closing, Public Company shall take all action necessary (a) to cause the number of members of Public Company Board to be fixed at seven, (b) to cause three persons identified in writing by Otic Pharma to the Public Company no later than 15 Business Days after the date of this Agreement and one person identified in writing by Otic Pharma promptly following the Closing, in each case under this clause (b) reasonably acceptable to the Public Company, to be appointed to Public Company Board, and (c) to cause, effective at the time of such appointment, either (i) the resignations of three members of the Public Company Board or (ii) the resignations of four members of the Public Company Board and the appointment to the Public Company Board of one person identified in writing by the Public Company to Otic Pharma no later than 15 Business Days after the date of this Agreement, in each case under this clause (c) reasonably acceptable to Otic Pharma.

6.14 Employee Communications. Public Company and Otic Pharma will use reasonable efforts to consult with each other, and will consider in good faith each other's advice, prior to sending any notices or other communication materials to its employees regarding this Agreement, the Transaction or the effects thereof on the employment, compensation or benefits of its employees.

6.15 State Takeover Laws. If any "fair price," "business combination" or "control share acquisition" statute or other similar statute or regulation is or may become applicable to any of the transactions contemplated by this Agreement, the parties hereto shall use their respective commercially reasonable efforts to (a) take such actions as are reasonably necessary so that the transactions contemplated hereunder may be consummated as promptly as practicable on the terms contemplated hereby and (b) otherwise take all such actions as are reasonably necessary to eliminate or minimize the effects of any such statute or regulation on such transactions.

6.16 Security Holder Litigation. Notwithstanding anything to the contrary herein, (a) Public Company shall have the right to control the defense and settlement of any litigation related to this Agreement, the Transaction or the other transactions contemplated by this Agreement brought by any stockholder or any holder of other securities of Public Company against Public Company and/or its directors or officers, provided that Public Company shall give Otic Pharma the opportunity to participate in the defense of any such litigation and shall not settle any such litigation (other than any settlement not requiring the payment of any amount to any third party in excess of the retentions or deductibles under any applicable insurance policies of Public Company) without the prior written consent of Otic Pharma (which consent shall not be unreasonably withheld, conditioned or delayed), and (b) Otic Pharma shall have the right to control the defense and settlement of any litigation related to this Agreement, the Transaction or the other transactions contemplated by this Agreement brought by any stockholder or any holder of other securities of Otic Pharma against Otic Pharma and/or its directors or officers, provided that Otic Pharma shall give Public Company the opportunity to participate in the defense of any such litigation and shall consider Public Company's advice with respect to such litigation.

6.17 Lock-Up; Regulation S.

(a) Until the date which is 180 days following the Closing Date, each Shareholder, the 104H Trustee or the 102 Trustee, as applicable, will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any securities of Public Company, including shares of Public Company Common Stock or securities convertible into or exchangeable or exercisable for any such securities, enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of such securities, whether any such aforementioned transaction is to be settled by delivery of such securities or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or otherwise to enter into any such transaction, swap, hedge or other arrangement.

(b) Each Regulation S Shareholder agrees (i) not to, in connection with the transactions contemplated by this Agreement, engage in any "directed selling efforts" within the United States, as such term is defined in Regulation S under the Securities Act, (ii) not to resell any Public Company Common Stock received pursuant to this Agreement except in accordance with the provisions of Regulation S under the Securities Act, pursuant to an effective registration statement or pursuant to an available exemption from registration and agrees not to engage in hedging transactions with regard to such shares of Public Company Common Stock, (iii) that Public Company will not register any proposed transfer of any shares of Public Company Common Stock by such Shareholder to the extent such transfer is proposed to not be made in accordance with the provisions of Regulation S, pursuant to an effective registration statement or pursuant to an available exemption from registration and (iv) not to sell or offer to sell any shares of Public Company Common Stock to any "U.S. person" (as such term is defined in Regulation S under the Securities Act), or for the account or benefit of any "U.S. person" (as such term is defined in Regulation S under the Securities Act), in each case until the date that is six-months following the Closing Date.

ARTICLE VII

CONDITIONS TO TRANSACTION

7.1 Conditions to Each Party's Obligation To Effect the Transaction. The respective obligations of each party to this Agreement to effect the Transaction shall be subject to the satisfaction prior to the Closing Date of the following conditions:

(a) Stockholder Approval. The Public Company Voting Proposal shall have been approved at the Public Company Meeting, at which a quorum is present, by the requisite vote of the stockholders of Public Company under applicable law and stock market regulation.

(b) Governmental Approvals. All authorizations, consents, including each of the Israeli Tax Rulings, orders or approvals of, or declarations or filings with, or expirations of waiting periods imposed by, any Governmental Entity in connection with the Transaction and the consummation of the other transactions contemplated by this Agreement, the failure of which to file, obtain or occur is reasonably likely to have a Public Company Material Adverse Effect or a Otic Pharma Material Adverse Effect, shall have been filed, been obtained or occurred on terms and conditions that would not reasonably be likely to have a Public Company Material Adverse Effect or a Otic Pharma Material Adverse Effect.

(c) No Injunctions. No Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule or regulation which is in effect and which has the effect of making the Transaction illegal or otherwise prohibiting consummation of the Transaction.

(d) NASDAQ Notification. The NASDAQ Listing Application shall have been approved.

7.2 Additional Conditions to the Obligations of Public Company. The obligations of Public Company to effect the Transaction shall be subject to the satisfaction on or prior to the Closing Date of each of the following additional conditions, any of which may be waived in writing exclusively by Public Company:

(a) Representations and Warranties. The representations and warranties of Otic Pharma and the Shareholders set forth in this Agreement and in any certificate or other writing delivered by Otic Pharma and the Shareholders pursuant hereto shall be true and correct (i) as of the date of this Agreement (except in the case of this clause (i), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date and (B) where the failure to be true and correct (without regard to any materiality, Otic Pharma Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Otic Pharma Material Adverse Effect) and (ii) as of the Closing Date as though made on and as of the Closing Date (except in the case of this clause (ii), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date, (B) for changes contemplated by this Agreement and (C) where the failure to be true and correct (without regard to any materiality, Otic Pharma Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Otic Pharma Material Adverse Effect); provided, however, that the representations and warranties made by Shareholders in Sections 2.1, 2.2(a) and 2.3 and the representations and warranties made by Otic Pharma in Sections 3.2, 3.4(a) and 3.7(i) shall not be subject to the qualification set forth in clause (C) above; provided, further, that the representations and warranties set forth in Section 3.2(a) shall be true and correct except for such inaccuracies as are in the aggregate de minimis.

(b) Performance of Obligations of Shareholders and Otic Pharma. The Shareholders and Otic Pharma shall have performed in all material respects all obligations required to be performed by them under this Agreement on or prior to the Closing Date.

(c) No Otic Pharma Material Adverse Effect. No Otic Pharma Material Adverse Effect shall have occurred since the date of this Agreement and be continuing.

(d) Third Party Consents. Otic Pharma shall have obtained (i) all consents and approvals of third parties listed in Section 7.2(d)(i) of the Otic Pharma Disclosure Schedule and (ii) any other required consent or approval of any third party (other than a Governmental Entity) the failure of which to obtain, individually or in the aggregate, is reasonably likely to have a Otic Pharma Material Adverse Effect (it being understood and agreed that the failure to obtain or effect any or all of the consents and approvals listed in Section 7.2(d)(ii) of the Otic Pharma Disclosure Schedule will not be reasonably likely to have a Otic Pharma Material Adverse Effect).

(e) Resignations. Public Company shall have received copies of the resignations, effective as of the Closing, of each director of Otic Pharma and its Subsidiaries.

(f) Officers' Certificate. Public Company shall have received an officers' certificate duly executed by each of the Chief Executive Officer and Chief Financial Officer of Otic Pharma to the effect that the conditions of Sections 7.2(a), (b) and (c) have been satisfied.

7.3 Additional Conditions to the Obligations of Otic Pharma. The obligation of Otic Pharma to effect the Transaction shall be subject to the satisfaction on or prior to the Closing Date of each of the following additional conditions, any of which may be waived, in writing, exclusively by Otic Pharma:

(a) Representations and Warranties. The representations and warranties of Public Company set forth in this Agreement and in any certificate or other writing delivered by Public Company pursuant hereto shall be true and correct (i) as of the date of this Agreement (except in the case of this clause (i), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date and (B) where the failure to be true and correct (without regard to any materiality, Public Company Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Public Company Material Adverse Effect) and (ii) as of the Closing Date as though made on and as of the Closing Date (except in the case of this clause (ii), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date, (B) for changes contemplated by this Agreement and (C) where the failure to be true and correct (without regard to any materiality, Public Company Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Public Company Material Adverse Effect); provided, however, that the representations and warranties made by Public Company in Sections 4.2, 4.4(a), 4.4(d) and 4.7(i) shall not be subject to the qualification set forth in clause (C) above; provided, further, that the representations and warranties set forth in Section 4.2(a) shall be true and correct except for such inaccuracies as are in the aggregate de minimis.

(b) Performance of Obligations of Public Company. Public Company shall have performed in all material respects all obligations required to be performed by them under this Agreement on or prior to the Closing Date.

(c) No Public Company Material Adverse Effect. No Public Company Material Adverse Effect shall have occurred since the date of this Agreement and be continuing.

(d) Third Party Consents. Public Company shall have obtained (i) all consents and approvals of third parties listed in Section 7.3(d)(i) of the Public Company Disclosure Schedule and (ii) any other consent or approval of any third party (other than a Governmental Entity) the failure of which to obtain, individually or in the aggregate, is reasonably likely to have an Public Company Material Adverse Effect (it being understood and agreed that the failure to obtain or effect any or all of the consents and approvals listed in Section 7.3(d)(ii) of the Public Company Disclosure Schedule will not be reasonably likely to have a Public Company Material Adverse Effect).

(e) Resignations. Otic Pharma shall have received copies of the resignations, effective as of the Closing, of the directors of Public Company who will not continue to serve in such roles after the Closing.

(f) Israeli Tax Rulings. Otic Pharma shall have prepared, filed and received all Israeli Tax Rulings with respect to the transactions contemplated hereunder.

(g) Office of the Chief Scientist. The Public Company shall have delivered to Otic Pharma an executed copy of an undertaking in the standard form required by the OCS from non-Israeli residents investing in Israeli companies which have received support from the OCS, substantially in the form attached hereto as Exhibit C (the "OCS Undertaking").

(h) Officers' Certificate. Otic Pharma shall have received an officers' certificate duly executed by each of the Chief Executive Officer and Chief Financial Officer of Public Company to the effect that the conditions of Sections 7.3(a), (b), and (c) have been satisfied.

ARTICLE VIII

TERMINATION AND AMENDMENT

8.1 Termination. This Agreement may be terminated at any time prior to the Closing (with respect to Sections 8.1(b) through 8.1(k), by written notice by the terminating party to the other party), whether before or, subject to the terms hereof, after approval of the Transaction by the stockholders of Otic Pharma or Public Company:

(a) by mutual written consent of Public Company and Otic Pharma;

(b) by either Public Company or Otic Pharma if the Transaction shall not have been consummated by May 31, 2017 (the "Outside Date") (provided that the right to terminate this Agreement under this Section 8.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been a principal cause of or resulted in the failure of the Transaction to occur on or before the Outside Date);

(c) by either Public Company or Otic Pharma if a Governmental Entity of competent jurisdiction shall have issued a non-appealable final order, decree or ruling or taken any other non-appealable final action, in each case having the effect of permanently restraining, enjoining or otherwise prohibiting the Transaction; provided, however, that a party hereto shall not be permitted to terminate this Agreement pursuant to this Section 8.1(c) if the issuance of any such order, decree, ruling or other action is attributable to the failure of such party (or any Affiliate of such party) to perform in any material respect any covenant in this Agreement required to be performed by such party (or any Affiliate of such party) at or prior to the Closing;

(d) by either Public Company or Otic Pharma if at the Public Company Meeting (including any adjournment or postponement permitted by this Agreement), at which a vote on the Public Company Voting Proposal is taken, the requisite vote of the stockholders of Public Company in favor of Public Company Voting Proposal shall not have been obtained;

(e) by Public Company, if Otic Pharma shall have knowingly and materially breached its obligations under Section 6.1 of this Agreement;

(f) by Otic Pharma, if at any time prior to the receipt of the Public Company Stockholder Approval: (i) Public Company Board shall have failed to give its recommendation to the approval of the Public Company Voting Proposal in the Proxy Statement or shall have withdrawn or modified its recommendation of the Public Company Voting Proposal; (ii) Public Company Board (or any committee thereof) shall have approved or recommended to the stockholders of Public Company an Acquisition Proposal; (iii) a tender offer or exchange offer for outstanding shares of Public Company Common Stock is commenced (other than by Otic Pharma or an Affiliate of Otic Pharma), and Public Company Board (or any committee thereof) recommends that the stockholders of Public Company tender their shares in such tender or exchange offer or, within ten Business Days after the commencement of such tender offer or exchange offer, Public Company Board fails to recommend against acceptance of such offer; or (iv) Public Company shall have knowingly and materially breached its obligations under Section 6.1 or Section 6.5(b) of this Agreement;

(g) by Public Company, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in this Agreement (other than those referred to elsewhere in this Section 8.1) on the part of Otic Pharma, which breach would cause the conditions set forth in Section 7.2(a) or (b) not to be satisfied; provided that Public Company is not then in material breach of any representation, warranty or covenant under this Agreement and provided, further, that if such breach or failure to perform is curable by Otic Pharma, as applicable, then this Agreement shall not terminate pursuant to this Section 8.1(g) as a result of such particular breach or failure until the earlier of the Outside Date or the expiration of a thirty (30) day period commencing upon delivery of written notice from Public Company to Otic Pharma of such breach or failure, and it being understood that this Agreement shall not terminate pursuant to this Section 8.1(g) as a result of such particular breach or violation if such breach or violation is cured prior to such termination becoming effective;

(h) by Otic Pharma, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in this Agreement (other than those referred to elsewhere in this Section 8.1) on the part of Public Company, which breach would cause the conditions set forth in Section 7.3(a) or (b) not to be satisfied; provided that Otic Pharma is not then in material breach of any representation, warranty or covenant under this Agreement and provided, further, that if such breach or failure to perform is curable by Public Company, then this Agreement shall not terminate pursuant to this Section 8.1(h) as a result of such particular breach or failure until the earlier of the Outside Date or the expiration of a thirty (30) day period commencing upon delivery of written notice from Otic Pharma to Public Company of such breach or failure, and it being understood that this Agreement shall not terminate pursuant to this Section 8.1(h) as a result of such particular breach or violation if such breach or violation is cured prior to such termination becoming effective;

(i) [Intentionally omitted]

(j) [Intentionally omitted]

(k) by Public Company if, at any time prior to the receipt of the Public Company Stockholder Approval, each of the following occur: (A) Public Company shall have received a Superior Proposal; (B) Public Company shall have complied in all material respects with its obligations under Section 6.1 in order to accept such Superior Proposal; (C) the Public Company Board approves, and Public Company concurrently with the termination of this Agreement enters into, a definitive agreement with respect to such Superior Proposal; and (D) prior to or concurrently with such termination, Public Company pays to Otic Pharma the amount contemplated by Section 8.3(c).

8.2 Effect of Termination. In the event of termination of this Agreement as provided in Section 8.1, this Agreement shall immediately become void and there shall be no liability or obligation on the part of Public Company, Otic Pharma, or their respective officers, directors, stockholders or Affiliates; provided that (a) any such termination shall not relieve any party from liability for any knowing and intentional breach of this Agreement and (b) the provisions of Sections 3.20 and 4.21 (Brokers; Fees and Expenses), Section 5.3 (Confidentiality), this Section 8.2 (Effect of Termination), Section 8.3 (Fees and Expenses) and Article IX (Miscellaneous) of this Agreement and the Confidentiality Agreement shall remain in full force and effect and survive any termination of this Agreement.

8.3 Fees and Expenses.

(a) Except as set forth in this Section 8.3, all fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring such expenses, whether or not the Transaction is consummated.

(b) Otic Pharma shall pay Public Company a termination fee of $1,500,000 (the "Otic Pharma Termination Fee") in the event of the termination of this Agreement:

(i) by Public Company pursuant to Sections 8.1(e); or

(ii) by Public Company pursuant to Section 8.1(g).

(c) Public Company shall pay Otic Pharma a termination fee of $1,000,000 (the "Public Company Termination Fee") in the event of the termination of this Agreement:

(i) by Otic Pharma pursuant to Section 8.1(f);

(ii) by Public Company pursuant to Section 8.1(k); or

(iii) by Public Company or Otic Pharma, as applicable, pursuant to Sections 8.1(b) or 8.1(h), so long as (A) prior to the termination of this Agreement, any person makes an Acquisition Proposal or amends an Acquisition Proposal made prior to the date of this Agreement with respect to Public Company; and (B) within 12 months after such termination Public Company enters into a definitive agreement to consummate, or consummates, any Acquisition Proposal (regardless of whether made before or after the termination of this Agreement); provided that for purposes of this Section 8.3(c)(iii), the references to 15% in the definition of Acquisition Proposal shall be deemed to be 50%).

(d) Any fee due under Section 8.3(b)(i) or 8.3(c)(i) shall be paid by wire transfer of same day funds within one Business Day of the date of termination of this Agreement. Any fee due under Section 8.3(b)(ii) or 8.3(c)(ii) shall be paid by wire transfer of same day funds on the date of termination of this Agreement (and shall be a condition to the effectiveness of such termination). Any fee due under Section 8.3(c)(iii) shall be paid by wire transfer of same-day funds within two Business Days after the date on which the transaction referenced in Section 8.3(c)(iii)(B) is consummated. If one party fails to promptly pay to the other any expense reimbursement or fee due hereunder, the defaulting party shall pay the costs and expenses (including legal fees and expenses) in connection with any action, including the filing of any lawsuit or other legal action, taken to collect payment, together with interest on the amount of any unpaid fee at the publicly announced prime rate of Bank of America, N.A. plus five percent per annum, compounded quarterly, from the date such expense reimbursement or fee was required to be paid.

(e) The parties hereto acknowledge that the agreements contained in this Section 8.3 are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the parties hereto would not enter into this Agreement. Notwithstanding Section 8.2 or any other provision of this Agreement, payment of the termination fees described in this Section 8.3 shall constitute the sole and exclusive remedy of Public Company or Otic Pharma, as applicable in connection with any termination of this Agreement in the circumstances in which such fees became payable. In the event that Public Company or Otic Pharma shall receive the payment of a termination fee, the receipt of such fee shall be deemed to be liquidated damages for any and all losses or damages suffered or incurred by Public Company and any of its Affiliates or Otic Pharma and any of its Affiliates, as applicable, or any other person in connection with this Agreement (and the termination hereof), the transactions contemplated hereby (and the abandonment thereof) or any matter forming the basis for such termination, and none of the Public Company, any of its Affiliates or Otic Pharma or any of its Affiliates, as applicable, or any other person, shall be entitled to bring or maintain any other claim, action or proceeding against Public Company or Otic Pharma, as applicable, or any of their respective Affiliates arising out of this Agreement, any of the transactions contemplated hereby or any matters forming the basis for such termination.

(f) The parties hereto acknowledge and agree that (i) in no event shall Otic Pharma be required to pay Otic Pharma Termination Fee on more than one occasion, nor shall Public Company be required to pay Public Company Termination Fee on more than one occasion and (ii) in each case whether or not such fee may be payable under more than one provision of this Agreement at the same or at different times and the occurrence of different events.

8.4 Amendment. This Agreement may be amended by the parties hereto, with respect to Public Company and Otic Pharma, by action taken or authorized by their respective Boards of Directors, and, with respect to the Shareholders, by action taken by the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital, at any time before or after approval of the matters presented in connection with the Transaction by the stockholders of any of the parties, but, after any such approval, no amendment shall be made which by law requires further approval by such stockholders without such further approval. This Agreement may not be amended except by an instrument in writing signed on behalf of each of Public Company, Otic Pharma and the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital.

8.5 Extension; Waiver. At any time prior to the Closing, Public Company or Otic Pharma, by action taken or authorized by their respective Boards of Directors, or the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital, may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other parties hereto, (b) waive any inaccuracies in the representations and warranties contained herein or in any document delivered pursuant hereto and (c) waive compliance with any of the agreements or conditions contained herein. Any agreement on the part of a party hereto to any such extension or waiver shall be valid only if set forth in a written instrument signed on behalf of such party. Such extension or waiver shall not be deemed to apply to any time for performance, inaccuracy in any representation or warranty, or noncompliance with any agreement or condition, as the case may be, other than that which is specified in the extension or waiver. The failure of any party to this Agreement to assert any of its rights under this Agreement or otherwise shall not constitute a waiver of such rights.

8.6 Procedure for Termination, Amendment, Extension or Waiver. A termination of this Agreement pursuant to Section 8.1, an amendment, modification or supplement of this Agreement pursuant to Section 8.4 or an extension or waiver of this Agreement pursuant to Section 8.5 shall, in order to be effective, require action by the respective boards of directors of the applicable parties.

ARTICLE IX

MISCELLANEOUS

9.1 Non-survival of Representations, Warranties and Agreements. None of the representations, warranties, covenants and agreements in this Agreement shall survive the Closing, except for the agreements contained in Article I, Article II, Section 6.9, 6.12 and 6.13 and this Article IX. This Section 9.1 shall have no effect upon any other obligations of the parties hereto, whether to be performed before or after the consummation of the Transaction.

9.2 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly delivered (i) three Business Days after being sent by registered or certified mail, return receipt requested, postage prepaid, or (ii) one Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable overnight courier service, in each case to the intended recipient as set forth below:

(a) if to Public Company, to

Tokai Pharmaceuticals, Inc.
Jodie P. Morrison
President and Chief Executive Officer
255 State Street, 6th Floor
Boston, MA 02109

with a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Stuart M. Falber, Esq.
Hal J. Leibowitz, Esq.
Telecopy: (617) 526-5000

(b) if to Otic Pharma, to

Otic Pharma, Ltd.
Gregory J. Flesher
Chief Executive Officer
19900 MacArthur Blvd., Suite 550
Irvine, California 92612

with copies (which shall not constitute notice) to:

Gibson, Dunn & Crutcher, LLP
555 Mission Street, Suite 3000
San Francisco, California 94105
Attn: Ryan A. Murr

and

Yigal Arnon & Co.
22 Rivlin Street
Jerusalem 9424018, Israel
Attn: Barry Levenfeld

Any party to this Agreement may give any notice or other communication hereunder using any other means (including personal delivery, messenger service, telecopy, ordinary mail or electronic mail), but no such notice or other communication shall be deemed to have been duly given unless and until it actually is received by the party for whom it is intended. Any party to this Agreement may change the address to which notices and other communications hereunder are to be delivered by giving the other parties to this Agreement notice in the manner herein set forth.

9.3 Entire Agreement. This Agreement (including the Schedules and Exhibits hereto and the documents and instruments referred to herein that are to be delivered at the Closing) constitutes the entire agreement among the parties to this Agreement and supersedes any prior understandings, agreements or representations by or among the parties hereto, or any of them, written or oral, with respect to the subject matter hereof and the parties hereto expressly disclaim reliance on any such prior understandings, agreements or representations to the extent not embodied in this Agreement. Notwithstanding the foregoing, the Confidentiality Agreement shall remain in effect in accordance with its terms.

9.4 No Third Party Beneficiaries. This Agreement is not intended to, and shall not, confer upon any other person any rights or remedies hereunder, except as set forth in or contemplated by the terms and provisions of Section 6.9.

9.5 Assignment. No party may assign any of its rights or delegate any of its performance obligations under this Agreement, in whole or in part, by operation of law or otherwise without the prior written consent of the other parties, and any such assignment without such prior written consent shall be null and void. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the parties hereto and their respective successors and permitted assigns. Any purported assignment of rights or delegation of performance obligations in violation of this Section 9.5 is void.

9.6 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties hereto agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.

9.7 Counterparts and Signature. This Agreement may be executed in two or more counterparts (including by facsimile or by an electronic scan delivered by electronic mail), each of which shall be deemed an original but all of which together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each of the parties hereto and delivered to the other parties, it being understood that all parties need not sign the same counterpart. This Agreement may be executed and delivered by facsimile or by an electronic scan delivered by electronic mail.

9.8 Interpretation. When reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or Section of this Agreement, unless otherwise indicated. The table of contents, table of defined terms and headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any party. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa. Any reference to any federal, state, local or foreign statute or law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation." Where this Agreement refers to information that was "made available", that means that such information was either (i) provided directly to the Public Company or Otic Pharma, as applicable, by the other party, (ii) included in the virtual data rooms established by Public Company and Otic Pharma created for the purposes of providing information to the other party in connection with this Agreement at least three Business Days prior to the execution and delivery of this Agreement or (iii) solely with respect to information made available by Public Company, filed with and publicly available on the SEC's EDGAR system prior to the date of this Agreement. No summary of this Agreement prepared by any party shall affect the meaning or interpretation of this Agreement.

9.9 Governing Law. All matters arising out of or relating to this Agreement and the transactions contemplated hereby (including its interpretation, construction, performance and enforcement) shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of laws of any jurisdictions other than those of the State of Delaware; provided, that this Agreement will be governed by and construed in accordance with the laws of the State of Israel solely to the extent necessary to effect the purchase by the Public Company and the sale by the Shareholders of the shares of Otic Pharma Share Capital and the transactions related thereto.

9.10 Remedies. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy will not preclude the exercise of any other remedy. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is

accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which they are entitled at law or in equity.

9.11 Submission to Jurisdiction. Each of the parties to this Agreement (a) consents to submit itself to the exclusive personal jurisdiction of the Court of Chancery of the State of Delaware, New Castle County, or, if that court does not have jurisdiction, a federal court sitting in Wilmington, Delaware in any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement, (b) agrees that all claims in respect of such action or proceeding shall be heard and determined in any such court, (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement or any of the transaction contemplated by this Agreement in any other court. Each of the parties hereto waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other party with respect thereto. Any party may make service on another party by sending or delivering a copy of the process to the party to be served at the address and in the manner provided for the giving of notices in Section 9.2. Nothing in this Section 9.11, however, shall affect the right of any party to serve legal process in any other manner permitted by law.

9.12 WAIVER OF JURY TRIAL. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT.

9.13 Disclosure Schedule. Each of the Otic Pharma Disclosure Schedule and the Public Company Disclosure Schedule shall be arranged in sections corresponding to the numbered sections contained in this Agreement, and the disclosure in any section shall qualify only (a) the corresponding section of this Agreement and (b) the other sections of this Agreement, to the extent that it is reasonably apparent from a reading of such disclosure that it also qualifies or applies to such other sections. The inclusion of any information in the Otic Pharma Disclosure Schedule or the Public Company Disclosure Schedule, as applicable, shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would result in a Otic Pharma Material Adverse Effect or a Public Company Material Adverse Effect, as applicable, or is outside the Ordinary Course of Business.

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

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: CEO

OTIC PHARMA, LTD.

By: /s/ Gregory J. Flesher
Name: Gregory J. Flesher
Title: Chief Executive Officer

SHAREHOLDER

INCENTIVE II MANAGEMENT LTD.

By: /s/ Eyal Lifschitz, Boris Lifschitz
Name: /s/ Eyal Lifschitz, Boris Lifschitz
Title:

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PURE ACOUSTICS INC.

By: /s/ Rami Ezratty
Name: Rami Ezratty
Title: President

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (ISRAEL), L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz
Name: /s/ Eyal Lifschitz, Boris Lifschitz
Peregrine Ventures Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (US INVESTORS), L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz
Name: /s/ Eyal Lifschitz, Boris Lifschitz
Peregrine Ventures Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (OTHER INVESTORS), L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz
Name: /s/ Eyal Lifschitz, Boris Lifschitz
Peregrine Ventures Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE II MANAGEMENT LTD.

By: /s/ Eyal Lifschitz, Boris Lifschitz
Name: /s/ Eyal Lifschitz, Boris Lifschitz
Peregrine Ventures Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

DAN WIZNIZER LTD.

By: /s/ Dan Wiziner
Name: Dan Wiziner
Title: CEO

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

ORBIMED ISRAEL PARTNERS LIMITED PARTNERSHIP

By: /s/ Nissim Darvish
Name: Nissim Darvish
Title: Senior Managing Director

By: /s/ Erez Chimovits
Name: Erez Chimovits
Title: Senior Managing Director

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PONTIFAX (ISRAEL) III LIMITED PARTNERSHIP

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title:

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PONTIFAX (CAYMAN) III LIMITED PARTNERSHIP

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title:

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Gadi Riesenfeld

Dr. Gadi Riesenfeld

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Yosef Krespi

Yosef Krespi

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

Yosef and Lusi Krespi

Yosef and Lusi Krespi

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SHAREHOLDER

/s/ Lisandro Yelin
Lisandro Yelin

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Eran Eilat

Dr. Eran Eilat

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Anat Nursella
Chen Schor (by proxy)

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

OTODYNE INC. (by proxy)

By: /s/ Gregory J. Flesher
Name: Gregory J. Flesher
Title: CEO

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Anat Nursella
Rodrigo Yelin (by proxy)

[Signature Page to Share Purchase Agreement]

Exhibit 12.1

CALCULATION OF RATIOS OF EARNINGS TO FIXED CHARGES AND RATIOS OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED STOCK DIVIDENDS

(dollars in thousands)

	For Years Ended December 31,				
	2016	2015	2014	2013	2012
Earnings (loss):					
Net Loss	$(37,959)	$(45,087)	$(23,296)	$(15,819)	$(9,683)
add: Fixed charges (see below)	232	278	173	122	114
	$(37,727)	$(44,809)	$(23,123)	$(15,697)	$(9,569)
Fixed charges:					
Interest expense on portion of rent expense representative of interest (1)	$ 232	$ 278	$ 173	$ 122	$ 114
Total fixed charges	$ 232	$ 278	$ 173	$ 122	$ 114
Consolidated ratios of earnings to fixed charges (2)	N/A	N/A	N/A	N/A	N/A
Deficiency of earnings available to cover fixed charges	$(37,959)	$(45,087)	$(23,296)	$(15,819)	$(9,683)
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ —	$ —	$ (94)	$ (34)
Consolidated ratios of earnings to combined fixed charges and preferred stock dividends (3)	N/A	N/A	N/A	N/A	N/A
Deficiency of earnings available to cover combined fixed charges and preferred stock dividends	$(37,959)	$(45,087)	$(23,296)	$(15,913)	$(9,717)

(1) One third of rent expense was included in the calculation as it is a reasonable approximation of the interest factor.

(2) We did not record earnings for the years ended December 31, 2016, 2015, 2014, 2013 and 2012. Accordingly, our earnings were insufficient to cover fixed charges for such periods, and we are unable to disclose a ratio of earnings to fixed charges for such periods.

(3) We did not record earnings for the years ended December 31, 2016, 2015, 2014, 2013 and 2012. Accordingly, our earnings were insufficient to cover fixed charges and preferred stock dividends for such periods, and we are unable to disclose a ratio of earnings to combined fixed charges and preferred stock dividends for such periods.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-3 (No. 333-207359) and S-8 (Nos. 333-210058, 333-203032, and 333-200413) of Tokai Pharmaceuticals, Inc. of our report dated March 3, 2017 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 3, 2017

Exhibit 31.1

CERTIFICATIONS

I, Jodie P. Morrison, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 3, 2017

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 Annual Report on Form 10-K 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: March 3, 2017

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 Annual Report on Form 10-K of Tokai Pharmaceuticals, Inc. (the "Company") for the fiscal year ended December 31, 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: March 3, 2017

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 Annual Report on Form 10-K of Tokai Pharmaceuticals, Inc. (the "Company") for the fiscal year ended December 31, 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: March 3, 2017

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

Exhibit 99.1

Section 13(r) Disclosure

The disclosures reproduced below with respect to the fiscal year ended December 31, 2016 were publicly filed with the Securities and Exchange Commission by Novartis AG on its Form 20-F (File No. 001-15024) on January 25, 2017, and are filed as an exhibit to this Annual Report on Form 10-K in accordance with Section 13(r) of the Securities Exchange Act of 1934, as amended. Novartis BioVentures, Ltd., which we consider to be our affiliate due to its stock ownership of our company, is an indirect wholly-owned subsidiary of Novartis AG. We have not independently verified or participated in the preparation of this disclosure.

From Novartis AG's Form 20-F for the year ended December 31, 2016

Disclosure pursuant to Section 219 of the Iran Threat Reduction & Syria Human Rights Act (ITRA)

At Novartis, it is our mission to discover new ways to improve and extend people's lives, regardless of where they live. This includes the compliant sale of medicines and other healthcare products worldwide. To help us fulfill this mission, we have representative offices located in Iran.

As of October 18, 2010, a non-US affiliate within our Innovative Medicines Division entered into a non-binding Memorandum of Understanding (MoU) with the Ministry of Health and Medical Education of the Islamic Republic of Iran. Pursuant to the MoU, the Iranian Ministry of Health acknowledges certain benefits that may apply to sales of certain Innovative Medicines Division medicines by third-party distributors in Iran. These include fast-track registration, market exclusivity, end-user subsidies and exemptions from customs tariffs. Novartis receives no payments from the Iranian Ministry of Health under the MoU and the MoU creates no obligations on the part of either Novartis or the Iranian Ministry of Health.

In the second quarter of 2016, a non-US affiliate within our Innovative Medicines Division submitted a non-binding written proposal for potential collaboration related to local manufacturing, scientific and medical activities between the Iranian Ministry of Health and certain non-US affiliates within our Innovative Medicines and Sandoz Divisions. In the third quarter of 2016, a non-US affiliate within our Innovative Medicines Division submitted a draft of a proposed binding Memorandum of Understanding (MoU), based on the proposal submitted during the second quarter of 2016, to the Embassy of the Islamic Republic of Iran in Bern, Switzerland, to seek support for a meeting with representatives of the Iranian Ministry of Health to negotiate and finalize the MoU. A draft of the proposed binding MoU was submitted to the Iranian Ministry of Health and the Ministry of Foreign Affairs of Iran in the fourth quarter of 2016.

In 2016, non-US affiliates relating to our Innovative Medicines and Sandoz Divisions made payments to government entities in Iran related to exit fees and other transactions ordinarily incident to travel by doctors and other medical professionals resident in Iran to attend conferences or other events outside Iran.

From time to time, including in 2016, non-US affiliates relating to our Innovative Medicines and Sandoz Divisions enter into agreements with hospitals, research institutes, medical associations and universities in Iran to provide grants, sponsor congresses, seminars and symposia, and with doctors and other healthcare professionals for consulting services, including participation in advisory boards and investigator services for observational (non-interventional) studies. Some of these hospitals and research institutes are owned or controlled by the government of Iran, and some of these doctors and healthcare professionals are employed by hospitals that may be public or government-owned.

Because our Innovative Medicines and Sandoz Divisions have operations in Iran, including employees, they obtain services and have other dealings incidental to their activities in that country, including paying taxes and salaries either directly or indirectly through a service provider, and obtaining office rentals, insurance, electricity, water and telecommunications services, office and similar supplies and customs-related services from Iranian companies that may be owned or controlled by the government of Iran.

Some beneficiaries of payments made by non-US affiliates relating to our Innovative Medicines and Sandoz Divisions in the course of the operations described above maintain accounts at banks that are included on the list of Specially Designated Nationals (SDNs). Nonetheless, pursuant to Executive Order 13599, non-US persons are not subject to secondary sanctions for engaging in activities that involve persons included on the Executive Order 13599 List, given that the activities in question do not involve persons on the SDN List or conduct that remains sanctionable.