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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, 2014

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.)**
One Broadway, 14th Floor Cambridge, Massachusetts	**02142**
(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, 2014, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock, and therefore, the registrant cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

As of March 15, 2015, the registrant had 22,382,340 shares of Common Stock, $0.001 par value per share, outstanding.

Portions of the registrant's definitive proxy statement for its 2015 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, 2014, 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:

- the anticipated timing, cost and conduct of our planned pivotal Phase 3 clinical trial and our efforts to complete the clinical development of galeterone for CRPC patients with AR-V7;
- the development of a clinical trial assay to be used in the planned pivotal Phase 3 trial and the development of the assay as a companion diagnostic to be used commercially with galeterone;
- the outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with AR-V7 or other indications or patient populations and any other future product candidates;
- the development of galeterone for the treatment of prostate cancer and of future product candidates, including compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- our plans to enter into collaborations for the commercialization of galeterone and any other future product candidates;
- the potential benefits of any future collaboration;
- the rate and degree of market acceptance and clinical utility of our products;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our 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.

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 clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Our lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies. As of February 28, 2015, we have administered galeterone to over 250 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone was well tolerated and in multiple prostate cancer patient populations showed clinically meaningful reductions in levels of prostate specific antigen, or PSA, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy. We are currently preparing to initiate our pivotal Phase 3 clinical trial of galeterone in the first half of 2015. We refer to this trial as our ARMOR3-Splice Variant, or ARMOR3-SV, trial.

We are focusing our initial development of galeterone on the treatment of patients with castration resistant prostate cancer, or CRPC, whose prostate tumor cells express an altered androgen receptor that is truncated. We intend to conduct our pivotal Phase 3 clinical trial in these patients who we believe may not be effectively treated by the therapies approved by the U.S. Food and Drug Administration, or FDA, in recent years. We believe that one of galeterone's multiple mechanisms of action, androgen receptor degradation, provides an opportunity to treat this population of patients. In our ongoing Phase 2 clinical trial of galeterone, which we refer to as our ARMOR2 trial, we observed clinically meaningful PSA reductions in patients that were identified as having altered androgen receptors that were truncated in a retrospective subset analysis of seven such patients. Six of these patients showed clinically meaningful PSA reductions of at least 50%. Although our initial development focus is on galeterone for the treatment of this population of patients, we are conducting our ongoing ARMOR2 trial of galeterone in multiple CRPC patient populations.

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

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

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

The truncated androgen receptors for which we are developing galeterone are missing the end of the receptor that contains the ligand binding domain. We describe patients with these truncated androgen receptors as having C-terminal loss. An example of one such truncated androgen receptor with C-terminal loss is the splice variant AR-V7, which is the most prevalent of the splice variants that cause C-terminal loss. We plan to conduct our pivotal Phase 3 clinical trial in patients with AR-V7. In patients with C-terminal loss, including AR-V7, the lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. In clinical trials conducted by researchers at MD Anderson

Cancer Center, or MD Anderson, The Johns Hopkins University, or Johns Hopkins, and Memorial Sloan Kettering Cancer Center, or Memorial Sloan Kettering, the presence in patients of truncated androgen receptors with C-terminal loss or AR-V7 was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide), two of the highest selling therapies for CRPC with aggregate reported worldwide 2014 sales of approximately $3.3 billion. We believe that these studies indicate that there is a need for effective treatments for CRPC patients with C-terminal loss, including AR-V7.

Our ARMOR3-SV trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in 148 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant, assessed in circulating tumor cells. The primary endpoint of the trial will be radiographic progression-free survival, or rPFS, as determined by a blinded, independent central imaging assessment. The secondary endpoints of the trial will include overall survival, safety and time to next anti-cancer intervention or time to next cytotoxic therapy. We expect to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016. We have reviewed the trial design with the FDA and European Medicines Agency, or EMA.

In addition to our planned pivotal Phase 3 clinical trial, we are conducting our ongoing ARMOR2 trial of galeterone for the treatment of multiple CRPC populations. Subject to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We have exclusive worldwide development and commercialization rights to galeterone.

In June 2012, the FDA notified us that we had obtained fast track designation for galeterone for the treatment of CRPC. The FDA may give a product fast track designation if the product 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 designated products, sponsors may have more frequent interactions with the FDA, and the FDA may initiate review of sections of a fast track designated product's new drug application, or NDA, on a rolling basis before the application is complete.

According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States during 2015, approximately 221,000 new cases of prostate cancer will be diagnosed, and approximately 28,000 men will die from the disease. Prostate cancer drugs represent a large and growing market. According to Decision Resources Group, an independent research firm, sales of prostate cancer drugs are expected to increase from $6.0 billion in 2013 to more than $9.0 billion in 2021, due to a growing aged population, a rising incidence of cancer and the introduction of new drugs for the treatment of prostate cancer. These new drugs include Zytiga and Xtandi, which are approved for the treatment of CRPC. Although Zytiga was only approved in 2011 and Xtandi in 2012, both of these drugs have experienced rapid sales growth, with reported worldwide 2014 sales of $2.2 billion for Zytiga and $1.1 billion for Xtandi. Despite their success, the need for new treatment options remains as each of these drugs has treatment limitations in CRPC patients and, as supported by the MD Anderson, Johns Hopkins and Memorial Sloan Kettering data, do not appear to be effective in CRPC patients with C-terminal loss, including AR-V7.

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. Ordinarily, the pathway and tumor growth are activated by the binding of testosterone and DHT to the ligand binding domain of androgen receptors. As a result, therapies that block this binding can be effective in disrupting the pathway and tumor cell growth. Zytiga blocks this binding by reducing the synthesis of testosterone through the inhibition of the enzyme CYP17. Xtandi blocks the binding of testosterone or DHT with the androgen receptor through androgen receptor antagonism. However, the effectiveness of Zytiga, Xtandi and other therapies based solely on one of these mechanisms of action requires a functional ligand binding domain. In the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, including AR-V7, there is no functional ligand binding domain, which causes the truncated

androgen receptor to be constitutively active. As a result, we believe that patients with truncated androgen receptors with C-terminal loss, including AR-V7, may not be effectively treated by these therapies.

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

Interim Clinical Trial Results. In November 2014, we announced interim data from our ARMOR2 trial at the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, or EORTC-NCI-AACR. The interim data included patients who had not previously undergone chemotherapy and had not received treatment with Zytiga or Xtandi, whom we refer to as CRPC treatment-naïve patients; patients whose disease progressed during treatment with Zytiga, whom we refer to as Zytiga-refractory patients; and patients whose disease progressed during treatment with Xtandi, whom we refer to as Xtandi-refractory patients. We reported that, as of October 14, 2014, our cut-off date for our data presentation at EORTC-NCI-AACR, in 60 evaluable CRPC treatment-naïve patients, galeterone showed clinically meaningful reductions in levels of PSA. Specifically, we reported the following:

- *Non-metastatic and metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 83% of patients showed maximal reduction in PSA levels of at least 30%, and 70% of patients showed maximal reduction in PSA levels of at least 50%.
- *Metastatic CRPC treatment-naïve patients at the selected Phase 2 dose of 2550 mg/day:* During the first 12 weeks of dosing, 85% of patients showed maximal reduction in PSA levels of at least 30%, and 77% of patients showed maximal reduction in PSA levels of at least 50%.

We also reported 12-week data for 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.

In addition, at EORTC-NCI-AACR, we presented data from a retrospective subset analysis in which seven treatment-naïve CRPC patients in ARMOR2 were identified as having truncated androgen receptors with C-terminal loss. Six of these patients had maximal reductions in PSA levels of at least 50%. The seventh patient, who did not show any reduction in PSA levels, 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. These clinical data are supportive of galeterone's mechanism of action of androgen receptor degradation, which does not require a functional ligand binding domain.

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

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

- ***Potential for improved efficacy.*** We believe that galeterone, which combines the mechanism of action of androgen receptor degradation with the mechanisms of action of CYP17 inhibition and androgen

receptor antagonism, may further improve progression-free survival and overall survival beyond that of products that depend on only a single mechanism of action.

- ***Potential for efficacy in CRPC patients with C-terminal loss, including AR-V7.*** Because galeterone's distinct mechanism of androgen receptor degradation does not require an intact ligand binding domain for efficacy, we believe galeterone may be effective in prostate cancer tumors that express altered androgen receptors with C-terminal loss, including AR-V7. In contrast, the mechanisms of action of Zytiga and Xtandi and other similar drugs in development all require the presence of a functional ligand binding domain in order to be effective in this population.
- ***Potential for lower risk of resistance.*** We believe that galeterone may reduce the risk of or delay the development of resistance to therapy because galeterone addresses multiple mechanisms of action simultaneously.
- ***Potential for broad utility in prostate cancer.*** We believe that galeterone may be well suited to treat different prostate cancer patient populations, from early-stage prostate cancer patients to end-stage salvage metastatic CRPC patients, because of its efficacy, safety and tolerability.
- ***Favorable safety profile.*** As of February 28, 2015, we have administered galeterone to over 250 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone demonstrated a favorable safety and tolerability profile.
- ***No requirement for steroids.*** Zytiga must be co-administered with the steroid prednisone to minimize the risk of mineralocorticoid excess, a potentially fatal syndrome characterized by hypertension, hypokalemia, fluid retention and edema. Unlike Zytiga, galeterone has not been shown in clinical trials to cause mineralocorticoid excess and, as a result, does not require co-administration of steroids.
- ***No associated seizure risk.*** Xtandi has shown a risk of grand mal seizures in clinical trials. Unlike Xtandi, galeterone is not in a class of therapeutics that has shown a risk of seizures. We have not had any reports of seizures in clinical trials of galeterone.
- ***Ease of dosing.*** Galeterone is dosed orally once per day, does not require the co-administration of steroids and can be taken with or without food. We believe that this convenient dosing regimen will enhance patient compliance. In contrast, Zytiga must be taken in a fasted state to avoid large increases in absorption, which may cause side effects. Zytiga must also be co-administered with steroids. The steroid co-administered with Zytiga must be taken with food, resulting in a staggered dosing regimen of pills three times per day.
- ***Potential for use as part of combination therapy.*** We believe that galeterone may prove to be well suited for use in combination with other therapies used across all patient populations of prostate cancer because of its favorable safety profile, ease of administration and highly selective, multiple mechanisms of action.

Our Strategy

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

- ***Complete the clinical development of and seek marketing approval for galeterone for the treatment of CRPC patients with prostate cancer tumors that express the AR-V7 splice variant.*** We have designed our ARMOR3-SV trial to be a randomized, open label clinical trial comparing galeterone to Xtandi in 148 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant. We expect to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016.

- ***Develop galeterone for other prostate cancer indications and patient populations.*** Although we are focusing our initial development of galeterone on the treatment of patients with CRPC whose prostate tumor cells express an altered androgen receptor, we are conducting our ongoing ARMOR2 trial of galeterone for the treatment of multiple CRPC patient populations. Subject to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We also plan to develop galeterone for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents.
- ***Explore the use of galeterone for other hormonally-driven diseases.*** We plan to explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway.
- ***Maximize the commercial potential of galeterone.*** We have worldwide development and commercialization rights to galeterone. If galeterone is approved in the United States, we intend to build a urology- and oncology-focused specialty sales organization in the United States to support the commercialization of galeterone. We intend to commercialize galeterone outside the United States through collaborations with third parties.
- ***Advance the development of our platform of androgen receptor degradation agents.*** We plan to identify and develop novel compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under an exclusive license from the University of Maryland, Baltimore, or UMB. We believe that such compounds may have utility as monotherapies or in combination with existing therapies in treating patients with androgen receptor signaling diseases, including prostate cancer patients with primary or acquired resistance to existing therapies.

The Treatment of Prostate Cancer

Prostate Cancer Overview

According to the American Cancer Society, in the United States, prostate cancer is the most frequently diagnosed cancer among men other than skin cancer. The American Cancer Society estimates that, in the United States during 2015, approximately 221,000 new cases of prostate cancer will be diagnosed, and approximately 28,000 men will die from the disease. Overall, in the United States, about one in seven men will be diagnosed with prostate cancer during his lifetime, and about one in 36 men will die from the disease.

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

Treatment of Advanced Prostate Cancer

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. The pathway is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. Testosterone is primarily produced in the testes, adrenal glands and, to a lesser extent, in prostate cancer tumor cells. DHT is a product of

enzymatic conversion of testosterone. Once binding has occurred, the bound androgen/androgen receptor complex passes into the nucleus of the tumor cell where it binds to DNA in the cancer cell, triggering abnormal cell growth and tumor progression.

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

Most advanced prostate cancer patients initially respond to ADT. However, after initiation of ADT, almost all advanced prostate cancer patients experience a recurrence in tumor growth despite the reduction of testosterone to castrate levels. These patients are considered to be “castration resistant,” and cancer that has reached this state is considered to be CRPC. The development of CRPC following initiation of ADT is due in part to tumor cells that have adapted to the hormone-deprived environment of the prostate and is generally diagnosed based on either rising levels of PSA or disease progression as evidenced by imaging tests or clinical symptoms. Decision Resources Group estimates that approximately 180,000 men in the United States currently have CRPC and are eligible for treatment with drug therapy. Patients treated with LHRH analogs typically remain on those drugs for the remainder of their lives in order to maintain castrate levels of testosterone.

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

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

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

Of these new agents, the two with the highest worldwide sales in 2013 were Zytiga and Xtandi. Zytiga was reported to have worldwide 2014 sales of $2.2 billion, and Xtandi was reported to have worldwide 2014 sales of $1.1 billion. Zytiga and Xtandi are members of a class of new drugs that act by disrupting the androgen receptor signaling pathway. We refer to this class of drugs as secondary hormonal treatments.

Zytiga is an oral secondary hormonal treatment approved by the FDA in April 2011 for use in combination with prednisone to treat men with post-chemotherapy metastatic CRPC. In December 2012, the FDA expanded

the approval of Zytiga in combination with prednisone to include treatment of pre-chemotherapy metastatic CRPC patients. Zytiga disrupts the androgen receptor signaling pathway by inhibiting CYP17 and reducing production of testosterone in the testes, adrenal glands and prostate cancer tumor cells.

Xtandi is an oral secondary hormonal treatment approved by the FDA in August 2012 to treat men with post-chemotherapy metastatic CRPC. In September 2014, the FDA expanded the approval of Xtandi to include treatment of pre-chemotherapy metastatic CRPC patients. Xtandi is an androgen receptor antagonist that disrupts the androgen receptor signaling pathway by blocking the binding of testosterone or the androgen DHT with the androgen receptor.

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

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

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

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

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

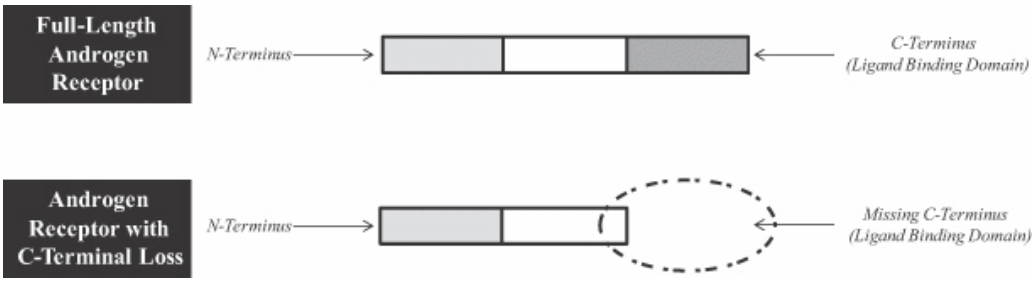
In addition to Zytiga and Xtandi, we are aware of a number of additional therapies that are in late stage clinical trials for prostate cancer, including additional secondary hormonal treatment candidates, which are designed to act by the same mechanisms of action of Zytiga and Xtandi.

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

Unmet Need in Prostate Cancer Patients with C-Terminal Loss

The growth and survival of prostate cancer tumor cells depend primarily on the functioning of the androgen receptor signaling pathway. The pathway and tumor cell growth is ordinarily activated by the binding of androgens, such as testosterone and DHT, to the ligand binding domain of androgen receptors in prostate cancer cells. All proteins, including androgen receptors, are made up of a chain of amino acids that has an N-terminus at one end of the chain and a C-terminus at the other end of the chain as shown in the full-length androgen receptor depicted in Figure 2 below. In the case of androgen receptors, the C-terminus contains the ligand binding domain. The effectiveness of therapies like Zytiga and Xtandi, which act solely through CYP17 inhibition or androgen receptor antagonism, requires a functional ligand binding domain. As depicted in Figure 2 below, in the case of prostate tumor cells that express truncated androgen receptors with C-terminal loss, there is no functional ligand binding domain. This lack of a functional ligand binding domain causes the truncated androgen receptor to be constitutively active, or continuously signaling, meaning that activation of the androgen receptor pathway and tumor growth occurs even in the absence of androgens and androgen binding. As a result, we believe that patients with truncated androgen receptors with C-terminal loss may not be effectively treated by these therapies.

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



These limitations of CYP17 inhibitors and androgen receptor antagonists have been supported by recent research from MD Anderson, Johns Hopkins and Memorial Sloan Kettering, 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.

MD Anderson. At The American Society of Clinical Oncology 2014 Annual Meeting, or ASCO, researchers from MD Anderson presented data from a clinical study in which 60 CRPC patients with bone metastases were treated with a sequential combination regimen of Zytiga and Xtandi. In the study, the researchers defined primary resistance as discontinuation of therapy due to symptomatic or imaging evidence of disease progression within four months of initiating treatment and benefit as discontinuation of therapy due to symptomatic or imaging evidence of disease progression at least four months after initiating treatment. In a subset of 15 patients who were

evaluable for C-terminal loss, four patients were identified as having C-terminal loss, including two who were identified as having AR-V7. In this study, the researchers used antibody-based assays to identify the presence of C-terminal loss and AR-V7. All four, or 100%, of these patients showed primary resistance. Of the 11 patients in the subset that did not have C-terminal loss or AR-V7, nine patients, or 82%, showed benefit. These data are set forth in Table 1 below.

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

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

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

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

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

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

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

Johns Hopkins. In a clinical trial conducted by Johns Hopkins, researchers prospectively evaluated the effect of AR-V7 in patients with metastatic CRPC on tumor responsiveness to treatment with Xtandi and Zytiga. In the trial, 31 patients received Xtandi, and 31 patients received Zytiga. In the trial, the presence of AR-V7 was determined by an analysis of circulating tumor cells isolated from the patient's blood. In the Xtandi-treated group, 12 of the 31 patients were identified as having AR-V7. None of these 12 patients with AR-V7 achieved the trial's primary endpoint of maximal PSA reduction of at least 50%. Eleven of the 12 patients with AR-V7 did not achieve any PSA reduction. Ten of the 19 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. In addition, the median rPFS and the median overall survival of the patients with AR-V7 was 2.1 months and 7.4 months, respectively, compared to 6.1 months and 16.0 months, respectively, in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvements in median rPFS and overall survival were statistically significant.

In the Zytiga-treated group, six of the 31 patients were identified as having AR-V7. None of the six patients with AR-V7 achieved any PSA reduction during treatment. Seventeen of the 25 patients who did not have AR-V7 achieved a maximal PSA reduction of at least 50%. The median rPFS and the median overall survival of the patients with AR-V7 was 2.3 months and 11.1 months, respectively, and in each case had not been reached in the patients without AR-V7. The differences between the AR-V7 and non-AR-V7 groups in terms of the number of patients achieving a maximal PSA reduction of 50% and the improvements in median rPFS and overall survival were statistically significant. The data from the Johns Hopkins trial are summarized in Table 3 below.

Table 3: Summary of Johns Hopkins Data

				Results					
Treatment	*N*	*AR-V7+*	*AR-V7 Status*	*PSA50*	*P-value**	*rPFS*	*P-value**	*Overall survival*	*P-value**
Xtandi	31	38% (12/31)	+	0%	0.004	2.1 months	<0.001	7.4 months	<0.001
			-	52%		6.1 months		16.0 months	
Zytiga	31	19% (6/31)	+	0%	0.004	2.3 months	<0.001	11.1 months	<0.001
			-	68%		Not Reached		Not Reached	

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

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

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

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

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

Memorial Sloan Kettering. At the European Society for Clinical Oncology 2014 Congress, researchers from Memorial Sloan Kettering presented data from a clinical study in which 85 metastatic CRPC patients were treated with Xtandi, Zytiga or taxane-based chemotherapy. Of the 46 patients who received either Xtandi or Zytiga, 21 showed no reduction in PSA levels and were considered resistant to therapy and 25 showed a reduction in PSA levels and were considered to have had a clinical benefit. All patients were screened at baseline for C-terminal loss. A retrospective analysis was conducted in which patients with C-terminal loss were assessed as having demonstrated primary resistance or clinical benefit. Of the six patients identified as having C-terminal loss, no patient showed a clinical benefit. Sixty-three percent of the patients who did not have C-terminal loss showed clinical benefit. These data are summarized in Table 5 below.

Table 5: Summary of Memorial Sloan Kettering C-Terminal Loss Findings

	N	Primary Resistance	Benefit
C-terminal loss	6	100% (6/6)	0% (0/6)
Negative for C-terminal loss	40	37% (15/40)	63% (25/40)

Galeterone

Overview

Our lead product candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that, like Zytiga and Xtandi, acts by disrupting the androgen receptor signaling pathway. Zytiga and Xtandi each disrupt the pathway at a single point using a single mechanism of action. In contrast, galeterone disrupts the pathway at multiple points by combining the mechanisms of action of Zytiga (CYP17 inhibition) and Xtandi (androgen receptor antagonism) with the additional mechanism of androgen receptor degradation. Unlike CYP17 inhibition and androgen receptor antagonism, the mechanism of action of androgen receptor degradation does not require a functional ligand binding domain. We believe that there are no approved drugs or drugs in clinical trials, other than galeterone, with the mechanism of action of androgen receptor degradation. We plan to initiate our pivotal Phase 3 clinical trial of galeterone in the first half of 2015.

In addition to our planned pivotal Phase 3 clinical trial, we are conducting our ongoing ARMOR2 trial of galeterone for the treatment of multiple CRPC populations. Subject to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations, as well as in hormone-sensitive prostate cancer. We have exclusive worldwide development and commercialization rights to galeterone.

Our initial development strategy for galeterone focuses on the treatment of patients with CRPC whose prostate tumor cells express AR-V7, an altered androgen receptor that is truncated. This strategy is consistent with the heightened awareness and interest in drug development of precision medicine therapies for the treatment of cancers caused by genetic and other alterations. We are not aware of any precision medicine therapies in late stage clinical trials for the treatment of prostate cancer specifically targeting C-terminal loss or splice variants other than galeterone.

Key Differentiating Attributes of Galeterone

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

- ***Potential for improved efficacy.*** We believe that galeterone, which combines the mechanism of action of androgen receptor degradation with the mechanisms of action of Zytiga (CYP17 inhibition) and Xtandi (androgen receptor antagonism), may further improve progression-free survival and overall survival beyond that of products that depend on only a single mechanism of action. At EORTC-NCI-AACR, we reported efficacy data from a total of 107 CRPC patients in our ARMOR2 trial that showed meaningful reductions in maximal PSA in patients in the trial.
- ***Potential for efficacy in CRPC patients with C-terminal loss, including AR-V7.*** Because galeterone's distinct mechanism of action of androgen receptor degradation does not require an intact ligand binding domain to be effective against prostate cancer tumors, we believe galeterone may be effective in prostate cancer tumors that express altered androgen receptors with C-terminal loss, including AR-V7. In contrast, the mechanisms of action of Zytiga and Xtandi and other similar drugs in clinical development all require the presence of the ligand binding domain in order to be effective.
- ***Potential for lower risk of resistance.*** We believe that galeterone may reduce the risk of or delay the development of resistance to therapy because galeterone addresses multiple mechanisms of action simultaneously. We believe that reducing resistance may delay the development of disease progression.

- ***Potential for broad utility in prostate cancer.*** We believe that galeterone may be well suited to treat different prostate cancer patient populations, from early-stage prostate cancer patients to end-stage salvage metastatic CRPC patients, because of its efficacy, safety and tolerability.
- ***Favorable safety profile.*** We have administered galeterone to over 250 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone demonstrated a favorable safety and tolerability profile. In our ARMOR2 trial, approximately 90% of all treatment-emergent adverse events reported as of October 14, 2014 were grade 1 or 2 in severity and were generally manageable and reversible.
- ***No requirements for steroids.*** Unlike Zytiga, galeterone has not been shown in clinical trials to cause mineralocorticoid excess and does not require co-administration of steroids. Because Zytiga has been shown in clinical trials to cause mineralocorticoid excess, a potentially fatal syndrome characterized by hypertension, hypokalemia, fluid retention and edema, Zytiga is required to be administered with prednisone to reduce the frequency of patients exhibiting mineralocorticoid excess. Despite the co-administration of prednisone, however, approximately 30% of patients treated with Zytiga in a pivotal Phase 3 trial developed symptoms of mineralocorticoid excess. In addition, the chronic use of prednisone poses other safety concerns. Side effects associated with chronic use of prednisone include muscle weakness, osteoporosis, diabetes and increased risk of infection.
- ***No associated seizure risk.*** Unlike Xtandi, we have not had any reports of seizures in clinical trials of galeterone. A 0.9% risk of grand mal seizures was reported in the Xtandi pivotal Phase 3 trial in post-chemotherapy CRPC patients. These seizures have been linked to the inhibition or antagonism by Xtandi of $GABA_A$, a receptor associated with the nervous system. Galeterone is not a $GABA_A$ antagonist.
- ***Ease of dosing.*** Unlike the complicated dosing regimen for Zytiga, galeterone is dosed orally once per day, does not require the co-administration of steroids and can be taken with or without food. We believe that this convenient dosing regimen will enhance patient compliance. In contrast, Zytiga must be taken in a fasted state to avoid large increases in absorption, which may cause side effects. Zytiga also must be co-administered with steroids. Prednisone, the steroid co-administered with Zytiga, must be taken with food in order to avoid potential development of gastric ulcers. As a result, Zytiga and prednisone cannot be taken together and dosing must be carefully coordinated with food intake, resulting in a staggered dosing regimen of pills three times per day.
- ***Potential for use as part of combination therapy.*** Combination therapy using drugs with different mechanisms of action has been an important component of cancer treatment. Combination therapy makes it possible to simultaneously attack different mechanisms responsible for the replication, progression and survival of tumor cells. This is important because of the genetic diversity within a tumor population and because not all cells are equally sensitive to a particular mechanism of action or drug. Because of galeterone's multiple mechanisms of action, galeterone acts as if it were a combination therapy. Moreover, because of galeterone's favorable safety profile, ease of administration and highly selective, multiple mechanisms of action, we believe that it may prove to be well suited for use in combination with other therapies.

Galeterone Clinical Development

In August 2009, we submitted an investigational new drug application, or IND, to the FDA for galeterone for the treatment of CRPC, and in November 2009, we commenced clinical trials of galeterone. As of October 14, 2014, our cut-off date for our data presentation at EORTC-NCI-AACR, we had administered galeterone to a total of 254 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. Specifically, as of such date, we had treated, in the Androgen Receptor Modulation Optimized for Response, or ARMOR, program, 121 CRPC patients in our ongoing ARMOR2 trial and 49 CRPC patients in our ARMOR1 trial. In four additional Phase 1 clinical trials, we also administered galeterone to 84 healthy volunteers.

ARMOR2 Trial

In December 2012, we initiated our ARMOR2 trial, an open label Phase 2 clinical trial of galeterone. The trial is designed as a two-part trial. Part 1 of the trial is a dose escalation phase designed to confirm the dose of galeterone to be evaluated in Part 2 of the trial. Part 2 of the trial is designed to evaluate the efficacy and safety of galeterone at the dose selected in Part 1 in distinct CRPC patient populations. The trial is being conducted at 28 sites in the United States and Canada. Enrollment in the trial has been completed. As of February 28, 2015, 19 patients were still participating in the extension portion of the trial.

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

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

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

Part 2 of ARMOR2 Trial. We completed enrollment in Part 2 of the ARMOR2 trial in July 2014. In total, we enrolled 93 patients. In ARMOR2, we are evaluating the following CRPC populations at a 2550 mg/day dose of galeterone:

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

Table 6 below summarizes the patient populations enrolled and primary endpoints for Part 2 of the ARMOR2 trial:

Table 6: Patient Populations and Primary Endpoints for Part 2 of the ARMOR2 Trial

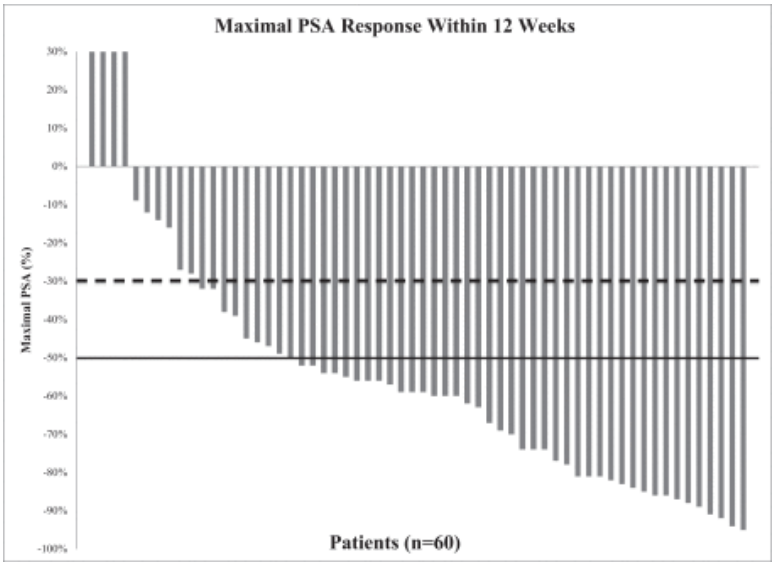
<table>
<tr><th>Patient Population</th><th>Number of Patients Enrolled</th><th>Primary Endpoint</th></tr>
<tr><td>Non-metastatic CRPC treatment-naïve patients</td><td rowspan="2">50</td><td rowspan="2">Percentage of patients with a maximal reduction in PSA levels of at least 30% from baseline to the end of the primary treatment phase</td></tr>
<tr><td>Metastatic CRPC treatment-naïve patients</td></tr>
<tr><td>Zytiga-refractory patients</td><td>34</td><td rowspan="2">Percentage of change in PSA levels from baseline to the end of the primary treatment phase</td></tr>
<tr><td>Xtandi-refractory patients</td><td>9</td></tr>
</table>

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

All patients 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 is continued until disease progression or patient withdrawal due to adverse events or other reasons.

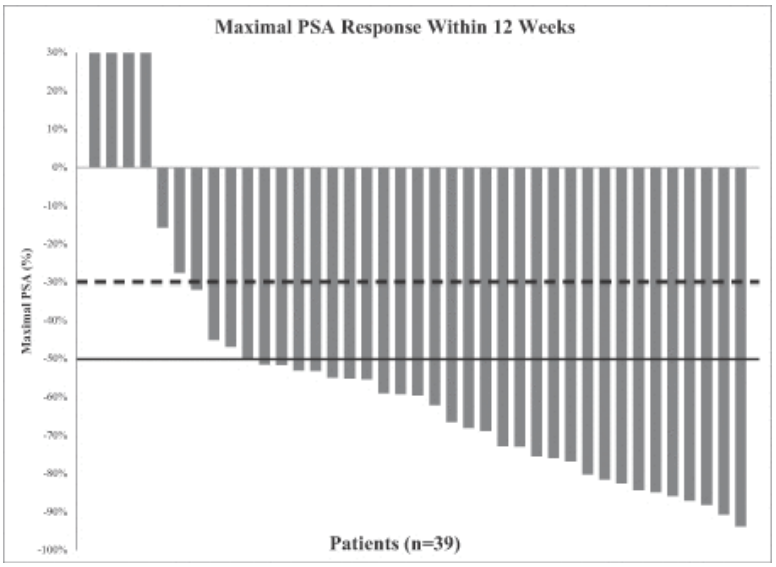
Clinical Data Presented at EORTC-NCI-AACR. In November 2014 at EORTCI-NCI-AACR, we presented interim efficacy and safety data from our ARMOR2 trial for patients who received the 2550 mg/day dose of galeterone. In 60 evaluable CRPC treatment-naïve patients in Part 1 and Part 2 of the trial who received 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%, as described in Figure 3 below.

Figure 3: ARMOR2: Maximal PSA Response Waterfall Plot in All Pre-Chemotherapy CRPC Treatment-Naïve Patients (n=60) (2550 mg dose)



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

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



We also reported 12-week data for 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 complete 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 circulating tumor cell, or CTC enumeration and characterization. At EORTC-NCI-AACR, 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. These data are supportive of galeterone's mechanism of action of androgen receptor degradation, which does not require a functional ligand binding domain.

At EORTC-NCI-AACR, we also presented interim safety results from all 107 patients treated as of October 14, 2014 in ARMOR2. In these patients, galeterone was well tolerated. Approximately 90% of all treatment-emergent adverse events reported were grade 1 or 2 in severity and were generally manageable and reversible. The majority of these events were assessed as not related or unlikely related to galeterone. In addition, there were no reported cases of seizure or mineralocorticoid excess. The most common adverse events were nausea, fatigue, pruritus, decreased appetite, diarrhea, hypokalemia and vomiting. Eight of these patients experienced a grade 3 or a grade 4 treatment-emergent increase in aminotransferase indicating elevated liver

enzyme levels. These events were asymptomatic, transient and all eight of these patients recovered following temporary drug withdrawal. Five of the eight patients have been re-challenged at a reduced dose level with none showing a recurrence of a grade 3 or higher adverse event. There were three patients with unexpected serious adverse events in the trial that were assessed by the investigators as possibly related to treatment with galeterone. These treatment-related serious adverse events involved a case of angioedema in a patient who was taking a medication associated with angioedema, an episode of dizziness and fainting in a patient with a history of nausea, diabetes and hypertension who had discontinued treatment with galeterone four days prior to the episode, and a case of hypocalcemia and hyperparathyroidism in a patient with a history of hypocalcemia and hyperparathyroidism. Under the Common Terminology Criteria for Adverse Events established by the National Cancer Institutes, adverse events are reported by grade. Grades 1 or 2 indicate mild to moderate adverse events, grade 3 indicates a severe but not life threatening event with required hospitalization, grade 4 indicates that the event is life threatening and a grade 5 event is death.

Reformulation of Galeterone

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

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

ARMOR1 Trial

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

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

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

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

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

Efficacy. Patients in each of the doses tested experienced reductions in PSA. In the 12 patients who received the highest dose in the study, 2600 mg/day, maximal PSA decreases of at least 30% were observed in 75% of the patients, and maximal PSA decreases of at least 50% were observed in 42% of the patients. Of the 49 patients in the trial, 22% experienced maximal PSA decreases of at least 50%, and 49% experienced maximal PSA decreases of at least 30%. We believe that these results, while favorable, were adversely impacted by the exposure variability associated with the food effect of the PIC formulation. Radiographic evidence of tumor shrinkage and overall tumor stabilization was seen in multiple patients as assessed by CT/MRI scans and bone scans as measured by RECIST. Thirty-nine patients had measurable disease at baseline, including five patients receiving the 2600 mg/day dose. Of the five patients, two had partial responses, and a third patient had a near partial response with a reduction in maximal PSA levels of 28%. Of the 39 patients, 22 had stable disease at the end of the 12-week treatment period.

Phase 1 Trials in Healthy Volunteers in Connection with Galeterone Reformulation

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

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

Pivotal Phase 3 Clinical Trial

We are currently preparing to initiate our pivotal Phase 3 clinical trial of galeterone. Our ARMOR3-SV trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in 148 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant. We have reviewed the trial design with the FDA and EMA.

Under the trial protocol, patients will be randomized on a one-to-one basis to receive either galeterone or the control arm treatment, Xtandi. Patients in the galeterone arm will receive a dose of 2550 mg/day, and patients in the Xtandi arm will receive a dose of 160 mg/day. All patients will continue to receive treatment until they have radiographic evidence of disease progression as determined by a blinded, independent central imaging assessment or patient withdrawal due to adverse events or other reasons. We plan to establish an independent data monitoring committee.

Only patients with the AR-V7 splice variant will be enrolled in the trial. These patients will be identified by analysis of a blood sample at a central laboratory using an AR-V7 specific assay. We have entered into a collaboration with Qiagen N.V., or Qiagen, to develop and commercialize this assay as a companion diagnostic. Delays in developing this assay could delay the initiation of the trial. We expect that we may need to screen more than 1,000 patients to identify and enroll the target number of patients with AR-V7.

The primary endpoint of the trial will be 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 must 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 be considered a clinically relevant outcome. The secondary endpoints will include overall survival, safety and time to next anti-cancer intervention or time to next cytotoxic therapy.

We expect to commence the trial in the first half of 2015 and to have top-line data from the trial by the end of 2016. However, we will not be able to initiate dosing of patients in the trial unless and until Qiagen completes its development of the clinical trial assay to identify CRPC patients with AR-V7. In addition, our anticipated time to top-line data is subject to the rates of patient enrollment and disease progression in the trial. The rate of patient enrollment in the trial, however, is difficult to predict as we have no experience recruiting patients with AR-V7 for a clinical trial, and the percentage of treatment-naïve CRPC patients with AR-V7 is subject to widely varying projections in published literature. Moreover, because we have not previously conducted a clinical trial of galeterone in patients with AR-V7 and clinical trials of Xtandi in AR-V7 have only been conducted in a limited number of patients, our assumption concerning rates of disease progression could be incorrect. As a result, there can be no assurance that we will initiate, have top-line data from or complete the trial when we anticipate.

Prospective Identification of AR-V7

We need to develop an analytically validated assay that sensitively detects AR-V7 in order to proceed with our planned pivotal Phase 3 clinical trial and develop and commercialize a companion diagnostic test for this assay in order to seek approval of, and commercialize, galeterone for patients with these types of truncated androgen receptors. We have entered into a collaboration with Qiagen to develop and commercialize the companion diagnostic. Clinical data obtained with the clinical trial assay in the Phase 3 trial will be used by Qiagen to support regulatory filings for the approval of the companion diagnostic for AR-V7 and by us to support our regulatory filings for approval of galeterone. We have also entered into an exclusive, worldwide license with Johns Hopkins to patent applications and know how covering certain assays to identify androgen receptor variants for use as a companion diagnostic with galeterone. One of these assays was used by Johns Hopkins in its prospectively designed clinical trial, reported in the New England Journal of Medicine, which assessed the impact of AR-V7 expression on patient responsiveness to Zytiga and Xtandi. Qiagen is currently

developing this assay as the companion diagnostic. We have discussed with the FDA our development strategy and plans for identifying AR-V7 patients in our pivotal Phase 3 clinical trial, including our plans to develop the assay as a companion diagnostic test. The FDA has advised us that we will not need to submit an IDE for the assay to the FDA before we screen patients in the trial. However, based on those discussions, we believe that the companion diagnostic test will need to be approved by the FDA through its Premarket Approval, or PMA, process. We anticipate that Qiagen will seek approval for the companion diagnostic test by the FDA in parallel with our seeking approval of galeterone in the United States.

We have consulted with the EMA regarding our development strategy and plans for identifying AR-V7 patients in our ARMOR3-SV trial. Based on these consultations, we believe that in order for us to use the assay in the ARMOR3-SV trial, the assay only needs to be validated for clinical use with an expectation that it will be CE marked in connection with the submission for regulatory approval in the European Union. We have arranged with Qiagen to meet this requirement. At the time we seek regulatory approval in the European Union, we will need to have the assay CE marked.

On March 13, 2015, we entered into a project work plan with Qiagen under a Master Collaboration Agreement, dated January 12, 2015, between us and Qiagen, which, together with the project work plan, we refer to as the Agreement. Pursuant to the Agreement, Qiagen has agreed to develop and commercialize an assay as a companion diagnostic test to identify CRPC patients with the splice variant AR-V7 for use with galeterone, our lead drug candidate. We expect to use the clinical trial assay developed by Qiagen in our planned pivotal Phase 3 clinical trial of galeterone in order to identify CRPC patients with AR-V7.

Under the Agreement, Qiagen is responsible for developing, and obtaining and maintaining regulatory approvals for, the companion diagnostic test in the United States, the European Union, Canada, Australia and such other countries as we and Qiagen may agree. In addition, Qiagen has agreed to use commercially reasonable and diligent efforts to manufacture the companion diagnostic test and to make the companion diagnostic test commercially available in those countries in which we have obtained regulatory approval for, and have valid patent claims covering, galeterone. Qiagen will be responsible for commercializing the companion diagnostic in each such country. If Qiagen elects not to commercialize the companion diagnostic test itself in any such country, for so long as there are valid patent claims covering galeterone in such country, Qiagen has agreed to procure alternative distribution channels or otherwise supply the companion diagnostic test to us in order for us to market galeterone in combination with the companion diagnostic test. Upon our request, we and Qiagen have also agreed to negotiate in good faith to expand the scope of the projects under the Agreement to, among other things, provide for the development and commercialization of the companion diagnostic test for use with galeterone in Japan.

Subject to the terms of the Agreement, we will pay Qiagen an approximate aggregate amount of up to $7.4 million over the term of the development program, including amounts payable to Qiagen for us to have the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test. In addition, we have agreed to reimburse Qiagen for certain direct, out-of-pocket costs incurred by Qiagen, including for sample materials, which costs are estimated to equal in the aggregate up to $1.9 million. These amounts are subject to adjustment if we and Qiagen determine that changes in the scope of the development program are required. Following commercialization, we will have no further payment obligations to Qiagen under the Agreement. However, we will not receive any revenues from future sales, if any, of the companion diagnostic test.

The Agreement expires on the later to occur of (i) the fifth anniversary of regulatory approval of the companion diagnostic test and (ii) the expiration of Qiagen's commercialization obligations under the Agreement. We are permitted to terminate the Agreement for convenience upon 180 days' written notice to Qiagen. Either party may terminate the Agreement upon 60 days' written notice to the other party based on uncured material breaches by the other party and may terminate the Agreement immediately based on the bankruptcy or insolvency of the other party.

Other Development Activities

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

Galeterone Mechanisms of Action

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

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

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

CYP17 Lyase Inhibition

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

We conducted preclinical studies of galeterone and abiraterone to evaluate their relative selectivity with respect to the inhibition of the hydroxylase and lyase functions of CYP17. In these studies, galeterone was shown

to selectively block the lyase function of CYP17 relative to the hydroxylase function. In contrast, abiraterone more selectively blocked the hydroxylase function relative to the lyase function, consistent with its published risk for mineralocorticoid excess.

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

Androgen Receptor Antagonism

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

Androgen Receptor Degradation

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

Preclinical Development

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

Activity in Hormone Treatment-Resistant Prostate Cancer

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

- increased CYP17 enzyme levels;
- increased production of testosterone and DHT;
- increased wild type or mutant androgen receptor levels;
- alterations in the androgen receptor, such as splice variants and point mutations;

- mutations in the androgen receptor that result in activation by steroids, such as prednisone and progesterone; and
- androgen receptor mutations which convert androgen antagonists into agonists thus leading to activation of the receptor.

Activity in Tumors Expressing Splice Variants, including AR-V7

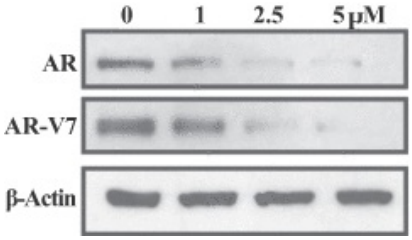
Androgen receptor splice variants are produced in tumor cells due to an aberrant RNA splicing event. As a result, a truncated androgen receptor protein is synthesized that lacks the C-terminal end of the protein, the region of the protein responsible for androgen binding. Tumor cells that express altered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

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

In preclinical studies, we measured androgen receptor degradation using cell lines that expressed full-length and splice variant androgen receptors. These cells model the expression patterns described in human tumor samples where full-length and splice variant androgen receptor proteins are co-expressed. As shown in Figure 5 below, levels of both full-length androgen receptor and AR-V7 were reduced in a dose-dependent fashion following galeterone treatment. In the figures below, we use as a control beta-actin (ß-Actin), a protein commonly used as a control in these types of experiments.

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

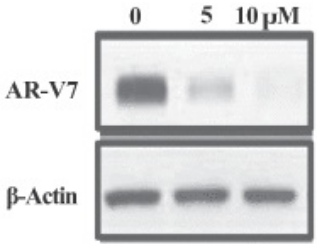
Galeterone Concentration (72 hr exposure)



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

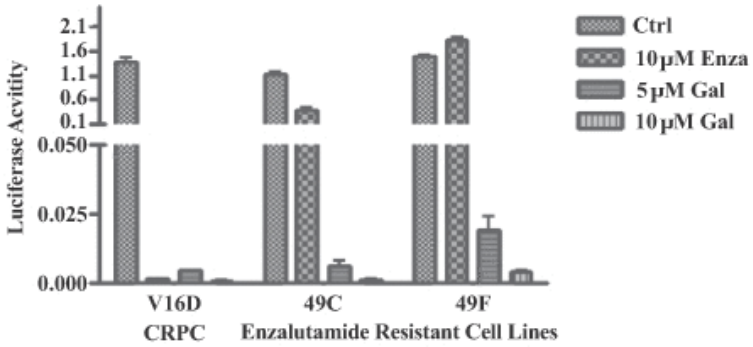
Figure 6: Galeterone Causes Decreased Levels of Androgen Receptor in Cell Line Only Expressing AR-V7

Galeterone Concentration (24 hr exposure)



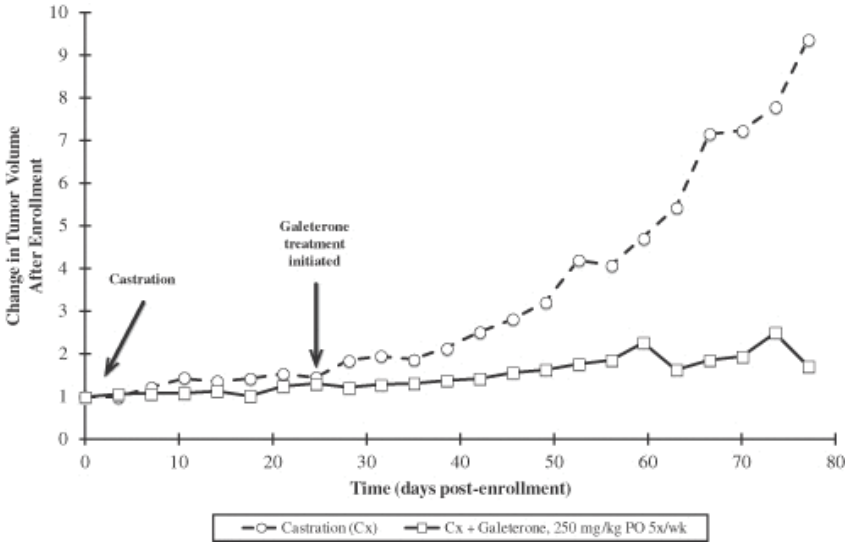
In addition, together with the Vancouver Prostate Centre, we examined whether degradation of androgen receptors translated into reduced androgen receptor signaling and reduced tumor growth in prostate cancer tumor cells which express AR-V7. The Vancouver Prostate Centre conducted a series of studies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

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



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

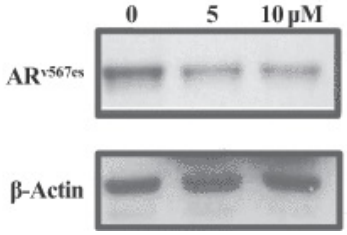
Figure 8: Galeterone Shows Tumor Growth Inhibition in LuCaP136 (AR-V7 Positive) Castration-Resistant Xenograft Model



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

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

Galeterone Concentration (24 hr exposure)



Activity in Androgen Receptor Point Mutations

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

Galeterone in Combination with Other Therapeutic Drugs

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

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

Androgen Receptor Degradation Compounds

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

Manufacturing

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

We have completed the production of formulated drug for use in our planned pivotal Phase 3 clinical trial using manufacturers operating under current Good Manufacturing Practices, or cGMP, to manufacture pivotal clinical trial materials.

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

Commercialization Strategy

We have worldwide development and commercialization rights to galeterone. To maximize the value of these rights, we intend to build a urology- and oncology-focused specialty sales and marketing organization in the United States to support the commercialization of galeterone. We believe that a specialty sales force will be able to target the key prescribing physicians in urology and oncology that treat CRPC. We currently do not have any sales or marketing capabilities or experience. We plan to establish the required capabilities within an

appropriate time frame ahead of any product approval and commercialization to support a product launch. To develop the appropriate internal commercial infrastructure in the United States, we will have to invest financial and management resources, some of which will have to be deployed prior to any confirmation that galeterone will be approved. We intend to commercialize galeterone outside the United States through collaborations with third parties.

Under the terms of our agreement with Qiagen, Qiagen is responsible for the commercialization of the AR-V7 companion diagnostic.

Competition

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

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

We believe that galeterone may be well suited to treat other prostate cancer patient populations. If galeterone is approved for additional indications, it may compete with other secondary hormonal treatments currently being marketed, such as Zytiga and Xtandi, or with secondary hormonal treatment drug candidates currently in development, such as ARN-509, ODM-201, ODM-204 and VT-464. Zytiga is marketed in the United States by Johnson & Johnson, and Xtandi is marketed in the United States by Astellas Pharma Inc. and Medivation, Inc. ARN-509 is being developed by Johnson & Johnson, ODM-201 is being developed by Bayer Healthcare and Orion Corporation, ODM-204 is being developed by Orion Corporation and VT-464 is being developed by Innocrin Pharmaceuticals, Inc. In addition, depending on the indication for which galeterone is approved, galeterone may compete with chemotherapy and other compounds that are not secondary hormonal treatments, including Jevtana and Provenge, and compounds that are in clinical development, such as Bavarian Nordic A/S's Prostvac.

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

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates,

their methods of use, related technology and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

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

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

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

Galeterone Patent Portfolio

As of February 28, 2015, we owned two issued U.S. patents, nine U.S. provisional and non-provisional patent applications, one issued foreign patent and 35 foreign applications in our galeterone patent portfolio. We also had rights under our license agreement with UMB to five issued U.S. patents and 70 issued foreign patents as well as three U.S. patent applications and 8 foreign applications. In addition, we have rights under a license agreement with Johns Hopkins to two U.S. patent applications and two foreign patent applications. Our owned and licensed patent and patent applications, if issued, are expected to expire on various dates from 2017 through 2034, without taking into account any possible patent term extensions.

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

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

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. 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.

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

Prodrugs, Metabolites and Analogs. We have filed patent applications or licensed from UMB patent applications directed to prodrugs, metabolites or analogs of galeterone. For example, we have licensed a U.S. patent application from UMB directed to certain prodrugs of galeterone. If issued, the term of the resulting patent, if issued, would be expected to expire in 2029. We have also filed patent applications in the United States and certain other countries including Australia, Brazil, Canada, China, the European Union, India and Japan directed to other prodrugs of galeterone. If issued, the term of the resulting patents would be expected to expire in 2030. Further, we

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

AR-V7 Specific Assay and Companion Diagnostic Test. We have an exclusive license from 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 and Qiagen may develop and commercialize. However, these patent applications do not provide any protection for galeterone or for galeterone's pharmaceutical formulations or uses.

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

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

License Agreement with University of Maryland, Baltimore

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

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

Under the terms of the license agreement, as amended, we are obligated to use commercially reasonable efforts to develop and commercialize one or more licensed products. We must also achieve specified milestone events by specified dates. 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 and October 2013 amendments. We are obligated to pay UMB an annual maintenance fee of $10,000 each year until the first commercial sale. In addition, we paid UMB a $50,000 milestone payment in 2009 upon the submission of our 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. We must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by our sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. Our royalty obligations are subject to specified reductions in the event that we are required to obtain additional licenses from third parties or in the event of specified competition from third-party products licensed by UMB. Our minimum annual royalty payment to UMB is $50,000 beginning in the year following the year in which the first commercial sale occurs. We must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, as of April 10, 2012, we assumed responsibility for all patent expenses related to the prosecution and maintenance of the licensed patents.

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. If all such milestones were 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, clearance, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products and medical devices. The processes for obtaining regulatory clearances and approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

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

Human Clinical Trials in Support of an NDA

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

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

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or IND so long as the

clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

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

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

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

Section 505(b)(2) NDAs

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

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies, trials or

measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Submission of an NDA to the FDA

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

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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

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

Fast Track, Breakthrough Therapy and Priority Review Designations

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

Specifically, the FDA may give a product fast track designation if the product 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 designated 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.

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

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the

product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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

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

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

The FDA 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 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 liability.

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

Abbreviated New Drug Applications for Generic Drugs

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

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

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

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

Hatch-Waxman Patent Certification and the 30-Month Stay

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

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

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

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

If the ANDA applicant or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA

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

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

Pediatric Studies and Exclusivity

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

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

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

Orphan Designation and Exclusivity

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

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

Patent Term Restoration and Extension

A patent claiming a new drug product or medical device may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a new drug product or medical device is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product or medical device is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs or medical devices for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Companion Diagnostics in the United States

We expect that we will rely upon an *in vitro* diagnostic test for use in selecting patients with AR-V7. In July 2014, the FDA issued final guidance stating that if an *in vitro* diagnostic is essential to the safe and effective use of a therapeutic product, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product. *In vitro* diagnostics marketed in the United States are regulated as medical devices. As a result, unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to the PMA process. Based on our discussions with the FDA, we believe that the companion diagnostic for galeterone will need to be approved through the PMA process.

510(k) Premarket Notification

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

Premarket Approval

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

Investigational Device Exemption

A clinical trial is typically required for a PMA and, in a small percentage of cases, the FDA may require a clinical trial in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical trial involving the device is subject to the FDA's IDE regulation. The IDE regulation distinguishes between significant and nonsignificant risk device trials and the procedures for obtaining approval to begin the trial differ accordingly.

Also, some types of trials are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating or treating disease or in preventing impairment to human health. Trials of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical trial. Nonsignificant risk devices are devices that do not pose a significant risk to the human subjects. A nonsignificant risk device trial requires only IRB approval prior to initiation of a clinical trial.

An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor, prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions or disapproved. The FDA typically grants IDE approval for a specified number of subjects to be enrolled at specified trial centers. The clinical trial must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations. The investigators must obtain subject informed consent, rigorously follow the investigational plan and trial protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. A clinical trial may be suspended or terminated by the FDA, the IRB or the sponsor at any time for various reasons, including a belief that the risks to the trial participants outweigh the benefits of participation in the trial. Approval of an IDE does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Review and Approval of Drug Products in the European Union

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

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

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

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

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

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

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

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

Review and Approval of In Vitro Diagnostics in the European Union

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country.

Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

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

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

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

Employees

As of December 31, 2014, we had 17 full-time employees and 1 part-time employee, 11 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 One Broadway, 14th Floor, Cambridge, Massachusetts 02142, and our telephone number is (617) 225-4305.

Information Available on the Internet

Our Internet website address is *www.tokaipharma.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 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 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.

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net loss was $23.3 million for the year ended December 31, 2014, $15.7 million for the year ended December 31, 2013 and $9.6 million for the year ended December 31, 2012. As of December 31, 2014, we had an accumulated deficit of $86.4 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 expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- conduct our planned pivotal Phase 3 clinical trial of galeterone for metastatic castration resistant prostate cancer, or CRPC, treatment-naïve patients whose prostate tumors express the splice variant AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for galeterone for this indication;
- develop an *in vitro* companion diagnostic test to identify CRPC patients with AR-V7 in collaboration with Qiagen Manchester Limited, or Qiagen;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; 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 for the treatment of CRPC patients with truncated androgen receptors such as AR-V7 and other indications and patient populations, as well as preclinical testing and clinical trials of any of our future product candidates, obtaining marketing and regulatory approval for these product candidates, successfully developing an *in vitro* companion diagnostic test to identify CRPC patients with AR-V7 in collaboration with third parties, partnering with third parties to manufacture our product candidates in commercial quantities, marketing and selling those products for which we may obtain regulatory approval and obtaining reimbursement from third-party payors. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

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

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

As of December 31, 2014, we had cash and cash equivalents of $105.3 million. We expect that our existing cash and cash equivalents will only be sufficient to enable us to complete our ongoing ARMOR2 trial, conduct our planned pivotal Phase 3 clinical trial of galeterone for metastatic CRPC treatment-naïve patients whose prostate tumors express the splice variant AR-V7, fund the development of an *in vitro* companion diagnostic test in collaboration with Qiagen to identify CRPC patients with AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of an NDA to the FDA for galeterone for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements into the first half of 2017. We will need to obtain substantial additional funding in order to submit an NDA to the FDA for galeterone for the treatment of CRPC patients with AR-V7, complete the development of, and commercialize, galeterone for these patients and other indications and patient populations and develop or commercialize any future product candidates. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, terminate or eliminate our product development programs and our commercialization efforts.

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

- the progress and results of our planned pivotal Phase 3 clinical trial of galeterone for the treatment of prostate cancer in metastatic CRPC treatment-naïve patients with AR-V7, and our efforts to complete the clinical development of galeterone and submit an NDA to the FDA for this indication;
- the progress and results of our ongoing ARMOR2 trial and any additional clinical trials of galeterone that we decide to conduct for the treatment of other indications and patient populations in prostate cancer, including for early-stage prostate cancer, and for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- the timing and outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with AR-V7 and other indications and patient populations, and of any other future product candidates;

- the progress and results of the development of an *in vitro* companion diagnostic test for identifying CRPC patients with AR-V7 under our agreement with Qiagen;
- the cost of commercialization activities, including product sales, marketing, manufacturing and distribution, for galeterone and our future product candidates for which we receive regulatory approval;
- the development of future product candidates, including our plans to seek to acquire or in-license additional compounds or technologies;
- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States; and
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

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

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

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

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

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

We currently have no products approved for sale and have only one product candidate, galeterone, in clinical development. We have invested substantially all of our efforts and financial resources in the development

of galeterone for the treatment of CRPC. We plan to initiate our pivotal Phase 3 clinical trial of galeterone in metastatic CRPC treatment-naïve patients with AR-V7 in the first half of 2015. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and commercialization of galeterone for CRPC patients with AR-V7. We also may develop galeterone for other indications or patient populations in prostate cancer or for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway and compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation. The success of galeterone or other product candidates will depend on several factors, including the following:

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

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

If clinical trials of galeterone and our future product candidates, including our ongoing Phase 2 clinical trial and our planned pivotal Phase 3 clinical trial of galeterone, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or are not otherwise successful, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of galeterone and our future product candidates.

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

We plan to initiate our pivotal Phase 3 clinical trial of galeterone in metastatic CRPC treatment-naïve patients with AR-V7 in the first half of 2015 and anticipate having top-line data from the trial by the end of 2016. We have entered into a collaboration with Qiagen to develop and commercialize an AR-V7 specific assay as a companion diagnostic to identify CRPC patients with AR-V7. We will not be able to initiate dosing of patients in the trial unless and until Qiagen completes its development of the clinical trial assay. In addition, our anticipated time to top-line data is subject to the rates of patient enrollment and disease progression in the trial. The rate of patient enrollment in the trial, however, is difficult to predict as we have no experience recruiting patients with AR-V7 for a clinical trial, and the percentage of CRPC patients with AR-V7 is subject to widely varying projections in published literature. Moreover, because we have not previously conducted a clinical trial of galeterone in patients with AR-V7 and clinical trials of Xtandi in AR-V7 have only been conducted in a limited number of patients, our assumption concerning rates of disease progression could be incorrect. As a result, there can be no assurance that we will initiate, have top-line data from or complete the trial when we anticipate.

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

Our ARMOR3-SV trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in 148 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant. The primary endpoint of the trial will be rPFS as determined by a blinded, independent central imaging assessment. We have not conducted any clinical trials of galeterone for patients with AR-V7, comparing galeterone to a comparator drug or using a primary endpoint of rPFS. As a result, the results of the clinical trials that we have conducted may not be predictive of the outcome of our ARMOR3-SV trial.

Moreover, we are unaware of any completed or currently ongoing pivotal trials of treatments for prostate cancer for which the sole primary endpoint to support initial FDA drug approval was rPFS. As a result, we cannot be assured as to how the FDA will interpret any rPFS data that we generate in our ARMOR3-SV trial. In August 2014, we met with the FDA to discuss plans for our ARMOR3-SV trial. At this meeting, the FDA advised us that, in its view, rPFS and the use of rPFS in the metastatic CRPC context is limited by difficulties in bone scan interpretation and the complexity of the criteria used to define progression, each of which creates uncertainty as to the ability of rPFS to predict improvements in morbidity or mortality. The FDA also advised us that if we used rPFS as the sole primary endpoint, this uncertainty would need to be overcome by a statistically persuasive large relative and absolute magnitude of improvement in rPFS as well as internal consistency across secondary endpoints, including a supportive result in overall survival.

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

- be delayed in obtaining marketing approval for galeterone or our future product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;

- be subject to restrictions on how the product is distributed or used; or
- have the product removed from the market after obtaining marketing approval.

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

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

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

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

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will

be completed on schedule, or at all. In addition to additional costs, significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates.

Galeterone could ultimately prove to be ineffective or unsafe.

As of February 28, 2015, we have administered galeterone to over 250 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. We are currently conducting our ARMOR2 trial. As of February 28, 2015, we had enrolled 121 patients in the trial with 19 patients still participating in the trial. However, we have yet to fully explore the safety and efficacy of galeterone. Ultimately, the results of our clinical trials to date, in which galeterone has been well tolerated and showed clinically meaningful reductions in levels of prostate specific antigen, or PSA, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy, may prove to be incorrect. No assessment of the efficacy, safety or side effects of a product candidate can be considered complete until all clinical trials needed to support a submission for marketing approval are complete, and success in early-stage clinical trials does not mean that subsequent trials will confirm the earlier findings, or that experience with use of a product in large-scale commercial distribution will not identify additional safety or efficacy issues. If we find that galeterone is not safe, or if its efficacy cannot be consistently demonstrated, we may not be able to commercialize, or may be required to cease distribution of, the product. Galeterone may also prove to be substantially identical or inferior to drugs already available, in which case the market for galeterone would be reduced or eliminated.

We plan to initiate our pivotal Phase 3 clinical trial of galeterone in metastatic CRPC treatment-naïve patients with AR-V7 in the first half of 2015. We believe that patients' prostate tumor cells may not be responsive to treatment with Zytiga and Xtandi in the presence of C-terminal loss, including AR-V7, but that galeterone, with its mechanism of androgen receptor degradation, may effectively treat these patients. There can be no assurance, however, that our beliefs and assumptions about the effectiveness of galeterone, Zytiga (abiraterone acetate) or Xtandi (enzalutamide) in the treatment of CRPC patients with C-terminal loss or AR-V7 are accurate. Our belief that patients' prostate tumor cells may not be responsive to treatment with Zytiga and Xtandi in the presence of C-terminal loss or AR-V7 is based on our understanding of the mechanisms of action of these products, data from clinical trials conducted by researchers at MD Anderson Cancer Center, or MD Anderson, Johns Hopkins University, or Johns Hopkins, and Memorial Sloan Kettering Cancer Center, or Sloan Kettering, and data from preclinical studies conducted by us and independent laboratories. However, the clinical studies conducted by MD Anderson, Johns Hopkins and Sloan Kettering only involved a limited number of patients with C-terminal loss or AR-V7 and were conducted in different patient populations, using different protocols and using different and unvalidated assays to identify patients with C-terminal loss or AR-V7. The patient populations, protocols and assays used in the MD Anderson, Johns Hopkins and Sloan Kettering studies may also differ from the patient populations, protocols and assays used in our planned pivotal Phase 3 clinical trial. In addition, it is possible that other factors were present that caused, or contributed to, the poor responsiveness of Zytiga and Xtandi in the presence of C-terminal loss and AR-V7 in the clinical studies. The outcome of preclinical testing and clinical studies may not be predictive of the success of later clinical trials and is often susceptible to varying interpretations and analyses. If Zytiga and Xtandi are found to be more responsive to C-terminal loss or AR-V7 than we anticipate, any clinical trial designed to compare galeterone to Zytiga and Xtandi for this patient population would be less likely to succeed.

Our belief that galeterone may be effective in CRPC patients with C-terminal loss, including AR-V7, is based on data from preclinical studies and a retrospective subset analysis that identified seven treatment-naïve CRPC patients in our ARMOR2 trial who had truncated androgen receptors with C-terminal loss pursuant to an unvalidated assay. We believe that these data support our view that galeterone may be effective in patients without an intact ligand binding domain. However, there can be no assurance that these data will be predictive of the success of our planned pivotal Phase 3 clinical trial of galeterone. Our planned pivotal Phase 3 clinical trial will be the first clinical trial to evaluate galeterone in prospectively identified patients with AR-V7 and will have

a design that is different than the design of our ARMOR2 trial, including primary endpoints that, unlike our ARMOR2 trial, are not based on PSA. The failure of our planned pivotal Phase 3 clinical trial of galeterone in this patient population would have a material adverse impact on our ability to obtain approval for galeterone and on our business, financial condition and prospects.

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

We may not be able to continue our ARMOR2 trial or conduct our planned pivotal Phase 3 clinical trial, or any other clinical trials, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

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

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

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

In particular, because we expect that our planned pivotal Phase 3 clinical trial of galeterone will be focused on CRPC patients with AR-V7, which we expect represents a small percentage of CRPC patients, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We expect that we may need to screen more than 1,000 patients to identify and enroll the target AR-V7 positive patients. However, because we have no experience recruiting patients with AR-V7 for a clinical trial and the percentage of CRPC patients with AR-V7 is subject to widely varying projections in published literature, we cannot be assured our projections for enrollment are accurate. Patient enrollment in our planned pivotal Phase 3 clinical trial may also be adversely affected by data that show little or no activity of Xtandi in patients with AR-V7 as patients in the trial will be randomized to the Xtandi arm and the trial will not provide for crossover to galeterone. Patient enrollment delays in our planned pivotal Phase 3 clinical trial or any of our other future clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for our planned pivotal Phase 3 clinical trial would result in significant delays. Any significant delays or increases in costs of our planned pivotal Phase 3 clinical trial could result in the need for us to obtain additional funding to complete the trial.

In addition, patients enrolled in our clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including experiencing adverse clinical events that may or may not be associated with our product candidates under evaluation. We are aware that other late stage trials in CRPC have been adversely affected by discontinuations by patients who prematurely leave the trial in response to an increase in their PSA levels during the trial. The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial or may lead to negative or insufficient results to support a filing for marketing and regulatory approval of the applicable product candidate.

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

If galeterone or our future product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Adverse or unexpected side effects or characteristics of galeterone, whether discovered by us or independently publicized by third parties during clinical trials, could cause an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of galeterone or our future product candidates, require us to conduct additional clinical trials or other tests or studies, and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities.

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

In order to develop and commercialize galeterone for the treatment of CRPC patients with AR-V7, we will need to develop an analytically validated assay that can be used to identify CRPC patients with AR-V7 and develop and commercialize this assay as an in vitro companion diagnostic test. If we or Qiagen are unable to successfully develop this assay or to develop, commercialize and obtain approval for an in vitro companion diagnostic test for this assay, or if there are significant delays in doing so, our planned pivotal Phase 3 clinical trial and the development of galeterone may be delayed, and we may not achieve marketing approval or realize the full commercial potential of galeterone.

We will need to develop an analytically validated assay that sensitively detects AR-V7 in order to proceed with our planned pivotal Phase 3 clinical trial and develop and commercialize a companion diagnostic test for this assay in order to seek approval of, and commercialize, galeterone for patients with these types of truncated androgen receptors. We have entered into a collaboration with Qiagen to develop and commercialize an AR-V7 specific assay as a companion diagnostic test to identify CRPC patients with AR-V7. We have also discussed with the FDA our development strategy and plans for identifying AR-V7 in our pivotal Phase 3 clinical trial, including our plans to develop the assay as an *in vitro* companion diagnostic test. Based on our discussions with the FDA, we will need to develop the assay before we screen patients in the trial.

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

If we or Qiagen are unable to successfully develop and obtain approval of an *in vitro* companion diagnostic test for this assay, or experience delays in doing so:

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

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

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

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

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

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

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

Even if galeterone or our future product candidates demonstrate safety and efficacy in clinical trials, regulatory agencies may not complete their review processes in a timely manner or grant regulatory approval at all. Additional delays may result if a regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates.

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

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

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

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

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

In order to market and sell our products in jurisdictions outside the United States, we or third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain foreign approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be separately approved for

reimbursement before the product can be approved for sale in that country. We intend to enter into arrangements with third parties under which they would market our products outside the United States. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to the Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

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

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

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

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

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

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

- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

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

We believe that galeterone may be well suited to treat other prostate cancer patient populations. If galeterone is approved for additional indications, it may compete with other secondary hormonal treatments currently being marketed, such as Zytiga and Xtandi, or with secondary hormonal treatment drug candidates currently in development, such as ARN-509, ODM-201, ODM-204 and VT-464. Galeterone could compete in

the future with products, including secondary hormonal treatments, some of which are marketed by several of the world's largest and most experienced pharmaceutical companies, who have substantially more financial resources than us and greater flexibility to engage in aggressive price competition to gain revenues and market share. Approved secondary hormonal treatments in the United States for CRPC include Zytiga, marketed by Janssen Biotech, Inc. and Xtandi, marketed by Astellas Pharma US, Inc. and Medivation, Inc. Approved non-hormonal agents for CRPC include Taxotere® (docetaxel) and Jevtana® (cabazitaxel), marketed by sanofi-aventis U.S. LLC; Provenge® (sipuleucel-T), marketed by Dendreon Corporation; and Xofigo® (radium-223), marketed by Bayer HealthCare Pharmaceuticals, Inc. It is uncertain whether we could compete with such products, and our failure to compete or decision to reduce the price of galeterone or other future products we may develop in order to compete could severely impact our business.

In addition, there are numerous prostate cancer products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. A number of these are in late stage development. These include secondary hormonal treatments such as Johnson & Johnson's ARN-509, Orion Corporation's ODM-201 and ODM-204 and Innocrin Pharmaceuticals, Inc.'s VT-464. Other compounds that are not secondary hormonal treatments in clinical development include Bavarian Nordic A/S's Prostvac. If a therapy for prostate cancer were developed that targeted the C-terminal loss or AR-V7 patient populations or altered the standard of care for the treatment of CRPC, such therapy could render galeterone irrelevant.

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

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

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

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

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and

establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we receive marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we receive marketing approval.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

Failure of Qiagen to successfully develop or commercialize an in vitro companion diagnostic test to prospectively identify prostate cancer patients with AR-V7 could harm our ability to commercialize galeterone.

We do not plan to internally develop an *in vitro* companion diagnostic test to prospectively identify prostate cancer patients with AR-V7 and, as a result, we will be dependent on the efforts of Qiagen to successfully develop and commercialize these tests. Qiagen:

- may not perform its obligations as expected or as required under our agreement with Qiagen;
- may encounter production difficulties that could constrain the supply of the *in vitro* companion diagnostic test;

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

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

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

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

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

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

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

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

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

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

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

If galeterone or any other product candidate that we may develop in the future is approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under current good manufacturing 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 manufacturing facilities are damaged or destroyed, or production at one of these facilities is otherwise interrupted, our business and prospects would be negatively affected.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

We are a party to a master license agreement with 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 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.

As of February 28, 2015, we owned two issued U.S. patents, nine U.S. provisional and non-provisional patent applications, one issued foreign patent and 35 foreign applications in our galeterone patent portfolio. We also had rights under our license agreement with UMB to five issued U.S. patents and 70 issued foreign patents as well as three U.S. patent applications and 8 foreign applications. In addition, we have rights under a license agreement with Johns Hopkins to two U.S. patent applications and two foreign patent applications. Our owned and licensed patent and patent applications, if issued, are expected to expire on various dates from 2017 through 2034, without taking into account any possible patent term extensions. Our success will depend, in part, on our ability to obtain and maintain patent protection for galeterone and other product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others.

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

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

We also have an exclusive license from 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 patents applications may provide protection for an AR-V7 specific assay or companion diagnostic test using this assay that we and Qiagen may develop and commercialize. However, these patent applications do not provide any protection for galeterone or for galeterone's pharmaceutical formulations or uses.

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

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 which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

Assuming the other requirements for patentability are met, in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is

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

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

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

- others may be able to make or use compounds that are similar to galeterone but that are not covered by the claims of our patents;
- the galeterone compound may become generic, and no patent protection will be available without regard to formulation or method of use;
- we or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulations;
- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- this may be especially likely for manufacturing processes or formulations;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that our owned or in-licensed issued patents or pending patent applications are not Orange Book eligible;
- it is possible that there are dominating patents to galeterone of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' inventions, as the case may be, or parts of our or their inventions of which we or they are not aware;

- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that the U.S. government may exercise any of its statutory rights to our owned or in-licensed patents or patent applications that was developed with government funding;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal challenges by third parties; or
- we may not develop additional proprietary technologies for which we can obtain patent protection.

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

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

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

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

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

We are aware of two issued U.S. patents having broad claims relating to a composition of matter or its use in regulating cellular differentiation or proliferation. We are also aware of certain third-party pending U.S. patent applications that have broad generic disclosures and disclosure of certain compounds possessing structural similarities to galeterone. Although we believe that it is unlikely that such applications will lead to issued claims that would cover galeterone and its use and still be valid, patent prosecution is inherently unpredictable and an

application could be allowed. Based on our analyses, if any of the above third-party patents or patent applications, if issued, were asserted against us, we do not believe our proposed products or activities would be found to infringe any valid claims of these patents. If we were to challenge the validity of an issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

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

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent or trade secret litigation longer than we could. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

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

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

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

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

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

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

Risks Related to Legal Compliance Matters

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;

- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may

require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

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

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

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

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

Risks Related to Our Common Stock

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 more than 70% of our common stock, based on the number of shares of our common stock outstanding as of March 15, 2015. 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 more than 55% of our common stock in the aggregate, based on the number of shares of our common stock outstanding as of March 15, 2015. As a result, each of these stockholders acting individually, as well as together, may exercise significant control over our management and affairs.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

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

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

Our stock price has been and in the future may be subject to substantial volatility. The stock market in general and the market for biotechnology companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock traded within a range of a high price of $30.00 and a low price of $9.67 per share for the period September 17, 2014, our first day of trading on The NASDAQ Global Market, through March 15, 2015. 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:

- results of clinical trials of galeterone and our future product candidates or those of our competitors;
- the success of competitive products or technologies;
- potential approvals of galeterone or other future product candidates for marketing by the FDA or equivalent foreign regulatory authorities or our failure to obtain such approvals;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize galeterone or other future products candidates;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to galeterone or any of our future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

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

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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 currently lease approximately 4,150 square feet of office space in Cambridge, Massachusetts pursuant to a lease agreement, as amended, that expires on a month-to-month basis.

In February 2015, we entered into a sublease with Boston Private Wealth LLC, a Massachusetts limited liability company, or the sublandlord, for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease, dated October 5, 2010, with the prime landlord, 255 State Street, LLC, a Delaware corporation. The term of the sublease commences on April 1, 2015 and expires on December 31, 2016. However, if the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will immediately terminate and we will have no recourse against the sublandlord for such termination. Under the sublease, we will be obligated to pay approximately $45,300 per month in lease payments through March 30, 2016 and, beginning on April 1, 2016, will be obligated to pay approximately $46,600 per month in lease payments through December 31, 2016.

ITEM 3. ***LEGAL PROCEEDINGS***

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

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, 2014:		
Third Quarter (beginning September 17, 2014)	$30.00	$15.10
Fourth Quarter	$17.87	$ 9.67

Holders of Our Common Stock

As of March 15, 2015, there were approximately 43 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.

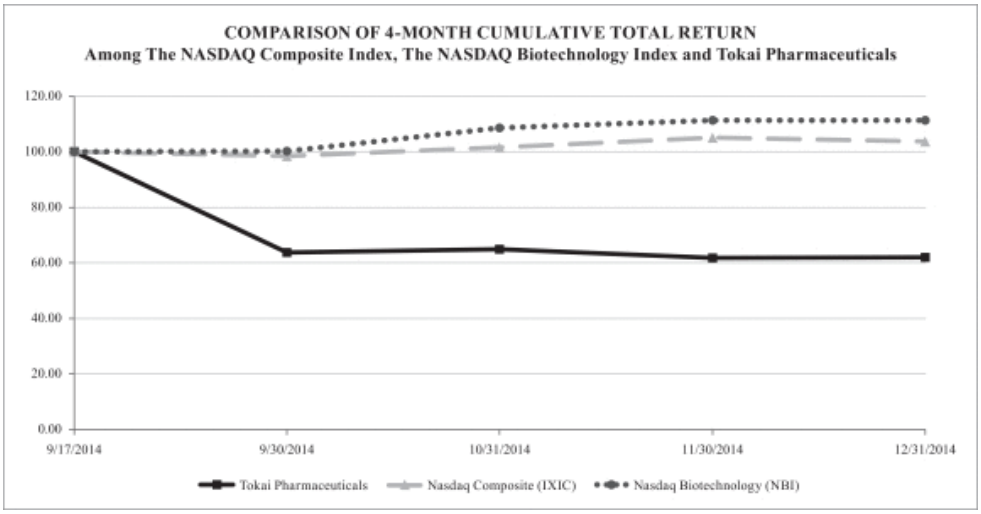
Dividends

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 Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the 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, 2014. 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.



Recent Sales of Unregistered Securities

Set forth below is information regarding shares of common stock issued and options and restricted stock unit awards granted by us during the year ended December 31, 2014 that were not registered under the Securities Act, and that have not otherwise been described in a quarterly report on Form 10-Q or in a current report on Form 8-K. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed. No underwriters were involved in any such issuances.

(a) Common Stock

Between January 1, 2014 and November 20, 2014, we issued an aggregate of 8,277 shares of common stock upon the exercise of options for aggregate consideration of $12,064.

(b) Stock Option and Restricted Stock Unit Grants

Between January 1, 2014 and November 20, 2014, we granted options to purchase an aggregate of 1,010,605 shares of common stock, with exercise prices ranging from $4.19 to $15.00 per share, and 54,604 shares of common stock subject to restricted stock unit awards to employees and directors pursuant to our equity compensation plans. In November 2014, we registered all of the shares of our common stock subject to outstanding options and restricted stock units, as well as options, restricted stock units and other awards issuable pursuant to, our equity compensation plans, pursuant to a registration statement on Form S-8 under the Securities Act.

The common stock described in paragraph (a) and the stock options, restricted stock unit awards and the common stock issuable upon the exercise of such stock options or upon the vesting of such restricted stock unit awards described in paragraph (b), in each case, prior to November 20, 2014, were issued pursuant to written

compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the securities described in paragraphs (a) and (b) are deemed restricted securities for purposes of the Securities Act. All of the certificates representing such securities included appropriate legends setting forth that the securities have not been registered and the applicable restrictions on transfer

Use of Proceeds from Registered Securities

On September 22, 2014, we completed the initial public offering of our common stock and issued and sold 6,480,000 shares of our common stock at a public offering price 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 pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock.

The offer and sale of all of the shares in the offering was 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. BMO Capital Markets Corp., Stifel, Nicolaus & Company, Incorporated and William Blair & Company, L.L.C. acted as joint book-running managers of the offering, and Janney Montgomery Scott LLC acted as co-manager of the offering.

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 affiliates of ours.

As of December 31, 2014, we estimate that we have used approximately $9.3 million of the net proceeds from the 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 money market accounts. There has been no material change in our planned use of the net proceeds from the initial public offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 17, 2014.

ITEM 6. *SELECTED FINANCIAL DATA*

The selected statements of operations data for the years ended December 31, 2014, 2013 and 2012 and the balance sheet data as of December 31, 2014 and 2013 have been derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report on Form 10-K. The balance sheet data as of December 31, 2012 is 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 consolidated 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,		
	2014	2013	2012
	(in thousands, except per share data)		
Consolidated Statement of Operations Data:			
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development (1)	14,577	12,201	7,370
General and administrative (1)	8,885	3,548	2,279
Total operating expenses	23,462	15,749	9,649
Loss from operations	(23,462)	(15,749)	(9,649)
Other income	166	24	—
Net loss and comprehensive loss	(23,296)	(15,725)	(9,649)
Accretion of redeemable convertible preferred stock to redemption value	—	(94)	(34)
Net loss attributable to common stockholders	$(23,296)	$(15,819)	$(9,683)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.60)	$ (38.02)	$(31.09)
Weighted average common shares outstanding, basic and diluted	6,469	416	311

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

	Year Ended December 31,		
	2014	2013	2012
	(in thousands)		
Research and development	$ 552	$ 91	$ 87
General and administrative	1,556	147	123
	$ 2,108	$ 238	$ 210

	As of December 31,		
	2014	2013	2012
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$105,256	$ 31,753	$ 11,691
Working capital	103,268	29,969	9,908
Total assets	107,744	32,287	11,962
Redeemable convertible preferred stock	—	85,345	49,845
Total stockholders' equity (deficit)	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 consolidated 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 clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Our lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies. As of February 28, 2015, we have administered galeterone to over 250 prostate cancer patients and healthy volunteers in Phase 1 and Phase 2 clinical trials. In these trials, galeterone was well tolerated and, in multiple prostate cancer populations, showed clinically meaningful reductions in levels of prostate specific antigen, a biochemical marker used to evaluate prostate cancer patients for signs of response to therapy. We are currently preparing to initiate our pivotal Phase 3 clinical trial of galeterone in the first half of 2015. We refer to this trial as our ARMOR3-Splice Variant, or ARMOR3-SV trial.

We are focusing our initial development of galeterone on the treatment of patients with castration resistant prostate cancer, or CRPC, whose prostate tumor cells express an altered androgen receptor that is truncated. These truncated androgen receptors are missing the end of the receptor that contains the ligand binding domain. We describe patients with these truncated androgen receptors as having C-terminal loss. An example of one such truncated androgen receptor with C-terminal loss is the splice variant AR-V7, which is the most prevalent of the splice variants that cause C-terminal loss. We intend to conduct our planned pivotal Phase 3 clinical trial of galeterone in CRPC patients with AR-V7.

We are currently conducting a Phase 2 clinical trial of galeterone for the treatment of multiple CRPC populations, which we refer to as our ARMOR2 trial. Subject to the availability of resources, we anticipate continuing the clinical development of galeterone in multiple CRPC populations. In June 2012, the U.S. Food and Drug Administration, or FDA, notified us that we had obtained fast track designation for galeterone for the treatment of CRPC. We have exclusive worldwide development and commercialization rights to galeterone.

Since our inception in March 2004, we have devoted substantially all of our resources to developing our product candidates, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Prior to 2007, we focused our efforts on the development of women's health products. In 2007, we changed our focus and began developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases, including our lead drug candidate, galeterone. To date, we have 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 and issued and sold 6,480,000 shares of our common stock at a public offering price 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 pursuant to the underwriters' partial exercise 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 $23.3 million for the year ended December 31, 2014, $15.7 million for the year ended December 31, 2013 and $9.6 million for the year ended December 31, 2012. As of December 31, 2014, we had an accumulated deficit of $86.4 million. These losses have resulted principally from costs incurred in connection with research and development activities, general and administrative costs associated with our operations and in-licensing our product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

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

- conduct our planned pivotal Phase 3 clinical trial of galeterone for metastatic CRPC treatment-naïve patients whose prostate tumors express the splice variant AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of a new drug application, or NDA, to the FDA for galeterone for this indication;
- develop an *in vitro* companion diagnostic test to identify CRPC patients with AR-V7 in collaboration with Qiagen Manchester Limited, or Qiagen;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; and
- operate as a public company.

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

As of December 31, 2014, we had cash and cash equivalents of $105.3 million. We expect that our existing cash and cash equivalents will only be sufficient to enable us to complete our ongoing ARMOR2 trial, conduct our planned pivotal Phase 3 clinical trial of galeterone in metastatic CRPC treatment-naïve patients whose prostate tumors express the splice variant AR-V7, fund the development of an *in vitro* companion diagnostic test in collaboration with Qiagen to identify CRPC patients with AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of an NDA to the FDA for galeterone for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements into the first half of 2017. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for galeterone or other product candidates that we may develop in the future are successful and result in regulatory approval or license or collaboration agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

The majority of our operating expenses 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, are expensed as incurred. Research and development expenses consist primarily of:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- third-party contract costs relating to development of an *in vitro* companion diagnostic test to identify CRPC patients with AR-V7;
- personnel costs, including salaries, related benefits and stock-based compensation for personnel engaged in research and development functions;
- consulting fees paid to third parties;
- costs related to compliance with regulatory requirements; and
- payments made under our third-party licensing agreements.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, payments made under our licensing agreements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses in the tables below. See "Results of Operations—Comparison of Year Ended December 31, 2014 and 2013" and "—Comparison of Year Ended December 31, 2013 and 2012."

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. 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 $14.6 million for the year ended December 31, 2014, $12.2 million for the year ended December 31, 2013 and $7.4 million for the year ended December 31, 2012. We expect that our research and development expenses will continue to increase in 2015 and 2016 as we pursue later stages of clinical development of galeterone and other product candidates that we may develop in the future.

We are currently conducting a Phase 2 clinical trial of galeterone for the treatment of CRPC. We anticipate initiating our planned pivotal Phase 3 clinical trial of galeterone in the first half of 2015. We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

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

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

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

General and Administrative Expenses

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

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

Other Income

Other Income. Other income consists of miscellaneous income unrelated to our core operations. Other income also includes interest income. Interest income consists of interest earned on our cash and cash equivalents. Our interest income has not been significant due to nominal investment balances and low interest earned on those balances. We expect that our interest income will increase in the future due to the investment of cash proceeds received from our initial public offering.

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2014, we had federal and state net operating loss carryforwards of $16.5 million and $13.0 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 $0.8 million and $0.3 million, respectively, as of December 31, 2014, which begin to expire in 2025 and 2023, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of $63.5 million that we have capitalized for income tax purposes as of December 31, 2014.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting

principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, 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 Consolidated 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 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. We expense raw materials used to manufacture our drug substance when received.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel 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 advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

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

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

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 consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The 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,		
	2014	2013	2012
Risk-free interest rate	1.83%	1.72%	0.79%
Expected term (in years)	5.95	5.98	6.07
Expected volatility	79.4%	79.7%	65.5%
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 are electing 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 Year Ended December 31, 2014 and 2013

The following table summarizes our results of operations for the years ended December 31, 2014 and 2013:

	Year Ended December 31,		Increase (Decrease)
	2014	2013	
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	14,577	12,201	2,376
General and administrative	8,885	3,548	5,337
Total operating expenses	23,462	15,749	7,713
Loss from operations	(23,462)	(15,749)	(7,713)
Other income	166	24	142
Net loss	$ (23,296)	$ (15,725)	$ (7,571)

Research and Development Expenses

	Year Ended December 31,		Increase (Decrease)
	2014	2013	
	(in thousands)		
Galeterone for prostate cancer	$ 10,970	$ 10,257	$ 713
Other early-stage development programs and additional indications for galeterone	139	40	99
Unallocated research and development expenses	3,468	1,904	1,564
Total research and development expenses	$ 14,577	$ 12,201	$ 2,376

Research and development expenses for the year ended December 31, 2014 were $14.6 million, compared to $12.2 million for the year ended December 31, 2013. The increase of $2.4 million was primarily due to increased costs of $0.7 million associated with our galeterone for prostate cancer program and an increase in unallocated research and development expenses of $1.6 million. The increase in costs of our galeterone for prostate cancer program consisted primarily of increased costs of clinical trials of $3.0 million and an increase of $0.1 million in costs related to non-clinical studies to support our galeterone for prostate cancer program, partially offset by decreased manufacturing costs of $2.3 million. The increase in clinical trial costs was due to an increased number of patients and sites in our ARMOR2 trial in the year ended December 31, 2014 as compared to the year ended December 31, 2013. The decrease in manufacturing costs was due to higher costs incurred in 2013 to manufacture galeterone for use in our ARMOR2 trial and in anticipation of our planned pivotal Phase 3 clinical trial of galeterone, including a large purchase of raw materials in 2013. Manufacturing costs in 2013 also included costs related to the technology transfer of our manufacturing process to a new vendor. The increase in unallocated research and development costs of $1.6 million for the year ended December 31, 2014 from the year ended December 31, 2013 was due to increased personnel related costs, including stock-based compensation expense, as a result of increased headcount in our research and development function.

General and Administrative Expenses

	Year Ended December 31,		Increase (Decrease)
	2014	2013	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 4,022	$ 1,731	$ 2,291
Professional and consultant fees	3,863	1,392	2,471
Facility related and other	1,000	425	575
Total general and administrative expenses	$ 8,885	$ 3,548	$ 5,337

General and administrative expenses for the year ended December 31, 2014 were $8.9 million, compared to $3.5 million for the year ended December 31, 2013. The increase of $5.4 million was primarily due to an increase in in personnel related costs of $2.3 million, an increase in professional and consultant fees of $2.5 million and an increase in facility related and other costs of $0.6 million. Personnel related costs increased by $2.3 million due primarily to stock-based compensation expense of $2.1 million compared to $0.2 million for the year ended December 31, 2013. The increase of $1.9 million in stock-based compensation expense is related to additional employee stock options and a higher value of our common stock, as well as $0.9 million recorded in the three months ended September 30, 2014 that was related to the vesting of a performance-based option grant upon the closing of our initial public offering in September 2014. Personnel related costs also increased as a result of increased headcount in our general and administrative function and an increase in overall compensation, partially offset by a decrease in personnel related costs due to severance paid to our former Chief Executive Officer in the year ended December 31, 2013. The increase in professional and consultant fees primarily consisted of a $1.1 million fee payable to a financial advisor upon the closing of our initial public offering in connection with strategic and financial advisory services unrelated to the offering and an increase in accounting, public relations and patent fees associated with ongoing business activities and our preparations to operate as a public company as well as consulting fees for an external market research study that was conducted in 2014. Facility related and other expenses increased primarily due to increased insurance costs of $0.2 million related to our being a public company, increased facility costs of $0.2 million to accommodate our additional employees and increased other taxes of $0.1 million.

Other Income

For the year ended December 31, 2014, other income consists primarily of collections of a loan receivable of $0.2 million from a former advisor, which had been fully reserved for in prior years.

Comparison of Year Ended December 31, 2013 and 2012

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

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

Research and Development Expenses

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

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

General and Administrative Expenses

	Year Ended December 31, 2013	Year Ended December 31, 2012	Increase (Decrease)
		(in thousands)	
Personnel related (including stock-based compensation)	$ 1,731	$ 1,207	$ 524
Professional and consultant fees	1,392	805	587
Facility related and other	425	267	158
Total general and administrative expenses	$ 3,548	$ 2,279	$ 1,269

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

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 our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

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 and issued and sold 6,480,000 shares of our common stock at a public offering price 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 pursuant to the underwriters' partial exercise 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. From our inception through September 30, 2014, we have received aggregate net proceeds of approximately $91.6 million from the sale of our redeemable convertible preferred stock and convertible promissory notes.

Cash Flows

As of December 31, 2014, we had cash and cash equivalents of $105.3 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,		
	2014	2013	2012
		(in thousands)	
Cash used in operating activities	$(21,121)	$(15,476)	$ (9,333)
Cash used in investing activities	(175)	(53)	(8)
Cash provided by financing activities	94,799	35,591	18,779
Net increase in cash and cash equivalents	$ 73,503	$ 20,062	$ 9,438

Operating activities. 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.

During the year ended December 31, 2013, cash used in operating activities was $15.5 million, resulting from our net loss of $15.7 million, partially offset by non-cash charges of $0.2 million. Our net non-cash charges during the year ended December 31, 2013 consisted primarily of stock-based compensation expense of $0.2 million.

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

Our net losses for 2014, 2013 and 2012 were primarily attributable to research and development activities related to galeterone and our general and administrative expenses, as we had no revenue in the periods. 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. We used a small amount of cash during the years ended December 31, 2014, 2013 and 2012 related to purchases of property and equipment and, in 2014 and 2013, to increase our restricted cash balance related to our corporate credit cards.

Financing activities. During the year ended December 31, 2014, net cash provided by financing activities was $94.8 million, primarily as a result of 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.

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

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

Funding Requirements

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

- conduct our planned pivotal Phase 3 clinical trial of galeterone for metastatic CRPC treatment-naïve patients whose prostate tumors express the splice variant AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of a new drug application, or NDA, to the FDA for galeterone for this indication;
- develop an *in vitro* companion diagnostic test to identify CRPC patients with AR-V7 in collaboration with Qiagen;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer, including early-stage prostate cancer, and the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- explore the use of galeterone for the treatment of other hormonally-driven diseases that are associated with the androgen receptor signaling pathway;
- identify and develop compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- enter into agreements with third parties to manufacture galeterone;
- establish a sales, marketing and distribution infrastructure to support the commercialization of galeterone in the United States;
- maintain, expand and protect our intellectual property portfolio;
- continue our other research and development efforts;
- acquire or in-license additional compounds or technologies; and
- operate as a public company.

As of December 31, 2014, we had cash and cash equivalents of $105.3 million. We expect that our existing cash and cash equivalents will be sufficient to enable us to complete our ongoing ARMOR2 trial, conduct our planned pivotal Phase 3 clinical trial of galeterone for metastatic CRPC treatment-naïve patients whose prostate tumors express the splice variant AR-V7, fund the development of an *in vitro* companion diagnostic test in collaboration with Qiagen to identify CRPC patients with AR-V7 and conduct other clinical trials and non-clinical studies to support the submission of an NDA to the FDA for galeterone for this indication, as well as to continue to fund our operating expenses and capital expenditure requirements into the first half of 2017. We have based this estimate on assumptions that may prove to be wrong, as we may use our available capital resources sooner than we currently expect or our clinical trials may take longer than we anticipate. Because of the numerous risks and uncertainties associated with the development of galeterone and because the extent to which we may enter into collaborations with third parties for development of this product candidate is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidate. Our future capital requirements for galeterone will depend on many factors, including:

- the progress and results of our planned pivotal Phase 3 clinical trial of galeterone for the treatment of prostate cancer in metastatic CRPC treatment-naïve patients with AR-V7, and our efforts to complete the clinical development of galeterone and submit an NDA to the FDA for this indication;

- the progress and results of our ongoing ARMOR2 trial and any additional clinical trials of galeterone that we decide to conduct for the treatment of other indications and patient populations in prostate cancer, including for early-stage prostate cancer, and for the treatment of prostate cancer in combination with currently marketed prostate cancer therapies and novel targeted agents;
- the timing and outcome of regulatory review of galeterone for the treatment of prostate cancer in CRPC patients with AR-V7 and other indications and patient populations, and of any other future product candidates;
- the progress and results of the development of an in vitro companion diagnostic test for identifying CRPC patients with AR-V7 under our agreement with Qiagen;
- 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, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute 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 or research programs of galeterone or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market galeterone that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2014:

	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)	$ 58	$ 58	$ —	$ —	$ —
Total(2) (3)	$ 58	$ 58	$ —	$ —	$ —

(1) We lease office space and obtain office support services in Cambridge, Massachusetts under a 30-day cancelable operating service agreement. In March 2015, we provided the landlord our notice to terminate this

agreement in April 2015. In February 2015, we entered into a sublease with a Massachusetts limited liability company, or the sublandlord, for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease with the prime landlord, a Delaware corporation. The term of the sublease commences on April 1, 2015 and expires on December 31, 2016. However, if the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will immediately terminate and we will have no recourse against the sublandlord for such termination. Future minimum lease payments under the sublease will be $0.4 million and $0.6 million for the years ending December 31, 2015 and 2016, respectively, aggregating $1.0 million in total minimum lease payments.

(2) We are party to a license agreement with University of Maryland, Baltimore, or UMB. We are obligated to pay UMB an annual maintenance fee of $10,000 each year until the first commercial sale. We are obligated to make milestone payments of $50,000 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. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain milestones. Because the achievement of these milestones has not occurred as of December 31, 2014, no liabilities for such contingencies have been recorded in our consolidated financial statements. We must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by our sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. Our royalty obligations are subject to specified reductions in the event that we are required to obtain additional licenses from third parties or in the event of specified competition from third-party products licensed by UMB. Our minimum annual royalty payment to UMB is $50,000 beginning in the year following the year in which the first commercial sale occurs. We must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, as of April 10, 2012, we assumed responsibility for all patent expenses related to the prosecution and maintenance of the licensed patents. As of December 31, 2014, we have not yet developed a commercial product using the licensed technologies and we have not entered into any sublicense agreements for the technologies. We have not included any of these amounts in the table as we cannot estimate or predict when, or if, these amounts will become due.

In January 2015, we entered into a license agreement with The Johns Hopkins University, or Johns Hopkins. We may terminate the agreement at any time upon 90 days' notice. 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. If all such milestones were 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.

In March 2015, we entered into a project work plan with Qiagen under a Master Collaboration Agreement, dated January 12, 2015, between us and Qiagen, which, together with the project work plan, we refer to as the Agreement, pursuant to which Qiagen will develop and commercialize an assay as a companion diagnostic test to identify CRPC patients with the splice variant AR-V7 for use with galeterone, our lead drug candidate. Subject to the terms of the Agreement, we will pay Qiagen fees to develop the assay, a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test and a contingent milestone payment of $1.0 million upon Qiagen obtaining pre-market approval of the assay, and will reimburse Qiagen for certain direct out-of-pocket costs incurred by Qiagen, including for sample material. These amounts are subject to adjustment if we and Qiagen determine that changes in the scope of the development program are required. Following commercialization, we will have no further payment obligations to Qiagen

under the Agreement. However, we will not receive any revenues from future sales, if any, of the companion diagnostic test.

(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

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update 2014-15, "*Presentation of Financial Statements — Going Concern* (*Subtopic 205-40).*" The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are evaluating the effect that this guidance will have on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of December 31, 2014 consisted of cash and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

Tokai Pharmaceuticals, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of 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. and its subsidiary at December 31, 2014 and December 31, 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company 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 26, 2015

Tokai Pharmaceuticals, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	As of December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$105,256	$ 31,753
Prepaid expenses and other current assets	2,255	425
Total current assets	107,511	32,178
Property and equipment, net	33	29
Deferred offering costs	—	30
Restricted cash	200	50
Total assets	$107,744	$ 32,287
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 765	$ 5
Accrued expenses	3,478	2,204
Total current liabilities	4,243	2,209
Total liabilities	4,243	2,209
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock (Series A, B-1, B-2, C, D-1, D-2, D-3 and E), $0.001 par value; no shares and 155,586,141 shares authorized at December 31, 2014 and 2013, respectively; no shares and 155,586,141 shares issued and outstanding at December 31, 2014 and 2013, respectively	—	85,345
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 5,000,000 and no shares authorized at December 31, 2014 and 2013, respectively; no shares issued or outstanding at December 31, 2014 and 2013, respectively	—	—
Common stock, $0.001 par value; 200,000,000 and 173,018,331 shares authorized at December 31, 2014 and 2013, respectively, and 22,382,340 and 493,292 shares issued and outstanding at December 31, 2014 and 2013, respectively	22	—
Additional paid-in capital	189,830	7,788
Accumulated deficit	(86,351)	(63,055)
Total stockholders' equity (deficit)	103,501	(55,267)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$107,744	$ 32,287

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

Tokai Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	14,577	12,201	7,370
General and administrative	8,885	3,548	2,279
Total operating expenses	23,462	15,749	9,649
Loss from operations	(23,462)	(15,749)	(9,649)
Other income	166	24	—
Net loss and comprehensive loss	(23,296)	(15,725)	(9,649)
Accretion of redeemable convertible preferred stock to redemption value	—	(94)	(34)
Net loss attributable to common stockholders	$ (23,296)	$ (15,819)	$ (9,683)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.60)	$ (38.02)	$ (31.09)
Weighted average common shares outstanding, basic and diluted	6,469,289	416,037	311,474

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

Tokai Pharmaceuticals, Inc.

Consolidated 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 Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2011	63,997,708	$ 30,895	306,817	$ —	$ 7,249	$ (37,681)	$ (30,432)
Issuance of Series D-3 redeemable convertible preferred stock, net of issuance costs of $34	34,696,042	18,916	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	2,843	—	4	—	4
Issuance of common stock	—	—	154,973	—	—	—	—
Stock-based compensation expense	—	—	—	—	210	—	210
Accretion of Series D-3 redeemable convertible preferred stock to redemption value	—	34	—	—	(34)	—	(34)
Net loss	—	—	—	—	—	(9,649)	(9,649)
Balances at December 31, 2012	98,693,750	49,845	464,633	—	7,429	(47,330)	(39,901)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of $94	56,892,391	35,406	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	157,804	—	215	—	215
Repurchase and forfeiture of unvested restricted stock	—	—	(129,145)	—	—	—	—
Stock-based compensation expense	—	—	—	—	238	—	238
Accretion of Series E redeemable convertible preferred stock to redemption value	—	94	—	—	(94)	—	(94)
Net loss	—	—	—	—	—	(15,725)	(15,725)
Balances at December 31, 2013	155,586,141	85,345	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

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

Tokai Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$ (23,296)	$(15,725)	$ (9,649)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,108	238	210
Depreciation expense	21	10	9
Release of reserve for loan to former advisor	(158)	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,830)	(190)	139
Accounts payable	760	(759)	(119)
Accrued expenses	1,274	950	77
Net cash used in operating activities	(21,121)	(15,476)	(9,333)
Cash flows from investing activities:			
Purchases of property and equipment	(25)	(23)	(8)
Change in restricted cash	(150)	(30)	—
Net cash used in investing activities	(175)	(53)	(8)
Cash flows from financing activities:			
Proceeds from initial public offering, net of underwriting discounts and commissions	97,929	—	—
Payments of initial public offering costs	(3,304)	(30)	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	35,406	18,775
Repayment of notes receivable	158	—	—
Proceeds from exercise of common stock options	16	215	4
Net cash provided by financing activities	94,799	35,591	18,779
Net increase in cash and cash equivalents	73,503	20,062	9,438
Cash and cash equivalents at beginning of period	31,753	11,691	2,253
Cash and cash equivalents at end of period	$105,256	$ 31,753	$11,691
Supplemental disclosure of non-cash investing and financing activities:			
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 94	$ 34
Conversion of redeemable convertible preferred stock to common stock	$ (85,345)	$ —	$ —
Conversion of convertible promissory notes and accrued interest and advance from stockholder to shares of redeemable convertible preferred stock	$ —	$ —	$ 141

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

Tokai Pharmaceuticals, Inc.

Notes to Consolidated 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 clinical-stage biopharmaceutical company focused on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company's lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate. Since its inception, the Company has devoted substantially all of its efforts to research and development, recruiting management, in-licensing technology and raising capital.

The Company was previously classified as a "development stage entity" in the Accounting Standards Codification and, as such, was required to present inception-to-date information in the Company's statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows. In June 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standards update that eliminated the concept of a development stage entity from U.S. generally accepted accounting principles and removed the related incremental reporting requirements. See Note 2 below for additional information on this new standard. The Company elected to early adopt the new standard in 2014. Accordingly, in contrast to the Company's financial statements and the notes thereto for the year ended December 31, 2013 included in Company's Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission ("SEC"), the financial statements contained in this report do not include inception-to-date information.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Galeterone, which is currently under development, and any product candidates that the Company may seek to develop in the future will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance-reporting capabilities.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying consolidated financial statements and footnotes include Diotima Pharmaceuticals, Inc. ("Diotima"), a variable interest entity in which the Company had a variable financial interest and was the primary beneficiary but had no ownership interest. In 2010, the Company formed and incorporated Diotima. Diotima operated as a stand-alone company with limited activity through April 2014. In early 2014, the license agreements relating to the Diotima compounds were terminated. Additionally, in April 2014, the board of directors and stockholders of Diotima approved the dissolution of Diotima, and Diotima was dissolved. All significant intercompany balances and transactions between the Company and Diotima have been eliminated in consolidation. See Note 7 for additional information on Diotima.

On September 22, 2014, the Company completed an initial public offering ("IPO") of its common stock, and issued and sold 6,480,000 shares of common stock at a public offering price 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 IPO price of $15.00 per share, pursuant to the underwriters' partial exercise 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 (Note 6).

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has incurred losses and negative cash flows from operations since inception. As of December 31, 2014, the Company had an accumulated deficit of $86,351. The Company believes its cash and cash equivalents balance of $105,256 as of December 31, 2014 will be sufficient to fund its anticipated level of operations for at least the next 12 months. The Company's ability to generate product revenue and operating cash flow will depend heavily on the successful development and eventual commercialization of galeterone and other product candidates that it may develop in the future. If the Company is unable to generate positive cash flows from operations, it may have to seek other sources of capital.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Concentration of Credit Risk and of Significant Suppliers

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

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

Fair Value Measurements

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

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents of $91,316 and $1,311 as of December 31, 2014 and 2013, respectively, were carried at fair value based on Level 2 inputs. The carrying values of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as other assets until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering or as a reduction to the carrying value of preferred stock issued. As of December 31, 2013, the Company had recorded $30 of deferred offering costs, included in other assets in the accompanying consolidated balance sheet in contemplation of the Company's IPO, which closed in September 2014. The Company has no deferred offering costs as of December 31, 2014.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over a three-year estimated useful life for computer equipment, which is the only type of property and equipment the Company holds. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

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 consolidated 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 consolidated 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;
- 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. To date, 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 consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

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

Income Taxes

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

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

Segment Data

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

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2014, 2013 and 2012, there was no difference between net loss and comprehensive loss.

Net Income (Loss) Per Share

In September 2014, upon the closing of the IPO, all of the outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 14,860,173 shares of the Company's common stock. Prior to this conversion, the Company followed the two-class method when computing net income (loss) per share as the Company had issued shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends, but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, the two-class method did not apply for periods in which the Company reported a net loss or a net loss attributable to common stockholders resulting from dividends or accretion related to its redeemable convertible preferred stock.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares, 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 attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, 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, 2014, 2013 and 2012 were excluded from the computation of diluted net loss per share for the years ended December 31, 2014, 2013 and 2012, because they had an anti-dilutive impact:

	December 31,		
	2014	2013	2012
Stock options to purchase common stock	2,146,927	1,124,116	807,657
Restricted common stock units	54,604	—	139,557
Redeemable convertible preferred stock (as converted to common stock)	—	14,860,173	9,426,337
Total options, restricted stock units and redeemable convertible preferred stock exercisable or convertible into common stock	2,201,531	15,984,289	10,373,551

Recently Issued and Adopted Accounting Pronouncements

In June 2014, the FASB issued Accounting Standards Update 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this guidance remove all incremental financial reporting requirements for development stage entities. Among other changes, this guidance will no longer require development stage entities to present inception-to-date information about income statement line items, cash flows, and equity transactions. This guidance is effective for public companies in the first annual period beginning after December 15, 2014 with early adoption permitted. The Company elected to apply this disclosure guidance to its financial statements for the year ended December 31, 2014 and as a result, no longer

discloses inception-to-date information in its statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows and the related notes thereto.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements — Going Concern* (*Subtopic 205-40)*. The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that this guidance will have on its consolidated financial statements.

3. Property and Equipment, net

	December 31,	
	2014	2013
Computer equipment	$ 91	$ 72
	91	72
Less: Accumulated depreciation	(58)	(43)
	$ 33	$ 29

Depreciation expense was $21, $10 and $9 for the years ended December 31, 2014, 2013 and 2012, respectively.

4. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2014 and 2013:

	December 31,	
	2014	2013
Accrued research and development expenses	$1,853	$1,370
Accrued payroll and related expenses	963	436
Accrued professional fees	497	338
Accrued other	165	60
	$3,478	$2,204

5. Redeemable Convertible Preferred Stock

During 2012, the Company issued 34,696,042 shares of Series D-3 redeemable convertible preferred stock to certain existing investors at $0.54617142 per share for gross proceeds of $18,950. The Company incurred issuance costs of $34 in connection with the sale and issuance of these shares of Series D-3 redeemable convertible preferred stock.

In May and October 2013, the Company issued an aggregate of 56,892,391 shares of Series E redeemable convertible preferred stock to existing and new investors at $0.62398475 per share for gross proceeds of $35,500.

The Company incurred issuance costs of $94 in connection with the sale and issuance of these shares of Series E redeemable convertible preferred stock.

Redeemable Preferred Stock consisted of the following as of December 31, 2013:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	4,500,000	4,500,000	$ 2,961	$ 2,961	429,799
Series B-1 redeemable convertible preferred stock	798,067	798,067	525	525	76,224
Series B-2 redeemable convertible preferred stock	1,503,819	1,503,819	989	989	143,631
Series C redeemable convertible preferred stock	15,999,998	15,999,998	3,330	3,920	1,528,176
Series D-1 redeemable convertible preferred stock	29,294,828	29,294,828	14,773	16,000	2,797,978
Series D-2 redeemable convertible preferred stock	3,661,846	3,661,846	2,000	2,000	349,747
Series D-3 redeemable convertible preferred stock	42,935,192	42,935,192	23,450	23,450	4,100,782
Series E redeemable convertible preferred stock	56,892,391	56,892,391	35,500	35,500	5,433,836
	155,586,141	155,586,141	$ 83,528	$85,345	14,860,173

Upon the closing of the Company's IPO in September 2014 (Note 6), all outstanding shares of the Company's redeemable convertible preferred stock were converted into 14,860,173 shares of common stock.

Prior to the conversion, the rights and preferences of the Company's outstanding redeemable convertible preferred stock were as follows:

Voting Rights

The holders of Redeemable Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of all Redeemable Preferred Stock, with the exception of holders of Series C redeemable convertible preferred stock, had the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Preferred Stock could convert on the record date for determination of stockholders entitled to vote. Holders of Series C redeemable convertible preferred stock were entitled to cast 0.45773175 of a vote for each share of common stock into which one share of Series C redeemable convertible preferred stock was convertible.

Dividends

The holders of all Redeemable Preferred Stock were entitled to receive dividends as specified in the Company's certificate of incorporation, as amended and restated. Dividends were non-cumulative, and holders of Redeemable Preferred Stock holders were not entitled to any accruing dividends.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company (each, a "Liquidation Event"), the redeemable convertible preferred stockholders were entitled to be paid out of the assets

of the Company in the order and preference as specified in the Company's certificate of incorporation, as amended and restated.

Conversion

Each share of Redeemable Preferred Stock was convertible at the option of the stockholder at any time without the payment of additional consideration, and automatically converted into shares of common stock upon the closing of the Company's IPO in September 2014 on a 10.47-for-1 basis.

Redemption Rights

At any time on or after May 10, 2018, shares of each of the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock were subject to mandatory redemption by the Company in three equal annual installments beginning 60 days after receipt of a notice of redemption from the holders of at least 60% of the combined voting power of the holders of the outstanding Series A, Series B-1 and Series B-2 redeemable convertible preferred stock, voting as a single class. As of December 31, 2013 the redemption price for the Series A, Series B-1 and Series B-2 redeemable convertible preferred stock was equal to $0.6581 per share, subject to appropriate adjustment for any stock splits, stock dividends, combinations or any other similar recapitalization affecting such shares, plus any dividends declared but unpaid thereon.

At any time on or after May 10, 2018, shares of the Series C, Series D-1, Series D-2, Series D-3 and Series E convertible preferred stock were subject to mandatory redemption by the Company in three equal annual installments beginning 60 days after receipt of a notice of redemption from the holders of at least 75% of the combined voting power of holders of the outstanding Senior Preferred Stock. As of December 31, 2013, the redemption price for the Series C, Series D-1, Series D-2, Series D-3 and Series E convertible preferred stock was equal to $0.2081, $0.5043, $0.54617142, $0.54617142 and $0.62398475 per share, respectively, subject to appropriate adjustment for any stock splits, stock dividends, combinations or any other similar recapitalization affecting such shares, plus any dividends declared but unpaid thereon.

6. 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 consolidated 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 and issued and sold 6,480,000 shares of common stock at a public offering price 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 IPO price of $15.00 per share, pursuant to the underwriters' partial exercise 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.

7. Diotima

The Company had a variable interest entity, Diotima, in which the Company had a variable financial interest and was the primary beneficiary but had no ownership interest. Accordingly, the Company consolidated Diotima. Expenses incurred by Diotima for the years ended December 31, 2014, 2013 and 2012 were $8, $60 and $85, respectively. In 2014, the Diotima's license agreements were terminated. In April 2014, the board of directors and stockholders of Diotima approved the dissolution of Diotima, and Diotima was dissolved.

8. Stock-Based Awards

2007 Stock Incentive Plan

Under the Company's 2007 Stock Incentive Plan, as amended (the "2007 Plan"), the Company was authorized to grant options, restricted stock, restricted stock units and other stock-based awards to the Company's employees, officers, directors, consultants and advisors. As of December 31, 2013, a total of 1,590,580 shares of common stock were reserved for issuance under the 2007 Plan. The Company's 2014 Stock Incentive Plan (the "2014 Plan") became effective upon effectiveness of the registration statement for the IPO in September 2014. Upon the effectiveness of the 2014 Plan, 43,923 shares of common stock that remained available for grant under the 2007 Plan became available for grant under the 2014 Plan, and no further awards were available to be issued under the 2007 Plan.

2014 Stock Incentive Plan

In August 2014, the Company's board of directors and stockholders approved the 2014 Plan, which became effective on September 16, 2014. Under the 2014 Plan, the Company may grant 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 reserved for issuance under the 2014 Plan is equal to the sum of (1) 1,700,000 shares of common stock, plus (2) the number of shares (up to 1,678,220 shares) equal to the sum of (i) 43,923 shares of common stock, which is the number of shares reserved for issuance under the 2007 Plan that remained available for grant under the 2007 Plan immediately prior to the effectiveness of the 2014 Plan, and (ii) the number of shares of common stock subject to outstanding awards under the 2007 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right, plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2015 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2024, equal to the least of 1,800,000 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year and an amount determined by the Company's board of directors. As of December 31, 2014, 1,176,086 shares remained available for issuance under the 2014 Plan. The number of authorized shares reserved for issuance under the 2014 Plan was increased by 895,305 shares effective as of January 1, 2015.

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, 2014, 2013 and 2012, the Company granted 1,039,155, 786,537 and 99,130 stock options, 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

In August 2014, the Company's board of directors and stockholders approved the 2014 Employee Stock Purchase Plan (the "ESPP"), which became effective on September 16, 2014. An aggregate of 225,000 shares of the Company's common stock are reserved for issuance under the ESPP. 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, commencing on January 1, 2015 and ending on December 31, 2024, in an amount equal to the least 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 and the number of shares reserved for issuance under the ESPP was not increased for the fiscal year beginning January 1, 2015.

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,		
	2014	2013	2012
Risk-free interest rate	1.83%	1.72%	0.79%
Expected term (in years)	5.95	5.98	6.07
Expected volatility	79.4%	79.7%	65.5%
Expected dividend yield	0%	0%	0%

The following table summarizes the Company's stock option activity from January 1, 2014 through December 31, 2014:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2013	1,124,116	$ 1.59	8.8	$ 2,346
Granted	1,039,155	9.77		
Exercised	(8,875)	1.64		
Forfeited	(7,469)	2.21		
Outstanding as of December 31, 2014	2,146,927	$ 5.54	8.6	$ 19,802
Options vested and expected to vest as of December 31, 2014	2,117,081	$ 5.48	8.6	$ 19,653
Options exercisable as of December 31, 2014	922,838	$ 2.08	7.8	$ 11,682

The aggregate intrinsic value was calculated based on the positive differences between the market value of the Company's common stock on December 31, 2014 and 2013, of $14.74 and $3.67 per share, respectively, and the exercise prices of the options.

The weighted average grant date fair value of stock options granted was $6.70, $1.17 and $0.84 per share for the years ended December 31, 2014, 2013 and 2012, respectively.

The total intrinsic value of stock options exercised was $35, $33 and $1 for the years ended December 31, 2014, 2013 and 2012, 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 activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2013	—	$ —
Issued	54,604	15.00
Vested	—	—
Forfeited	—	—
Unvested restricted common stock as of December 31, 2014	54,604	$ 15.00

During 2014, the Company granted 54,604 restricted stock units with time-based vesting conditions which lapse over 4 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 have 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. As of December 31, 2014, the Company estimates that all shares of restricted stock units with an intrinsic value of $478 and a weighted average remaining contractual term of 3.67 years will ultimately vest. The Company did not grant restricted stock units in 2013 or 2012.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its statements of operations:

	Year Ended December 31,		
	2014	2013	2012
Research and development	$ 552	$ 91	$ 87
General and administrative	1,556	147	123
	$2,108	$238	$210

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, 2014, the Company had an aggregate of $7,044 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.41 years.

9. Commitments and Contingencies

Leases

The Company leases its office space and obtains certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. Payments under this service agreement include monthly rent and certain fee-for-service charges.

During the years ended December 31, 2014, 2013 and 2012, the Company recognized $520, $366 and $341, respectively, of rental expense related to office space.

In February 2015, the Company entered into a sublease with a Massachusetts limited liability company (the "sublandlord") for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease, dated October 5, 2010, with the prime landlord. The term of the sublease commences on April 1, 2015 and expires on December 31, 2016. However, if the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will immediately terminate and the Company will have no recourse against the sublandlord for such termination. Future minimum lease payments under this lease will be $408 and $555 for the years ending December 31, 2015 and 2016, respectively, aggregating $963 in total minimum lease payments. The Company will record exit costs of $133 in the first quarter of 2015 in connection with terminating its existing lease.

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 the option and acquired exclusive rights to licensed improvements under three 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 an additional $50 milestone payment to UMB for each additional IND filed for a licensed product and a $100 milestone payment upon the approval of each NDA for a licensed product by the U.S. Food and Drug Administration. Because the achievement of these milestones has not occurred as of December 31, 2014, no liabilities for such milestone payments have been recorded in the Company's consolidated financial statements.

The Company must also pay UMB low-single digit percentage royalties on aggregate worldwide net sales of licensed products, including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. The royalty obligations are subject to specified reductions in the event that additional licenses need to be obtained from third parties or in the event of specified competition from third-party products licensed by UMB. Minimum annual royalty payments to UMB are $50 beginning in the year following the year in which the first commercial sale occurs. The Company must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents. As of December 31, 2014, the Company has not yet developed a commercial product using the licensed technologies, and it has not entered into any sublicense agreements for the technologies. In connection

with this license agreement, the Company incurred license, milestone and maintenance fees of $10, $20 and $60 for the years ended December 31, 2014, 2013 and 2012, respectively.

In January 2015, the Company entered into an exclusive license agreement with The Johns Hopkins University ("Johns Hopkins"). Pursuant to the license agreement, Johns Hopkins granted the Company 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 the Company 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, the Company is obligated to diligently develop, manufacture and sell licensed products. The Company is 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 the Company fails to achieve such milestone events and does not cure such failure within a specified termination notice period. Johns Hopkins may also terminate the agreement upon a material breach by the Company under the agreement if the Company does not cure such breach within a specified notice period or upon the Company's bankruptcy or insolvency. The Company may terminate the agreement at any time upon 90 days' notice.

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. The Company is obligated to pay Johns Hopkins an annual minimum royalty of up to $30. The Company is also obligated 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 in the aggregate $700. The Company 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. The Company must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse Johns Hopkins for patent costs.

Commercial 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 "Agreement"). Pursuant to the Agreement, Qiagen has agreed to develop and commercialize an assay as a companion diagnostic test to identify castration resistant prostate cancer ("CRPC") patients with the splice variant AR-V7 for use with galeterone, the Company's lead drug candidate. The Company expects to use the clinical trial assay developed by Qiagen in its planned pivotal Phase 3 clinical trial of galeterone in order to identify CRPC patients with AR-V7.

Under the Agreement, Qiagen is responsible for developing, and obtaining and maintaining regulatory approvals for, the companion diagnostic test in the United States, the European Union, Canada, Australia and such other countries as the parties may agree. In addition, Qiagen has agreed to use commercially reasonable and diligent efforts to manufacture the companion diagnostic test and to make the companion diagnostic test commercially available in those countries in which the Company has obtained regulatory approval for, and has valid patent claims covering, galeterone. Qiagen will be responsible for commercializing the companion

diagnostic in each such country. If Qiagen elects not to commercialize the companion diagnostic test itself in any such country, for so long as there are valid patent claims covering galeterone in such country, Qiagen has agreed to procure alternative distribution channels or otherwise supply the companion diagnostic test to the Company in order for the Company to market galeterone in combination with the companion diagnostic test. Upon the request of the Company, the parties have also agreed to negotiate in good faith to expand the scope of the projects under the Agreement to, among other things, provide for the development and commercialization of the companion diagnostic test for use with galeterone in Japan.

Subject to the terms of the Agreement, the Company will pay Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test, fees for the development of the assay and a contingent milestone payment of $1,000 upon Qiagen obtaining pre-market approval of the assay, and will reimburse Qiagen for certain direct out-of-pocket costs incurred by Qiagen, including for sample material. These amounts are subject to adjustment if the parties determine that changes in the scope of the development program are required. Following commercialization, the Company will have no further payment obligations to Qiagen under the Agreement. However, the Company will not receive any revenues from future sales, if any, of the companion diagnostic test.

The Agreement expires on the later to occur of (i) the fifth anniversary of regulatory approval of the companion diagnostic test and (ii) the expiration of Qiagen's commercialization obligations under the Agreement. The Company is permitted to terminate the Agreement for convenience upon 180 days' written notice to Qiagen. Either party may terminate the Agreement upon 60 days' written notice to the other party based on uncured material breaches by the other party and may terminate the Agreement immediately based on the bankruptcy or insolvency of the other party.

Advisor Agreement

The Company paid a financial advisor $1,053 that was contingent upon the closing of its IPO in connection with strategic and financial advisory services unrelated to the offering. The Company recorded this amount as general and administrative expenses in its consolidated statement of operations and comprehensive loss for the year ended December 31, 2014.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. In addition, the Company maintains directors and officers insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2014.

10. Income Taxes

During the years ended December 31, 2014, 2014 and 2013, 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,		
	2014	2013	2012
Federal statutory income tax rate	(34.0%)	(34.0%)	(34.0%)
Federal research and development tax credit	(0.9)	(0.7)	(1.2)
State taxes, net of federal benefit	(4.5)	(5.6)	(5.4)
Stock-based compensation expense	1.1	0.4	0.6
Other	0.2	0.1	—
Change in deferred tax asset valuation allowance	38.1	39.8	40.0
Effective income tax rate	0.0%	0.0%	0.0%

Net deferred tax assets as of December 31, 2014 and 2013 consisted of the following:

	December 31,	
	2014	2013
Current deferred tax assets:		
Accrued expenses	$ 414	$ 201
Total current deferred tax assets	414	201
Noncurrent deferred tax assets:		
Capitalized research and development expenses	24,945	19,250
Net operating loss carryforwards	6,292	3,989
Research and development tax credit carryforwards	1,008	889
Other	613	73
Total noncurrent deferred tax assets	32,858	24,201
Total gross deferred tax assets	33,272	24,402
Valuation allowance	(33,272)	(24,402)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2014, 2013 and 2012 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2014	2013	2012
Valuation allowance as of beginning of year	$24,402	$18,138	$14,129
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	8,870	6,264	4,009
Valuation allowance as of end of year	$33,272	$24,402	$18,138

As of December 31, 2014, the Company had net operating loss carryforwards for federal and state income tax purposes of $16,500 and $13,000, respectively, which begin to expire in 2024 and 2030, respectively. As of December 31, 2014, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $809 and $302, respectively, which begin to expire in 2025 and 2023, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") due to ownership changes that have occurred previously or that could occur in

the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. 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. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

As of December 31, 2014 and 2013, the Company's gross deferred tax asset balance of $33,272 and $24,402, respectively, was comprised principally of capitalized research and development expenses, net operating loss carryforwards, and research and development tax credit carryforwards.

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, 2014 and 2013. 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, 2014 or 2013.

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 2011 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. To date, the Company has not made any contributions to the plan.

12. Related Party Transactions

The Company has an outstanding loan to a former advisor of the Company of $250 that accrued interest at 2.92% per annum that was due in 2007. In 2007, unpaid principal and interest in the amount of $220 was deemed uncollectable by the Company, and as a result, was fully reserved for by the Company. As of December 31, 2013, no payments had been received by the Company, and the unpaid principal and interest balance remained fully reserved. In 2014 the Company started to receive repayment of this note. The Company is recording payments received as other income in 2014 as cash is received. As a result, the Company recorded other income of $158 for the year ended December 31, 2014 representing cash collected during that period.

13. Selected Quarterly Financial Data (Unaudited)

	Three Months Ended							
	Dec. 31, 2014	Sept. 30, 2014	June 30, 2014	March 31, 2014	Dec. 31, 2013	Sept. 30, 2013	June 30, 2013	March 31, 2013
Statements of Operations Data:								
Revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Loss from operations	(6,261)	(6,424)	(5,885)	(4,892)	(5,549)	(3,365)	(4,444)	(2,391)
Net loss	(6,208)	(6,390)	(5,851)	(4,847)	(5,525)	(3,365)	(4,445)	(2,390)
Net loss attributable to common stockholders	(6,208)	(6,390)	(5,851)	(4,847)	(5,540)	(3,365)	(4,524)	(2,390)
Basic and diluted net loss attributable to common stockholders per share	$ (0.28)	$ (2.71)	$(11.68)	$ (9.79)	$(11.23)	$ (6.82)	$(12.95)	$ (7.20)

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, 2014. 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, 2014, 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

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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 three months ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

None.

PART III

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

The information required by this Item 10 will be included under the captions "Executive Officers," "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement to be filed with the SEC with respect to our 2015 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 "Investor & Media — Corporate Governance" section of our website, *www.tokaipharma.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 12 will be included under the captions "Executive and Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" in our definitive proxy statement to be filed with the SEC with respect to our 2015 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 under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in our definitive proxy statement to be filed with the SEC with respect to our 2015 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, as applicable, under the captions "Employment Agreements," "Potential Payments Upon Termination or Change in Control," "Board Determination of Independence" and "Related Person Transactions" in our definitive proxy statement to be filed with the SEC with respect to our 2015 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 under the captions "Audit Fees and Services" and "Pre-Approval Policies and Procedures" in our definitive proxy statement to be filed with the SEC with respect to our 2015 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 consolidated financial statements included herein, see Index to the Consolidated Financial Statements on page 100 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 consolidated financial statements or the notes thereto.

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 26, 2015

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 26, 2015
/s/ Lee H. Kalowski Lee H. Kalowski	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2015
/s/ Seth L. Harrison Seth L. Harrison	Chairman of the Board	March 26, 2015
/s/ Timothy J. Barberich Timothy J. Barberich	Director	March 26, 2015
/s/ Stephen Buckley, Jr. Stephen Buckley, Jr.	Director	March 26, 2015
/s/ David A. Kessler David A. Kessler	Director	March 26, 2015
/s/ Joseph A. Yanchik III Joseph A. Yanchik III	Director	March 26, 2015

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014)
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
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

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
10.15	Employment Agreement, dated as of August 21, 2014, between the Registrant and Lee H. Kalowski (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1/A (File No. 333-198052) filed on September 2, 2014)
10.16*+	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Lee H. Kalowski
10.17+	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)
10.18*	Sublease Agreement, dated as of February 27, 2015, between the Registrant and Boston Private Wealth LLC
10.19†	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)
10.20*†	License Agreement, dated as of January 9, 2015, between the Registrant and The Johns Hopkins University
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.
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 requested 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 10.10

AMENDMENT TO EMPLOYMENT LETTER

This Amendment to Employment Letter (this "Amendment") is entered into as of January 15, 2015 (the "Effective Date"), by and between Tokai Pharmaceuticals, Inc. ("the Company"), having a place of business at One Broadway, 14th floor, Cambridge, MA 02142, and Jodie P. Morrison (the "Executive") residing at 23 Walton Lane, Wakefield, MA 01880.

WHEREAS, the Company and the Executive are parties to an employment letter, dated July 16, 2014 (the "Original Letter"); and

WHEREAS, the Parties wish to amend the Original Letter to address the benefits provided to the Executive in the event of a termination of her employment.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I—AMENDMENTS TO ORIGINAL LETTER

1.1 Section 10 of the Original Letter is hereby amended and restated in its entirety to be and read as follows:

"10. Termination Without Cause or for Good Reason.

a. *Severance Benefits in Connection with Termination*. Subject to Sections 10(b) and (c), if the Company terminates your employment without Cause (as defined below), or you terminate your employment for Good Reason (as defined below), (i) you will receive as severance pay an amount equal to 12 months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings, and payable over a 12-month period in accordance with the Company's regular payroll practices) and (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of 12 months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease.

b. *Severance Benefits in Connection with Termination Upon or Within One Year Following a Change in Control Event.* Subject to Section 10(c), if, upon or during the 12-month period commencing upon a Change in

Control Event (as defined below), your employment with the Company or the acquiring or succeeding company is terminated by the Company or the acquiring or succeeding company without Cause or, upon or during the 12 month period commencing upon the Change in Control Event, you terminate your employment with the Company or the acquiring or succeeding company for Good Reason, then, in lieu of the severance and other benefits provided for in Section 10(a), to the extent applicable, (i) you will receive as severance pay (x) an amount equal to 18 months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings and payable over an 18-month period in accordance with the Company's regular payroll practices) and (y) an amount equal to 100% of your then-current annual target bonus (subject to all applicable federal, state and local taxes and withholdings and payable in a lump sum), (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of 18 months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease, and (iii) notwithstanding the terms of any stock option agreement, restricted stock agreement, restricted stock unit agreement or other stock award ("Equity Awards"), the vesting of all Equity Awards held by you on the date of termination shall be automatically accelerated, effective as of the date of termination, such that such Equity Awards shall become 100% fully vested.

c. *Conditions of Severance Benefits*. You will not receive your severance pay or the other benefits set forth in Sections 10(a) and (b) of this letter unless (i) you are in full compliance with the Non-Competition Agreement described in Section 7 and (ii), within 60 days following your last day of employment (or such lesser period as is then required by the Severance Agreement), you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"). Upon the satisfaction of the Severance Conditions, your receipt of severance pay and other benefits shall commence (or in the case of any lump sum payment, shall be paid and, in the case of any Equity Awards, shall vest) on the Company's first payroll date following the eighth day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment will not begin before the first business day of that subsequent year), and shall continue for the periods described in Sections 10(a) and (b), as applicable. Any severance pay or other benefits payable under this

Section 10 will be subject to the terms and conditions set forth in Section 11, below.

d. *Definitions.* For the purposes of this Section 10:

(i) "Cause" means: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (x) engaged in dishonesty, willful misconduct or gross negligence in connection with the performance of your duties or services to the Company, (y) breached your Non-Competition Agreement, or (z) violated Company policies or procedures in a manner that has materially injured, or is reasonably likely to materially injure, the Company's business or reputation.

(ii)"Change in Control Event" means:

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control Event: (x) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(b) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting

Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination: provided that, where required to avoid additional taxation under Section 409A, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(iii) "Good Reason" means: (a) a material adverse change in your duties, responsibilities, title or reporting relationship, (b) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (c) the relocation of the Company following a Change in Control Event, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (a) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (b) provide the Company with at least 30 days to cure, and (c) if not cured, resign for Good Reason within 30 days following expiration of the cure period."

ARTICLE II—MISCELLANEOUS

2.1 Original Letter, as Amended. Other than as set forth in this Amendment, the Original Letter remains unchanged and in full force and effect, and in the event that there is any conflict between the terms of this Amendment and the Original Letter, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to the Original Letter to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Timothy J. Barberich
Timothy J. Barberich
Chairman of the Compensation Committee
of the Board of Directors

EXECUTIVE

By: /s/ Jodie P. Morrison
Jodie P. Morrison

AMENDMENT TO EMPLOYMENT LETTER

This Amendment to Employment Letter (this "Amendment") is entered into as of January 15, 2015 (the "Effective Date"), by and between Tokai Pharmaceuticals, Inc. ("the Company"), having a place of business at One Broadway, 14th floor, Cambridge, MA 02142, and John S. McBride (the "Executive") residing at 89 West Main Street, Westborough, MA 01581.

WHEREAS, the Company and the Executive are parties to an employment letter, dated January 30, 2014 (the "Original Letter"); and

WHEREAS, the Parties wish to amend the Original Letter to address the benefits provided to the Executive in the event of a termination of his employment.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I—AMENDMENTS TO ORIGINAL LETTER

1.1 Section 12 of the Original Letter is hereby amended and restated in its entirety to be and read as follows:

"12. Termination Without Cause or for Good Reason.

a. *Severance Benefits in Connection with Termination*. Subject to Sections 12(b) and (c), if the Company terminates your employment without Cause (as defined below), or you terminate your employment for Good Reason (as defined below), (i) you will receive as severance pay an amount equal to six months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings, and payable over a six-month period in accordance with the Company's regular payroll practices) and (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of six months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease.

b. *Severance Benefits in Connection with Termination Upon or Within One Year Following a Change in Control Event.* Subject to Section 12(c), if, upon or during the 12 month period commencing upon a Change in Control Event (as defined below), your employment with the Company or

the acquiring or succeeding company is terminated by the Company or the acquiring or succeeding company without Cause or, upon or during the 12 month period commencing upon the Change in Control Event, you terminate your employment with the Company or the acquiring or succeeding company for Good Reason, then, in lieu of the severance and other benefits provided for in Section 12(a), to the extent applicable, (i) you will receive as severance pay (x) an amount equal to 12 months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings and payable over an 12-month period in accordance with the Company's regular payroll practices) and (y) an amount equal to 100% of your then-current annual target bonus (subject to all applicable federal, state and local taxes and withholdings and payable in a lump sum), (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of 12 months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease, and (iii) notwithstanding the terms of any stock option agreement, restricted stock agreement, restricted stock unit agreement or other stock award ("Equity Awards"), the vesting of all Equity Awards held by you on the date of termination shall be automatically accelerated, effective as of the date of termination, such that such Equity Awards shall become 100% fully vested.

c. *Conditions of Severance Benefits*. You will not receive your severance pay or the other benefits set forth in Sections 12(a) and (b) of this letter unless (i) you are in full compliance with the Non-Competition Agreement described in Section 8 and (ii), within 60 days following your last day of employment (or such lesser period as is then required by the Severance Agreement), you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"). Upon the satisfaction of the Severance Conditions, your receipt of severance pay and other benefits shall commence (or in the case of any lump sum payment, shall paid and, in the case of any Equity Awards, shall vest) on the Company's first payroll date following the eighth day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment will not begin before the first business day of that subsequent year), and shall continue for the periods described in Sections 12(a) and (b), as applicable. Any severance pay or other benefits payable under this

Section 12 will be subject to the terms and conditions set forth in Exhibit A.

d. *Definitions.* For the purposes of this Section 12:

(i) "Cause" means: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) breached or threatened to breach the Non-Competition Agreement, (iii) violated Company policies or procedures, and/or (iv) failed to perform your assigned duties to the Company's satisfaction, following notice of such failure by the Company and a period of fifteen (15) days to cure.

(ii)"Change in Control Event" means:

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control Event: (x) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(b) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting

Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination: provided that, where required to avoid additional taxation under Section 409A, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(iii) "Good Reason" means: (a) a material adverse change in your duties, responsibilities, title or reporting relationship, (b) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (c) the relocation of the Company following a Change in Control Event, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (a) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (b) provide the Company with at least 30 days to cure, and (c) if not cured, resign for Good Reason within 30 days following expiration of the cure period."

ARTICLE II—MISCELLANEOUS

2.1 Original Letter, as Amended. Other than as set forth in this Amendment, the Original Letter remains unchanged and in full force and effect, and in the event that there is any conflict between the terms of this Amendment and the Original Letter, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to the Original Letter to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Timothy J. Barberich
Timothy J. Barberich
Chairman of the Compensation Committee
of the Board of Directors

EXECUTIVE

By: /s/ John S. McBride
John S. McBride

AMENDMENT TO EMPLOYMENT LETTER

This Amendment to Employment Letter (this "Amendment") is entered into as of January 15, 2015 (the "Effective Date"), by and between Tokai Pharmaceuticals, Inc. ("the Company"), having a place of business at One Broadway, 14th floor, Cambridge, MA 02142, and Karen Ferrante (the "Executive") residing at 150 Adirondack Drive, East Greenwich, RI 02818.

WHEREAS, the Company and the Executive are parties to an employment letter, dated April 7, 2014 (the "Original Letter"); and

WHEREAS, the Parties wish to amend the Original Letter to address the benefits provided to the Executive in the event of a termination of her employment.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I—AMENDMENTS TO ORIGINAL LETTER

1.1 Section 13 of the Original Letter is hereby amended and restated in its entirety to be and read as follows:

"13. Termination Without Cause or for Good Reason.

a. *Severance Benefits in Connection with Termination*. Subject to Sections 13(b) and (c), if the Company terminates your employment without Cause (as defined below), or you terminate your employment for Good Reason (as defined below), (i) you will receive as severance pay an amount equal to your then current base salary for a period equal to (x) the number of full months worked if the termination of your employment with the Company occurs prior to April 7, 2015 or (y) 12 months if the termination of your employment with the Company occurs on or after April 7, 2015 (in each case, subject to all applicable federal, state and local taxes and withholdings, and payable over the period set forth in Section 13(a)(i)(x) or 13(a)(i)(y), as applicable, in accordance with the Company's regular payroll practices) and (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of six months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease.

b. *Severance Benefits in Connection with Termination Upon or Within One Year Following a Change in Control Event*. Subject to Section 13(c), if, upon or during the 12 month period commencing upon a Change in Control Event (as defined below), your employment with the Company or the acquiring or succeeding company is terminated by the Company or the acquiring or succeeding company without Cause or, upon or during the 12 month period commencing upon the Change in Control Event, you terminate your employment with the Company or the acquiring or succeeding company for Good Reason, then, in lieu of the severance and other benefits provided for in Section 13(a), to the extent applicable, (i) you will receive as severance pay (x) an amount equal to 12 months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings and payable over an 12-month period in accordance with the Company's regular payroll practices) and (y) an amount equal to 100% of your then-current annual target bonus (subject to all applicable federal, state and local taxes and withholdings and payable in a lump sum), (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of 12 months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease, and (iii) notwithstanding the terms of any stock option agreement, restricted stock agreement, restricted stock unit agreement or other stock award ("Equity Awards"), the vesting of all Equity Awards held by you on the date of termination shall be automatically accelerated, effective as of the date of termination, such that such Equity Awards shall become 100% fully vested.

c. *Conditions of Severance Benefits*. You will not receive your severance pay or the other benefits set forth in Sections 13(a) and (b) of this letter unless (i) you are in full compliance with the Non-Competition Agreement described in Section 9 and (ii), within 60 days following your last day of employment (or such lesser period as is then required by the Severance Agreement), you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"). Upon the satisfaction of the Severance Conditions, your receipt of severance pay and other benefits shall commence (or in the case of any lump sum payment, shall paid and, in the case of any Equity Awards, shall vest) on the Company's first payroll date following the eighth day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment

will not begin before the first business day of that subsequent year), and shall continue for the periods described in Sections 13(a) and (b), as applicable. Any severance pay or other benefits payable under this Section 13 will be subject to the terms and conditions set forth in Exhibit A.

d. *Definitions.* For the purposes of this Section 13:

(i) "Cause" means: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) breached or threatened to breach the Non-Competition Agreement, (iii) violated Company policies or procedures, and/or (iv) failed to perform your assigned duties to the Company's satisfaction, following notice of such failure by the Company and a period of fifteen (15) days to cure.

(ii) "Change in Control Event" means:

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control Event: (x) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(b) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"),

unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination: provided that, where required to avoid additional taxation under Section 409A, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(iii) "Good Reason" means: (a) a material adverse change in your duties, responsibilities, title or reporting relationship, (b) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (c) the relocation of the Company following a Change in Control Event, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (a) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (b) provide the Company with at least 30 days to cure, and (c) if not cured, resign for Good Reason within 30 days following expiration of the cure period."

ARTICLE II—MISCELLANEOUS

2.1 Original Letter, as Amended. Other than as set forth in this Amendment, the Original Letter remains unchanged and in full force and effect, and in the event that there is any conflict between the terms of this Amendment and the Original Letter, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to the Original Letter to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Timothy J. Barberich
Timothy J. Barberich
Chairman of the Compensation Committee
of the Board of Directors

EXECUTIVE

By: /s/ Karen Ferrante
Karen Ferrante

AMENDMENT TO EMPLOYMENT LETTER

This Amendment to Employment Letter (this "Amendment") is entered into as of January 15, 2015 (the "Effective Date"), by and between Tokai Pharmaceuticals, Inc. ("the Company"), having a place of business at One Broadway, 14th floor, Cambridge, MA 02142, and Lee H. Kalowski (the "Executive") residing at 207 East 74th St., PH-D, New York, NY 10021.

WHEREAS, the Company and the Executive are parties to an employment letter, dated August 21, 2014 (the "Original Letter"); and

WHEREAS, the Parties wish to amend the Original Letter to address the benefits provided to the Executive in the event of a termination of his employment.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE I—AMENDMENTS TO ORIGINAL LETTER

1.1 Section 14 of the Original Letter is hereby amended and restated in its entirety to be and read as follows:

"14. Termination Without Cause or for Good Reason.

a. *Severance Benefits in Connection with Termination*. Subject to Sections 14(b) and (c), if the Company terminates your employment without Cause (as defined below), or you terminate your employment for Good Reason (as defined below), (i) you will receive as severance pay an amount equal to six months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings, and payable over a six-month period in accordance with the Company's regular payroll practices) and (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of six months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease.

b. *Severance Benefits in Connection with Termination Upon or Within One Year Following a Change in Control Event.* Subject to Section 14(c), if, upon or during the 12 month period commencing upon a Change in Control Event (as defined below), your employment with the Company or

the acquiring or succeeding company is terminated by the Company or the acquiring or succeeding company without Cause or, upon or during the 12 month period commencing upon the Change in Control Event, you terminate your employment with the Company or the acquiring or succeeding company for Good Reason, then, in lieu of the severance and other benefits provided for in Section 14(a), to the extent applicable, (i) you will receive as severance pay (x) an amount equal to 12 months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings and payable over an 12-month period in accordance with the Company's regular payroll practices) and (y) an amount equal to 100% of your then-current annual target bonus (subject to all applicable federal, state and local taxes and withholdings and payable in a lump sum), (ii) provided that you are eligible for and elect COBRA coverage, the Company will pay the amount of premiums it pays for active employees with similar coverage for you and your covered beneficiaries but not more each month than the monthly amount it was paying for your coverage when your employment ended until the earlier of 12 months after your employment ends or the date you (or, as applicable, your beneficiaries) become eligible for coverage at a new employer, provided that if the Company's paying such premiums violates nondiscrimination laws, the payments will cease, and (iii) notwithstanding the terms of any stock option agreement, restricted stock agreement, restricted stock unit agreement or other stock award ("Equity Awards"), the vesting of all Equity Awards held by you on the date of termination shall be automatically accelerated, effective as of the date of termination, such that such Equity Awards shall become 100% fully vested.

c. *Conditions of Severance Benefits*. You will not receive your severance pay or the other benefits set forth in Sections 14(a) and (b) of this letter unless (i) you are in full compliance with the Non-Competition Agreement described in Section 10 and (ii), within 60 days following your last day of employment (or such lesser period as is then required by the Severance Agreement), you timely execute and return a severance and release of claims agreement provided by the Company (the "Severance Agreement") and, if applicable, allow it to become effective by not revoking your acceptance (the "Severance Conditions"). Upon the satisfaction of the Severance Conditions, your receipt of severance pay and other benefits shall commence (or in the case of any lump sum payment, shall paid and, in the case of any Equity Awards, shall vest) on the Company's first payroll date following the eighth day after you execute the Severance Agreement (provided that if the 60 day period described above ends in a calendar year subsequent to the year in which you are terminated, payment will not begin before the first business day of that subsequent year), and shall continue for the periods described in Sections 14(a) and (b), as applicable. Any severance pay or other benefits payable under this

Section 14 will be subject to the terms and conditions set forth in Exhibit A.

d. *Definitions.* For the purposes of this Section 14:

(i) "Cause" means: (a) your conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (b) a good faith finding by the Company that you have (i) engaged in dishonesty, willful misconduct or gross negligence, (ii) breached or threatened to breach the Non-Competition Agreement, (iii) violated Company policies or procedures, and/or (iv) failed to perform your assigned duties to the Company's satisfaction, following notice of such failure by the Company and a period of fifteen (15) days to cure.

(ii)"Change in Control Event" means:

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control Event: (x) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(b) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting

Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination: provided that, where required to avoid additional taxation under Section 409A, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(iii) "Good Reason" means: (a) a material adverse change in your duties, responsibilities, title or reporting relationship, (b) a material reduction in your annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (c) the relocation of the Company following a Change in Control Event, such that your daily commute is increased by at least 50 miles. To terminate your employment for Good Reason you must (a) provide notice to the Company of the event giving rise to the Good Reason within 90 days after such event occurs, (b) provide the Company with at least 30 days to cure, and (c) if not cured, resign for Good Reason within 30 days following expiration of the cure period."

ARTICLE II—MISCELLANEOUS

2.1 Original Letter, as Amended. Other than as set forth in this Amendment, the Original Letter remains unchanged and in full force and effect, and in the event that there is any conflict between the terms of this Amendment and the Original Letter, the terms of this Amendment will prevail.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to the Original Letter to be executed as of the Effective Date.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Timothy J. Barberich
Timothy J. Barberich
Chairman of the Compensation Committee
of the Board of Directors

EXECUTIVE

By: /s/ Lee H. Kalowski
Lee H. Kalowski

Exhibit 10.18

SUBLEASE

This SUBLEASE (the **"Sublease"**) is dated as of the 27 day of February, 2015 and is made by and between Boston Private Wealth LLC, a Massachusetts limited liability company (**"Sublandlord"**), and Tokai Pharmaceuticals, Inc., a Delaware corporation (**"Subtenant"**).

Recitals

WHEREAS, pursuant to that certain Lease, dated as of October 5, 2010, between 255 State Street, LLC, a Delaware corporation (**"Prime Landlord"**), as landlord, and Sublandlord (as successor-in-interest to Silver Bridge Advisors LLC), as tenant (the **"Prime Lease"**, a redacted copy of which is attached hereto as Exhibit A), Sublandlord leases from Prime Landlord certain premises (the **"Premises"**, as depicted on Exhibit B to the Prime Lease) consisting of approximately 15,981 rentable square feet of space on the sixth (6th) floor of the building commonly known as 255 State Street, Boston, Massachusetts (the **"Building"**); and

WHEREAS, Subtenant desires to sublease from Sublandlord the entire Premises (as subleased to Subtenant, the **"Subleased Premises"**), and Sublandlord is willing to sublease the Subleased Premises to Subtenant on the provisions, covenants and conditions hereinafter set forth.

Agreement

NOW, THEREFORE, for good and valuable consideration, the mutual covenants made herein, and other consideration, the receipt and sufficiency of which are hereby acknowledged and agreed, Sublandlord hereby subleases to Subtenant and Subtenant hereby subleases from Sublandlord the Subleased Premises, on the terms and conditions set forth below:

1. **Defined Terms.** All terms defined in the Prime Lease and used herein shall, unless otherwise defined herein, have the meanings ascribed to such terms in the Prime Lease.

2. **Term.** The term of this Sublease (the **"Sublease Term"**) shall commence on April 1, 2015 (the **"Commencement Date"**) and shall expire on December 31, 2016 (the **"Expiration Date"**), unless sooner terminated in accordance with the provisions of this Sublease. Time is of the essence of this Sublease.

3. **As-Is Condition; Surrender.** Sublandlord shall deliver the Subleased Premises to Subtenant at the commencement of the Sublease Term, broom-clean and free of all occupants and their property (except for the furniture being conveyed to Subtenant as described in Section 4 below) but otherwise "as-is, where-is and with all faults" at the time of the execution of this Sublease, without representation or warranty, express or implied, and Subtenant hereby waives, disclaims and renounces any such representation or warranty. Without limitation of the provisions of Section 7 of this Sublease, Subtenant hereby acknowledges that any alterations or additions proposed by Subtenant shall be subject to the prior written consent of Prime Landlord and Sublandlord (which consent, in the case of Sublandlord, shall not be unreasonably withheld, conditioned or delayed) and shall be performed in accordance with all of the requirements of the Prime Lease, including Section 6.2.5 thereof. Upon the expiration or earlier termination of this Sublease, Subtenant shall deliver the Subleased Premises to Sublandlord in vacant, broom-clean

condition, and in the condition required under the Prime Lease, provided that Subtenant shall not be required to remove any fixtures, equipment, alterations or improvements that were installed in the Subleased Premises prior to the Commencement Date of the Sublease Term.

Subtenant acknowledges that it has inspected the Subleased Premises and the improvements therein, or has caused an inspection thereof to be made, and is fully familiar and satisfied therewith and acknowledges and agrees that, except as otherwise expressly provided herein, no representations have been made or are made hereby by Sublandlord and no responsibility has been assumed by Sublandlord as to the condition (including, but not limited to, compliance with applicable law), value or suitability of the Subleased Premises, the Building (including the common areas thereof) or any improvements thereon or therein.

4. **Furniture.** Effective as of the Commencement Date, Sublandlord shall convey to Subtenant, in consideration of the sum of $1.00 pursuant to a customary bill of sale (specifically excluding any warranties) to be agreed upon in good faith by Sublandlord and Subtenant, all furniture and equipment in the Subleased Premises as of the date of this Sublease other than the items of furniture and equipment listed in Exhibit B hereto. The items of furniture and equipment listed in Exhibit B shall be removed by Sublandlord from the Subleased Premises, at its expense, prior to the Commencement Date.

5. **Rent.**

A. Subtenant shall pay to Sublandlord, in advance, in monthly installments, without withholding, offset or reduction (except as otherwise expressly provided herein), Basic Rent in the following amounts: (i) for the period starting on the Commencement Date and ending on the day preceding the first anniversary thereof, $543,354.00 per annum, payable in monthly installments of $45,279.50; and (ii) for the period starting on the first anniversary of the Commencement Date and ending on the Expiration Date, $559,335.00 per annum, payable in monthly installments of $46,611.25. Subtenant shall be entitled to its pro rata share of any reduction or abatement of Basic Rent to the extent of any actual reduction or abatement of Base Rent allocable to the Subleased Premises received by Sublandlord under the terms of the Prime Lease. Basic Rent for any partial calendar months at the beginning or end of the Sublease Term shall be prorated on a daily basis. Subtenant acknowledges that Sublandlord's payments of Fixed Rent for the Premises are paid to Prime Landlord on the first, day of each calendar month during the Term and Subtenant therefore covenants and agrees that its payments of Basic Rent hereunder shall be paid to Sublandlord at least five (5) business days prior to the first of each calendar month.

B. Subtenant hereby acknowledges that the Subleased Premises are separately metered for electricity. During the Sublease Term, Subtenant shall pay, directly to the appropriate utility provider, any and all costs of electricity utilized in the Subleased Premises and in support of any of Subtenant's equipment, wherever located.

C. During the Sublease Term, in the event that Subtenant shall request any additional services or utilities to the Subleased Premises (including, without limitation, for HVAC) for which an additional charge is imposed by Prime Landlord, Subtenant shall promptly pay such amount to Prime Landlord; provided, however, that if Prime Landlord requires

Sublandlord to pay for any such services for the benefit of Subtenant, then Subtenant shall reimburse Sublandlord for such costs within fifteen (15) days after Subtenant's receipt of an invoice therefor from Sublandlord.

D. All amounts payable by Subtenant to Sublandlord pursuant to this Sublease in addition to Basic Rent shall be deemed to be **"Additional Rent"** and, in the event of any non-payment thereof, Sublandlord shall have all of the rights and remedies provided herein (including, without limitation, those rights and remedies set forth in Article 8 of the Prime Lease and incorporated herein by reference), at law or in equity for non-payment of rent. The obligation of Subtenant to pay to Sublandlord all amounts of Basic Rent and Additional Rent due hereunder, and under the Prime Lease as and to the extent incorporated herein and as modified hereby, shall survive the expiration of the Sublease Term or earlier termination of this Sublease.

6. **Use: Permits and Approvals.** The Subleased Premises shall be used for the Permitted Use only and for no other uses. Subtenant shall obtain all governmental permits and approvals for Subtenant's use of the Subleased Premises, at Subtenant's sole cost and expense, and shall provide evidence thereof to Sublandlord, prior to undertaking any regulated use thereof.

7. **Subordination to and Incorporation of Terms of the Lease.**

A. This Sublease is in all respects subject and subordinate to all of the terms, provisions, covenants, stipulations, conditions and agreements of the Prime Lease, and, except as otherwise expressly provided in this Sublease, all of the terms, provisions, covenants, stipulations, conditions, rights, obligations, remedies and agreements contained in the Prime Lease are incorporated in this Sublease by reference and made a part hereof as if herein set forth at length, and shall, as between Sublandlord and Subtenant (as if they were the Landlord and Tenant, respectively, under the Prime Lease and the word "Lease" were "Sublease", the word "Premises" were "Subleased Premises" and the phrase "Fixed Rent" were "Basic Rent"), constitute the terms of this Sublease, except that Subtenant shall have no termination rights, rights of first offer, rights of first refusal, expansion rights, contraction rights and/or extension rights which may be granted to Sublandlord under the Prime Lease, and except that the following provisions are specifically excluded: (i) Section 1.1 (other than the definitions of Permitted Use and Commercial General Liability Insurance limits, which are incorporated by reference), Section 2.1(e), Section 2.1(f), Section 2.2, Section 2.3, Section 2.4, Section 2.5, Article 3 (other than Section 3.6, which is incorporated by reference), Article 4 (other than Section 4.2.2, Section 4.2.4, Section 4.2.5 and Section 4.3, all of which are incorporated by reference), Article 5, the second (2nd) paragraph of Section 9.1 (a), Article 10, Section 11.1, Section 11.3~ Section 11.4, Section 11.7, Section 11.14, Article 13, Exhibit C, Exhibit D, Exhibit F, Exhibit G, Exhibit I and Exhibit J; and (ii) such other terms of the Prime Lease which do not relate to the Subleased Premises or are inapplicable to, inconsistent with, or specifically modified by, the terms of this Sublease (which provisions, for purposes of this Sublease, are hereby deemed deleted in their entirety). Notwithstanding the reference to Article 5 and Exhibit D in the preceding sentence, the Prime Landlord's covenants in said Article 5 and Exhibit D shall apply to the Subleased Premises during the Sublease Term, provided that Sublandlord shall have no obligation to perform such covenants but, in the event that Prime Landlord defaults in its obligations to perform such covenants, Sublandlord shall use commercially reasonable efforts to enforce its

rights against the Prime Landlord in accordance with Section 7.E of this Sublease. In addition, within Section 6.2.1(f) of the Prime Lease as incorporated by reference, the phrase "Wilmer Cutler Pickering Hale and Dorr LLP" is hereby deleted and "Tokai Pharmaceuticals, Inc." is substituted therefor.

B. In furtherance of the foregoing, Subtenant shall not take any action or do, or permit to be done, anything which (i) is or may be prohibited to Sublandlord, as tenant under the Prime Lease, (ii) might result in a violation of or default under any of the terms, covenants, conditions or provisions of the Prime Lease or any other instrument to which this Sublease is subordinate, or (iii) would result in any additional cost or other liability to Sublandlord. In the event of any inconsistency between this Sublease and the Prime Lease, such inconsistency shall be resolved in favor of that obligation which is more onerous to Subtenant or that restriction which is more restrictive of Subtenant, as the case may be.

C. Subtenant shall not be entitled to receive an abatement of rent hereunder unless and until Sublandlord receives an abatement of rent under the Prime Lease, and then only to the extent a portion of such abatement is attributable to damage, interruption of services or other condition pertaining to the Subleased Premises.

D. Except as specifically set forth herein to the contrary, all acts to be performed by, and all of the terms, provisions, covenants, stipulations, conditions, obligations and agreements to be observed by, Sublandlord, as tenant under the Prime Lease, shall, to the extent that the same relate to the Subleased Premises, be performed and observed by Subtenant, and Subtenant's obligations in respect thereof shall run to Sublandlord or Prime Landlord, as Sublandlord may reasonably determine to be appropriate or as may be required by the respective interests of Sublandlord and Prime Landlord.

E. Sublandlord shall have no responsibility to Subtenant for, and shall not be required to provide, any of the services or make any of the repairs, restorations or installations or to provide any of the amenities (including, without limitation, parking) which Prime Landlord has agreed to make or provide, or cause to be made or provided, under the Prime Lease and Subtenant shall rely upon, and look solely to, Prime Landlord for the provision of such services and the performance of such repairs and restorations. Subtenant shall not make any claim against Sublandlord for any damage which may result from, nor shall Subtenant's obligations hereunder (including, without limitation, Subtenant's obligation to pay all Basic Rent and Additional Rent when due) be impaired by reason of (a) the failure of Prime Landlord to keep, observe or perform any of its obligations under the Prime Lease, or (b) the acts or omissions of Prime Landlord or any of its agents, contractors, servants, employees, invitees or licensees. If Prime Landlord shall default in any of its obligations to Sublandlord with respect to the Subleased Premises, Subtenant shall be entitled to request that Sublandlord use commercially reasonable efforts to enforce Sublandlord's rights against Prime Landlord with respect thereto. Sublandlord agrees to use commercially reasonable efforts to enforce Sublandlord's rights against Prime Landlord. In no event shall Sublandlord have any obligation to bring any legal action or proceeding to enforce Sublandlord's rights against Prime Landlord.

F. If the term of the Prime Lease is terminated with respect to the Subleased Premises for any reason prior to the expiration or earlier termination of the Sublease Term, this

Sublease shall immediately terminate and Sublandlord shall not be liable to Subtenant by reason thereof.

G. The parties agree that unless otherwise expressly modified herein, the time limits set forth in the Prime Lease for the giving of notices, making demands, payment of any sum, the performance of any act, condition or covenant, or the exercise of any right, remedy or option, are modified for the purpose of this Sublease by (i) shortening the same in each instance by five (5) business days if requiring performance by Subtenant, and (ii) by lengthening the same in each instance by five (5) business days if requiring performance by Sublandlord. Sublandlord and Subtenant shall, promptly after receipt thereof, furnish to each other a copy of each notice, demand or other communication received from Prime Landlord with respect to the Subleased Premises.

H. Sublandlord represents and warrants to Subtenant the following: (i) the copy of the Prime Lease attached hereto as Exhibit A is a true and complete copy of the Prime Lease; (ii) the Prime Lease has not been modified, amended or supplemented in any way, and remains in full force and effect; (iii) the Sublandlord's leasehold interest and estate in the Prime Lease and the Sublease Premises has not been previously assigned, subleased, transferred, mortgaged, pledged or encumbered pursuant to any agreement which remains in effect; (iv) neither Sublandlord nor Prime Landlord is presently in default of any provisions or covenants of the Prime Lease, nor, to the best of Sublandlord's knowledge, are there any facts or circumstances that, with the passage of time or the giving of notice, or both, could ripen into a default by either Prime Landlord or Sublandlord under the Prime Lease; and (v) Sublandlord has not exercised the termination option set forth in Article 13 of the Prime Lease.

I. Sublandlord shall, in its capacity as tenant under the Prime Lease, perform and fulfill all of its covenants, obligations and agreements under the Lease in accordance with the provisions thereof, and shall not do anything which would cause the Lease to be terminated or forfeited. Unless Sublandlord first obtains Subtenant's prior written consent which may be granted or withheld in Subtenant's reasonable discretion, Sublandlord covenants that it will not agree to voluntarily terminate the Prime Lease (except for any termination right granted to Sublandlord as a result of a casualty or condemnation or as otherwise specifically set forth in the Prime Lease) nor will it enter into any agreement that will modify or amend the Prime Lease so as to materially and adversely affect Subtenant's right to use and occupy the Sublease Premises, or materially increase or materially affect the obligations of Subtenant under this Lease. Further, Sublandlord will promptly provide Subtenant with copies of all notices of default that Sublandlord delivers to, or receives from, the Prime Landlord under the Prime Lease.

8. **Indemnification; Insurance.** Subtenant shall indemnify Sublandlord and hold Sublandlord harmless from and against any and all claims, demands, suits, judgments, liabilities, costs and expenses, including reasonable attorney's fees, arising out of or in connection with Subtenant's use and possession of the Subleased Premises, or arising out of the failure of Subtenant, its agents, contractors or employees to perform any covenant, term or condition of this Sublease or of the Prime Lease to be performed by Subtenant hereunder. Without limitation of the foregoing, all insurance to be provided by Subtenant under the provisions of Section 4.2.4 of the Prime Lease shall name both Prime Landlord and Sublandlord as additional insureds

thereunder. The provisions of this Section 8 shall survive the expiration or earlier termination of this Sublease.

9. **Assignment and Subletting.** Subtenant will not, by operation of law or otherwise, assign, mortgage or encumber this Sublease, nor sub-sublet or permit the Subleased Premises or any part thereof to be used by others, nor shall Subtenant participate in any transaction which would constitute an assignment or sublease under the terms of Section 6.2.1 of the Prime Lease, without Prime Landlord's and Sublandlord's prior written consent in each instance in accordance with and subject to the provisions of Section 6.2.1 of the Prime Lease. The consent to any particular assignment or sub-subletting shall not in any manner be construed to relieve Subtenant from obtaining Prime Landlord's and Sublandlord's express written consent to any further assignment or subletting.

If this Sublease shall be assigned, or if the Subleased Premises or any part thereof shall be sub-sublet or occupied by any person or persons other than Subtenant, Subtenant shall continue to be liable for the performance of all the provisions of this Sublease. Sublandlord may, after default by Subtenant beyond any applicable notice and cure period, collect rent from the assignee, sub-subtenant or occupant and apply the net amount collected to the Basic Rent herein reserved, but no such assignment, subletting, occupancy or collection of rent shall be deemed a waiver of the covenants in this Sublease, nor shall it be deemed acceptance of the assignee, sub-subtenant or occupant as a tenant, or a release of Subtenant from the full performance by Subtenant of all the terms, conditions and covenants of this Sublease.

If the aggregate rent and all other amounts and charges payable to Subtenant under such assignment or sub-sublease, less the out-of-pocket costs and commercially reasonable leasing incentives of Subtenant for such transaction, exceed the Basic Rent payable hereunder with respect to the space transferred (pro rated on a square footage basis), Subtenant shall pay to Sublandlord, as Additional Rent, fifty percent (50%) of such excess (of which Sublandlord shall pay to Prime Landlord fifty percent (50%) of such excess, as required by the Prime Lease), payable monthly at the time of payment of Basic Rent.

10. **Security Deposit.** On the date of execution hereof, Subtenant shall deposit with Sublandlord as security for the performance by Subtenant of the terms of this Sublease cash in the amount of $45,279.50 to be held by Sublandlord as security for the faithful performance of every provision of this Sublease, including but not limited to the provisions relating to the payment of Basic Rent, Additional Rent and all other amounts for which Subtenant is obligated hereunder (the **"Security Deposit"**), it being expressly understood that the Security Deposit is not an advance payment of rent or any other amount and is not a measure of Sublandlord's damages in case of default by Subtenant. Sublandlord shall not be required to keep the Security Deposit separate from its general funds, and Subtenant has no, and expressly waives any, right or interest in the Security Deposit other than as set forth in the immediately following paragraph. Sublandlord may use, apply on Subtenant's behalf, or retain (without liability for interest) during the term of this Sublease (and during any period following the term of this Sublease when any obligation of Subtenant hereunder is continuing) the whole or any part of the Security Deposit for the payment of Basic Rent, Additional Rent or any other amount in default or that, at the time of any default, is owing by Subtenant or is an accrued obligation of Subtenant, or for the payment of any amount which Sublandlord may spend or become obligated to spend hereunder

by reason of Subtenant's default, or to compensate Sublandlord for other loss or damage authorized hereunder which Sublandlord may suffer hereunder by reason of Subtenant's default or for which Subtenant has provided an indemnity hereunder, including but not limited to any deficiency or damage incurred in reletting the Subleased Premises. If any portion of the Security Deposit is to be so used or applied, Subtenant shall, upon written demand therefor, deposit cash with Sublandlord in an amount sufficient to restore the Security Deposit to the amount set forth in this Section 10, and Subtenant's failure to do so shall be deemed a default by Subtenant under this Sublease.

Provided Subtenant shall comply and be in compliance with all of the terms of this Sublease, any remaining portion of the Security Deposit after any application or use in accordance with the immediately preceding paragraph shall be paid to Subtenant within sixty (60) days after the later of (a) the expiration of the term of this Sublease and surrender of possession of the Subleased Premises to Sublandlord, or (b) such time as any amount due or accrued or that may become due or may accrue from Subtenant in accordance with this Sublease has been determined and paid in full.

Subtenant shall not assign or encumber any interest in the Security Deposit, and neither Sublandlord nor its successors and assigns shall be bound by any attempted assignment or encumbrance.

11. **Brokers.** Sublandlord and Subtenant represent and warrant to the other that they have not dealt with any broker in connection with this Sublease other than DTZ and NAI Hunneman (collectively, the **"Broker"**), and that, to their knowledge, no broker or person other than the Broker had any part or was instrumental in any way in bringing about this transaction. Sublandlord and Subtenant shall indemnify and hold the other harmless from and against any and all loss, claims, liabilities, damages and expenses and court costs, arising out of or in connection with any breach or alleged breach of the above representations by it. Sublandlord shall be responsible for any brokerage commission owed the Broker with respect to this Sublease pursuant to a separate agreement. The provisions of this Section 11 shall survive the expiration or earlier termination of this Sublease.

12. **Parking.** Subtenant shall have the right to use four (4) parking spaces in the Boston Harbor Garage (or elsewhere) designated by Prime Landlord from time to time, such use to be on the terms and conditions set forth in Section 2.1(e) of the Prime Lease, and Subtenant shall pay all charges for such four (4) parking spaces directly to the party entitled thereto as set forth in the Prime Lease (whether or not the same are used by Subtenant).

13. **Miscellaneous.**

A. Counterparts. This instrument may be signed in counterpart originals, which, taken together, shall constitute a single original instrument.

B. Notices. Notices to Sublandlord or Subtenant required or permitted hereunder shall be sent in the manner prescribed in the Prime Lease to 10 Post Office Square, Boston, Massachusetts 02109 in the case of notices to Sublandlord and to the Subleased Premises to the attention of the Chief Operating Officer in the case of notices to Subtenant.

C. Amendments. This Sublease may not be changed or terminated orally but only by an agreement in writing signed by both Sublandlord and Subtenant.

D. No Waiver. The failure of either party to insist on strict performance of any covenant or condition hereof, or to exercise any option contained herein, shall not be construed as a waiver of such covenant, condition or option in any other instance.

E. Memorandum of Lease. Subtenant shall not record this Sublease or any memorandum hereof.

F. Governing Law. This Sublease has been negotiated, executed and delivered in the Commonwealth of Massachusetts, and the parties agree that the rights and obligations of the parties under this Sublease shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts.

G. Severability. The invalidity of any of the provisions of this Sublease will not impair or affect in any manner the validity, enforceability or effect of the rest of this Sublease.

H. Entire Agreement. All understandings and agreements, oral or written, heretofore made between the parties hereto are merged in this Sublease, which alone fully and completely expresses the agreement between Sublandlord and Subtenant.

I. Relationship Between the Parties. This Sublease does not create the relationship of principal and agent, nor does it create any partnership, joint venture, or any association or relationship between Sublandlord and Subtenant other than as and to the extent specifically provided in this Sublease, the sole relationship of Sublandlord and Subtenant being that of sublandlord and subtenant as provided in this Sublease.

J. Remedies Cumulative. Except as specifically provided herein, all rights and remedies of Sublandlord under this Sublease shall be cumulative and none shall exclude any other rights and remedies allowed by law.

K. Condition Precedent. The effectiveness of this Sublease is expressly subject to and conditional upon Sublandlord's obtaining of Prime Landlord's written consent to this Sublease pursuant to Section 6.2.1 of the Prime Lease. The term of this Sublease shall not commence until the foregoing condition is satisfied. Sublandlord shall have no liability for any delay or failure of said condition being satisfied, but Basic Rent shall be abated and the Sublease Term shall not commence until its satisfaction. If for any reason Prime Landlord's written consent to this Sublease is not received by Sublandlord on or before March 31, 2015 (the **"Outside Date"**), then Subtenant may elect to cancel this Sublease by giving notice to Sublandlord within ten (10) days after the Outside Date (which cancellation shall be ineffective, and this Sublease shall remain in full force and effect, if such consent is received prior to the receipt of such notice of cancellation). If notice of cancellation has been given in accordance with the provisions of this Section, then Sublandlord shall promptly refund to Subtenant any prepaid rent, security deposit or other sums paid by Subtenant to Sublandlord upon the execution hereof in connection with this Sublease and this Sublease shall thereupon be deemed null and

void and of no further force and effect with neither party having any rights or claims against the other.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Sublease as an instrument under seal as of the date first written above.

SUBLANDLORD:

Boston Private Wealth LLC, a Massachusetts limited liability company

By: /s/ Patrick Tylando
Name: Patrick Tylando
Title: CFO

SUBTENANT:

Tokai Pharmaceuticals, Inc., a Delaware corporation

By: /s/ Lee Kalowski
Name: Lee Kalowski
Title: Chief Financial Officer

EXHIBIT A

Prime Lease

LEASE

by and between

255 State Street, LLC,

as Landlord

and

Silver Bridge Advisors LLC,

as Tenant

255 State Street

Boston, Massachusetts

Dated: October 5, 2010

Table of Contents

(Notice of Lease and Subordination, Nondisturbance and Attornment Agreement recorded with the Suffolk County Registry of Deeds and filed for registration with the Suffolk County Registry District of the Land Court. Original counterparts of Lease, Notice of Lease and Subordination, Nondisturbance and Attornment Agreement and copy of Guaranty filed with WilmerHale Valuable Papers files.)

255 STATE STREET

BOSTON, MASSACHUSETTS

LEASE

by and between

255 STATE STREET, LLC
as Landlord

and

SILVER BRIDGE ADVISORS LLC
as Tenant

dated as of
October 5, 2010

255 STATE STREET

LEASE

Table of Contents

EXHIBITS:

ARTICLE 1
Reference Data

1.1 Subject Referred To.

Each reference in this Lease to any of the following subjects shall be construed to incorporate the data stated for that subject in this Section 1.1.

Date of this Lease:	October 5, 2010
Building:	The building (the "Building") in the City of Boston being located on a parcel of land described in Exhibit A attached hereto and commonly known as 255 State Street.
Property:	Collectively, the Building and the land on which the Building is located.
Landlord:	255 State Street, LLC, a Delaware limited liability company
Original Notice Address of Landlord:	c/o Pembroke Real Estate, Inc. 255 State Street Boston, MA 02109 With a copy to: FMR LLC 82 Devonshire Street Boston, MA 02109 Attn: Real Estate Counsel
Tenant:	Silver Bridge Advisors, LLC, a Delaware limited liability company
Original Notice Address of Tenant:	Silver Bridge Advisors, LLC 60 State Street Boston, MA 02109 With a copy to Guarantor: Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 Attn: Managing Partner

Premises:	A portion of the sixth (6th) floor of the Building, substantially as shown on the plans attached hereto as Exhibit B.	
Rentable Area of the Premises:	15,981 square feet of Rentable Area.	
Rentable Area of the Building:	221,033 square feet of Rentable Area.	
Original Term:	The period beginning on the Commencement Date and ending on the Expiration Date, both dates inclusive, subject to Section 2.3 and Article 13.	
Extension Option:	Tenant has the right to extend the Original Term for one (1) additional period of five (5) years, in accordance with and subject to Section 2.3.	
Commencement Date:	October 5, 2010	
Rent Commencement Date:	August 1, 2011	
Expiration Date:	December 31, 2016	
Allowance:		
Annual Fixed Rent Rate and Monthly Fixed Rent Rate:		
Period of Time:	Annual Fixed Rent Rate:	Monthly Fixed Rent Rate:
August 1, 2011 - December 31, 2012		
January 1, 2013 - December 31, 2014		
January 1, 2015 - December 31, 2016		
Base Operating Costs:	An amount equal to the Operating Costs payable for calendar year 2011.	
Base Taxes:	An amount equal to the Taxes payable for fiscal year 2011, which commenced on July 1, 2010 and expires on June 30, 2011.	

Tenant's Percentage:	7.23%, i.e. the ratio of the Rentable Area of the Premises to the total Rentable Area of the Building.
Permitted Use:	First-class general business offices and no other purpose or purposes.
Commercial General Liability Insurance Limits:	$3,000,000.00 per occurrence $5,000,000.00 general aggregate
Brokers:	Cushman & Wakefield of Massachusetts, Inc. and Richards Barry, Joyce & Partners
Guarantor:	Wilmer Cutler Pickering Hale and Dorr LLP

1.2 Exhibits

The Exhibits listed in the Table of Contents and attached hereto are incorporated in this Lease by reference and are to be construed as a part of this Lease.

1.3 Definitions

For the purposes of this Lease, the following terms shall be as defined below or as defined in the Section of this Lease referenced below:

"ADA" shall mean the Americans with Disabilities Act of 1990, 42 U.S.C. §12101 et seq., as amended and modified from time-to-time, together with the regulations and guidelines promulgated thereunder.

"Additional Rent" shall mean all sums other than Fixed Rent payable by Tenant to Landlord under this Lease, including Tenant's Percentage of the Tax Excess, Tenant's Percentage of the Operating Costs Excess, late charges, overtime or excess service charges, and interest and other costs related to Tenant's failure to perform any of its obligations under this Lease.

"Allowance" shall be as defined in Section 1.1.

"Annual Fixed Rent Rate" shall be as defined in Section 1.1.

"Base Operating Costs" shall be as defined in Section 1.1.

"Base Taxes" shall be as defined in Section 1.1.

"Broker" shall be the broker or brokers listed in Section 1.1.

"Building" shall be as defined in Section 1.1.

"Building Holidays" shall mean New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and such other days which are observed from time-to-time by the Commonwealth of Massachusetts, the City of Boston, the labor unions servicing the Building, and Landlord with respect to the Building,

"Capital Expenditures" shall be as defined in Section 4.2.3(d).

"Commencement Date" shall be as defined in Section 1.1.

"Condenser Water Charge" shall be as defined in Section 5.1.1.

"Construction Documents" shall be as defined in Section 3.3(a).

"Default Rate" shall mean a fluctuating interest rate per annum equal to the lesser of (a) 3% above the Prime Rate, or (b) the maximum legally permitted rate.

"Environmental Laws" shall be as defined in Section 6.2.3.

"Event of Default" shall be as defined in Article 8.

"Extension Term" shall be as defined in Section 2.3(a).

"Fair Rental Value" shall be as defined in Section 2.3(c).

"Fixed Rent" shall mean the fixed rent payable at the Annual Fixed Rent Rate and the Monthly Fixed Rent Rate, respectively.

"Force Majeure Event" shall be as defined in Section 11.5.

"Hazardous Materials" shall be as defined in Section 6.2.3.

"Hazardous Materials Activities" shall be as defined in Section 6.2.3.

"Improved Space" shall mean the Premises or the portion thereof which is improved in connection with the initial build-out of the Premises.

"Landlord" shall be as defined in Sections 1.1 and 11.4.

"Landlord Affiliate" shall mean any entity controlled by, controlling or under common control with Landlord.

"Landlord's Contribution" shall be as defined in Section 3.2.

"Landlord's Engineers" shall be as defined in Section 3.3(a).

"Landlord Plan Notice" shall be as defined in Section 3.3(b).

"Latent Defects" shall mean material defects in the Premises which materially and adversely affect Tenant's use of the Premises, which defects are not, despite the exercise

of commercially reasonable efforts by Tenant, susceptible of being detected (and are not detected) at the time of delivery of the Premises to Tenant.

"Lease" shall mean this lease, as amended and in effect from time to time.

"Lease Year" shall mean each successive twelve (12) month period during the Term, with the first such Lease Year commencing on the Rent Commencement Date and each successive Lease Year commencing on the next succeeding anniversary of the Rent Commencement Date.

"Monthly Fixed Rent Rate" shall be as defined in Section 1.1.

"Normal Business Hours" shall mean from 8:00 a.m. to 6:00 p.m. Monday through Friday and from 9:00 a.m. to 1:00 p.m. on Saturdays, except on Building Holidays.

"Operating Costs" shall be as defined in Section 4.2.3(b).

"Operating Costs Excess" shall be as defined in Section 4.2.3(a).

"Original Notice Address of Landlord" shall be as defined in Section 1.1.

"Original Notice Address of Tenant" shall be as defined in Section 1.1.

"Original Term" shall be as defined in Section 1.1.

"Outside Services" shall be as defined in Section 5.3.

"Permitted Uses" shall be as defined in Section 1.1.

"Premises" shall be as defined in Section 1.1.

"Prime Rate" shall mean the prime rate published (or the highest published prime rate if more than one is published) by the Wall Street Journal (or if such publication ceases, a comparable substitute reasonably designated by Landlord).

"Property" shall be as defined in Section 1.1.

"Rent" shall be as defined in Section 4.1(a).

"Rent Commencement Date" shall be as defined in Section 1.1.

"Rentable Area" shall mean with regard to any area, the rentable area thereof as determined by Landlord from time-to-time.

"Rentable Area of the Premises" shall be as defined in Section 1.1.

"Rules and Regulations" shall be as defined in Section 6.1.10.

"Specialty Alterations" shall mean Alterations which are not standard office installations such as kitchens, executive bathrooms, raised computer floors, computer room installations, supplemental HVAC equipment, safe deposit boxes, vaults, libraries or file rooms requiring reinforcement of floors, internal staircases, slab penetrations, conveyors, dumbwaiters, print rooms and model shops, and other Alterations of a similar character.

"Stairway/Common Area Work" shall be as defined in Section 3.2.

"Successor Landlord" shall be as defined in Section 9.1(b).

"Tax Excess" shall be as defined in Section 4.2.1(a).

"Taxes" shall be as defined in Section 4.2.1(d).

"Tax Year" shall mean any calendar year all or part of which occurs during the term.

"Tenant" shall be as defined in Section 1.1.

"Tenant's Architect" shall be as defined in Section 3.3(a).

"Tenant's Percentage" shall be as defined in Section 1.1.

"Tenant's Work" shall be as defined in Section 3.1.

"Term" shall mean the Original Term, subject to Article 13; and, if Tenant validly exercises the option to extend the Term in accordance with the provisions of Section 2.3, "Term" shall mean the Original Term and the Extension Term, collectively.

ARTICLE 2
Premises and Term

2.1 Premises.

(a) Landlord hereby leases to Tenant and Tenant hereby leases from Landlord, for the Term, subject to and with the benefit of the terms, covenants, conditions and provisions of this Lease, the Premises. Not included in the Premises are the roof, exterior walls, the common stairways, stairwells, elevators and elevator shafts, and pipes, ducts, conduits, wires, and appurtenant fixtures serving exclusively or in common other parts of the Building, and if the Premises consist of less than the entire rentable area of any floor, the central core area of such floor, if any.

(b) Tenant shall have, as an appurtenance to the Premises, rights to use in common with others, subject to reasonable rules and regulations established from time-to-time by Landlord of which Tenant is given notice: (1) the common lobbies, hallways, stairways, loading docks and bays, and elevators of the Building; (2) common walkways necessary for access to the Building; and (3) if

the Premises consist of less than the entire rentable area of any floor, the common toilets and other common facilities in the central core area of such floor.

(c) Landlord reserves the right from time-to-time the following rights: (1) to install, use, maintain, repair, replace and relocate for service to the Premises and/or other parts of the Building the areas within the Premises above the dropped ceiling and below the floor for pipes, ducts, conduits, wires and appurtenant fixtures, (2) to alter or relocate any other common facility, (3) to make any repairs and replacements to the Premises which Landlord is obligated to perform, and (4) in connection with any excavation made upon adjacent land of Landlord or others, to enter and to permit others to enter, upon the Premises to do such work as the person causing such excavation deems necessary to preserve the walls of the Building from injury or damage and to support the same.

(d) In connection with the exercise of the foregoing rights of access (excepting routine access such as access for providing cleaning, repair or maintenance services, or other usual and customary services) Landlord shall provide Tenant notice pursuant to Section 6.1.6 and exercise reasonable efforts (i) to minimize interference with the usual and customary operations of the Tenant in the Premises in accordance with the provisions of this Lease, and (ii) to cause any construction work performed in the Premises to be performed in a workmanlike manner.

(e) As an appurtenance to the Premises, for the period of time through October 31, 2013, Tenant shall receive four (4) parking passes for use in the Boston Harbor Garage. Tenant will pay to Landlord, as Additional Rent, the rate established by the operator of the Boston Harbor Garage from time to time for such parking passes. If, at any time, including, without limitation during any portion of the Term after October 31, 2013, such parking passes are not available in the Boston Harbor Garage, then Landlord shall provide Tenant with four (4) parking passes for use at a comparable parking garage located within a four (4) block radius of the Building, and Tenant will pay to Landlord, as Additional Rent, the rate established by the operator of such garage from time to time for such parking passes.

(f) Tenant shall have, as an appurtenance to the Premises, subject to reasonable rules and regulations established from time-to-time by Landlord and notice of which is provided to Tenant, the right to install, operate, and maintain an antenna, satellite dish or similar telecommunication equipment on the roof of the Building, together with lines and cables connecting such equipment in the existing risers of the Building (collectively, the "Rooftop Equipment"). All Rooftop Equipment (including, the size, location, weight and manner of attachment thereof) and any penetrations of, or changes, alterations or other improvements on or to the roof of the Building, shall be subject to the prior approval of Landlord in each instance, such approval not to be unreasonably withheld. Tenant shall be solely and exclusively responsible for all costs, expenses and charges, of every kind, of installing, operating, maintaining, repairing, replacing, and removing the

Rooftop Equipment and Landlord shall have no liability or obligation in connection therewith. If, in the reasonable judgment of Landlord, any electrical, electromagnetic, radio frequency or other interference shall result from the operation of any of the Rooftop Equipment, and such interference has not been corrected to the reasonable satisfaction of Landlord within thirty (30) days after notice thereof to Tenant (which notice shall be accompanied by a reasonably detailed technical analysis as to the basis of Landlord's judgment), then Landlord may require that Tenant immediately remove from the specific item of equipment causing such interference. Tenant shall, at its sole cost and expense, and at its sole risk, install, operate and maintain the Rooftop Equipment in a good and workmanlike manner, and in compliance with all electric, communication, and safety codes, ordinances, standards, regulations and requirements, now in effect or hereafter promulgated, including those established by the Federal Communications Commission (the "FCC"), the Federal Aviation Administration ("FAA") or any successor agency of either the FCC or FA A, the City of Boston, and the rules and regulations adopted in FCC document OET 65 (which rules and regulations have also been adopted by OSHA). Landlord shall not be liable to Tenant for any stoppages or shortages of electrical power furnished to the Rooftop Equipment or to the roof area as a result of any act, omission or requirement of the public utility serving the Building, or the act or omission of any other tenant, invitee or licensee or their respective agents, employees or contractors, or for any other Force Majeure Event. Neither Landlord nor its agents shall have any responsibility or liability for the conduct or safety of any of Tenant's representatives, repair, maintenance and engineering personnel while in or on any part of the roof area. Tenant shall have no right of access to the roof of the Building unless Tenant has given Landlord reasonable advance notice and unless Tenant's representatives are accompanied by a representative of Landlord. Landlord will make a representative available to Tenant (i) during Ordinary Business Hours upon reasonable advance notice and (ii) during emergencies, as soon as practicable (taking into account the circumstances) after receipt of a request from Tenant. At the expiration or prior termination of this Lease, Tenant shall remove all of the Rooftop Equipment (including all cables and conduits installed in connection therewith) and shall be responsible for the cost of repairing any damage to the Building caused by the installation or the removal of the Rooftop Equipment. Landlord shall have the right, upon thirty (30) days notice to Tenant, relocate the Rooftop Equipment to another area on the roof of the Building equally suitable for Tenant's use. In such event, Landlord may, at its sole cost and expense, relocate the Rooftop Equipment.

2.2 Term. The Original Term shall begin on the Commencement Date and shall continue to the Expiration Date, unless sooner terminated as hereinafter provided. When the Commencement Date, Rent Commencement Date, and Expiration Date have been determined, Landlord and Tenant shall execute and deliver a Commencement Date Agreement, in the form attached hereto as Exhibit C, confirming the Commencement Date, Rent Commencement Date, and the Expiration Date.

2.3 Extension Option. (a) Provided that as of the date of the Extension Notice (as hereinafter defined) and as of the commencement of the Extension Term (i) this Lease is in full force and effect, (ii) the original Tenant or any Permitted Assignee (as defined in Section 6.2.1) named herein is in occupancy of the entire Premises, (iii) Tenant is not in default beyond any applicable grace period, and (iv) Tenant has not assigned this Lease or sublet all or any part of the Premises, Tenant shall have the right to extend the term of this Lease for one (1) additional period of five (5) years, such period to begin immediately upon the expiration of the Original Term of this Lease (the "Extension Term"). All of the terms, covenants and provisions of this Lease shall apply to such Extension Term, except that (x) the Annual Fixed Rent Rate for the Extension Term shall be equal to 95% of the Fair Rental Value of the Premises at the commencement of such Extension Term, as determined pursuant to this Section 2.3, and (y) Landlord shall have no obligation to make any alterations or improvements to the Premises, or to provide any allowances, inducements or other payments of any kind to Tenant in connection therewith. If Tenant shall elect to exercise the aforesaid option, it shall do so by giving Landlord notice (an "Extension Notice") in writing of its intention to do so not later than twelve (12) months prior to the expiration of the Original Term of this Lease. Accordingly, if Tenant fails timely to exercise its option for the Extension Term and to deliver the Extension Notice on or before the exercise date specified above, then Tenant shall have no further right or option to extend the term of this Lease hereunder or otherwise.

(b) If Tenant timely and properly gives such Extension Notice with regard to the Extension Term, the Term of this Lease shall be automatically extended for the Extension Term without the execution of any additional documents, unless Tenant rescinds such Extension Notice in accordance with the terms and conditions provided in Section 2.3(d). Without limiting the foregoing, if Tenant elects to exercise its option to extend the Term for the Extension Term, in accordance with this Section 2.3 and the foregoing conditions precedent are fully and completely satisfied, and Tenant does not rescind its Exercise Notice as provided in Section 2.3(d), then Landlord and Tenant shall enter into an amendment to this Lease to confirm such exercise and to document all modifications to this Lease resulting from the exercise of such option; provided, however, the execution of such amendment shall not be a condition precedent to the valid exercise by Tenant of the extension option granted herein.

(c) For the purposes hereof, the "Fair Rental Value" of the Premises shall mean the fair rental value thereof that would be agreed upon between a landlord and a tenant executing a lease renewal or extension with respect to comparable space in a comparable building located in Boston, Massachusetts for a comparable term, upon all of the other business terms of this Lease, assuming the following:

(i) the landlord and tenant are well informed and well advised and each is acting in what it considers to be its own best interests;

(ii) the rental shall reflect the location of the Building, the condition of the Premises and all residual value of any improvements to the Premises; and

(iii) the transaction takes into consideration the Additional Rent to be paid by Tenant and all applicable brokerage commissions.

(d) Landlord will deliver a written notice (the "Fair Market Value Notice") to Tenant setting forth the Landlord's determination of the Fair Market Value within ten (10) business days after receipt of the Exercise Notice. If Tenant disagrees with Landlord's designation of the Fair Rental Value, and the parties cannot agree thereon, then within thirty (30) days after receipt of the Fair Market Value Notice, Tenant shall notify Landlord of such disagreement and the Fair Rental Value shall be determined by the appraisal process set forth in Article 10 hereof. Notwithstanding anything to the contrary contained herein, upon receipt of the Fair Market Value Notice, Tenant shall have ten (10) business days to notify Landlord (a "Rescission Notice") that Tenant rescinds its exercise of its right to extend pursuant to this Section 2.3. If Tenant fails to timely and properly give such Rescission Notice, then the Term of this Lease shall be automatically extended for the Extension Term without the execution of any additional documents.

(e) If Tenant exercises its right of appraisal and the appraisal has not been concluded at the commencement of the Extension Term, Tenant shall pay annual Fixed Rent at the rate in effect on the last day of the Original Term (with a reconciliation and any required adjustment promptly upon the determination of Fair Rental Value for the Extension Term as provided herein) and Additional Rent as provided in Section 4.2 hereof. If the Fair Rental Value as determined by appraisal is greater than or less than Fair Rental Value as determined by Landlord, then any adjustment required to correct the amount previously paid shall be made by payment by the appropriate party ten (10) days after such determination of Fair Rental Value.

(f) Time is of the essence of this Section 2.3.

2.4 Right of First Offer.

(a) ROFO Rights. If at any time between the first (1st) anniversary of the Commencement Date and the date which twelve (12) months prior to the Expiration Date (as the same may be extended pursuant to Section 2.3), Landlord in its sole discretion determines that any separately demised rentable area on the sixth (6th) floor of the Building (each such area, a "ROFO Space") has become "available for leasing" (as hereinafter defined), and provided that the conditions precedent set forth in Section (c) below are then satisfied, then prior to offering to lease such ROFO Space to any third parties, Landlord shall deliver notice thereof to Tenant (the "ROFO Notice") setting forth a description of the ROFO Space in question (including the rentable area thereof), the Landlord's determination of Annual Fixed Rental Rate and Additional Rent for such ROFO Space, the other

material business terms upon which Landlord is willing to lease the ROFO Space, including, without limitation, that the lease term with respect to the ROFO Space shall be co-terminus with the expiration of the Term of this Lease, as the same may be extended or terminated as provided in this Lease, and the date Landlord anticipates that the ROFO Space will become available for leasing. Provided that all of the conditions precedent set forth in this Section 2.4 are fully satisfied by Tenant, Tenant shall have the option (the "ROFO Option"), exercisable by Tenant delivering written notice (the "Acceptance Notice") to Landlord within twenty (20) calendar days after delivery by Landlord of the ROFO Notice, to lease all of the subject ROFO Space upon all of the terms and conditions set forth in the ROFO Notice, including the Annual Fixed Rental Rate and Additional Rent for the ROFO Space designated by Landlord as set forth therein. Time shall be of the essence as to Tenant's giving of the Acceptance Notice with respect to any ROFO Space.

If (a) Tenant fails to deliver an Acceptance Notice within such twenty (20) day period, or (b) if Tenant timely delivers an Acceptance Notice as aforesaid but does not execute and deliver a final fully executed amendment to this Lease with respect to the leasing of the ROFO Space, in form and substance reasonably satisfactory to Landlord, within thirty (30) days after delivery by Landlord of the proposed lease amendment to Tenant, which lease amendment shall, inter alia, contain the same terms as those set forth in the ROFO Notice, then Tenant shall be deemed to have rejected the option to lease the applicable ROFO Space (the "Rejected ROFO Space"). In such event, except as expressly and specifically provided in Section 2.4(f), Tenant shall have no further rights or claims with respect to the Rejected ROFO Space, Landlord shall have no further liabilities or obligations to Tenant with respect to the Rejected ROFO Space, and Landlord may elect to lease the Rejected ROFO Space to third parties upon such terms and conditions as Landlord may determine in its discretion.

(b) Available for Leasing, etc. For purposes of this Section 2.4, space shall be deemed "available for leasing" when Landlord has determined in its discretion that (a) the space is vacant, or (b) the respective tenant or occupant which first leases the subject ROFO space after the date of this Lease will not extend or renew the terms of its lease or other occupancy agreement for the ROFO Space and that said tenant or occupant is not interested either in extending or renewing its lease or other occupancy agreement for the ROFO Space or in entering into a new lease for such ROFO Space. For purposes of this Section 2.4, space shall not be deemed "available for leasing" if, at the time in question (a) any person or entity leases or occupies the ROFO Space, whether pursuant to a lease or other agreement (unless such person or entity confirms to the satisfaction of Landlord that it does not intend to extend or renew the term of the lease or other occupancy agreement for the ROFO space or enter into a new lease for such ROFO Space) or (b) any person or entity holds any option or right to lease or occupy the ROFO Space, or to renew its lease or right(s) of occupancy thereof, or any other rights or claims thereto. Without limitation, so long as a tenant or other occupant leases or occupies all or a portion of the ROFO Space, Landlord shall be free to extend or

renew any such tenancy or occupancy, whether or not pursuant to a lease or other agreement, and such space shall not be deemed to be "available for leasing." In no event shall Landlord be liable to Tenant for any failure by any then existing tenant or occupant to vacate any ROFO Space by any particular date. Nothing set forth in this Section 2.4 shall be construed to keep space in the Building vacant if Landlord elects, in its sole discretion, to do so, and such vacant space shall in no event be deemed to be "available for leasing" hereunder. Landlord represents and warrants that, as of the date of this Lease, no other person or entity has any option or right to lease or occupy the ROFO Space.

(c) Conditions. Landlord shall have no obligation to deliver a ROFO Notice and Tenant shall have no right to exercise any ROFO Option unless all of the following conditions have been satisfied both on the date of the Acceptance Notice and on the ROFO Space Commencement Date (as hereinafter defined): (a) No Event of Default shall exist under this Lease; and (b) the original Tenant named herein or a Permitted Assignee is occupying the entire Premises then demised under this Lease.

(d) Terms. Effective as of the date on which Landlord delivers the ROFO Space to Tenant (the "ROFO Space Commencement Date"):

(i) The ROFO Space shall be added to and be deemed to be a part of the Premises for all purposes under this Lease (except as otherwise provided in this Section 2.4);

(ii) The ROFO Space shall be delivered in broom-clean condition, free of all tenants and occupants and otherwise in its "as is" condition; Landlord shall not be obligated to perform any work or improvements or to provide any allowances or inducements with respect thereto;

(iii) Annual Fixed Rental Rate, Monthly Fixed Rental Rate, and Additional Rent for the ROFO Space shall be as set forth in the ROFO Notice; and

(iv) Tenant shall pay all Additional Rent payable under this Lease with respect to the applicable ROFO Space, except to the extent that any such Additional Rent is included in the amounts payable under clause (iii) above.

(e) Amendment. If Tenant exercises the ROFO Option, upon request made by Landlord, Tenant will execute, acknowledge and deliver to Landlord an amendment to this Lease confirming the ROFO Space Commencement Date, Annual Fixed Rental Rate, Monthly Fixed Rental Rate, and Additional Rent payable with respect to the ROFO Space, the incorporation of the ROFO Space into the Premises, and the modifications to this Lease resulting therefrom, as provided in subsection (d). The failure of either party to execute and deliver such an amendment shall not affect the rights, liabilities or obligations of the parties with respect to the ROFO Space.

(f) Reoffer. The ROFO Option of Tenant hereunder with respect to each respective ROFO Space shall terminate and expire on the earlier to occur of (a) Tenant's failure to exercise its Right of First Offer within the twenty (20) day period provided above or to execute and deliver a lease amendment within the thirty (30) day period provided above, or (b) the date Landlord would have provided Tenant a ROFO Notice if Tenant had satisfied all of the conditions set forth in Section 2.4(c) above. Notwithstanding the foregoing, if (i) Tenant was entitled to exercise its ROFO Option but failed to deliver an Acceptance Notice within the twenty (20) day period provided above, or to execute and deliver a lease amendment within the thirty (30) day period provided above, and (ii) either (x) Landlord does not enter into a lease for the respective ROFO Space within a period of twelve (12) months following the date of the ROFO Notice, or (y) thereafter prior to entering into a lease (or leases) for such ROFO Space Landlord proposes to lease the respective ROFO Space to a prospective tenant on terms that are "materially more favorable" than those set forth in the ROFO Notice previously delivered to Tenant, then in either situation Tenant's rights with respect to the respective ROFO Space shall be revived and Tenant shall once again have a ROFO Option with respect to the respective ROFO Space. For purposes hereof, the terms offered to a prospect shall be deemed to be "materially more favorable" from those set forth in the ROFO Notice if there is a reduction of more than seven and one half percent (7.5%) in the "bottom line" cost per rentable square foot of the ROFO Space to the prospective tenant, when compared with the "bottom line" cost per rentable square foot for the ROFO Space under the ROFO Notice, determined by considering all of the economic terms of both proposals, respectively, including, among other relevant factors, the fixed rent, the tax and expense escalation, the additional rent, any free rent periods, and any other concessions and allowances.

(g) Expiration. Notwithstanding any provision contained herein to the contrary, if and when the date which is twelve (12) months prior to then-scheduled Expiration Date of the Term of this Lease occurs (as such expiration date may be extended pursuant to Section 2.3 of this Lease), then, except for the remainder of any time period hereunder for response by Tenant to a ROFO Notice previously delivered to Tenant or the tendering of an amendment after delivery of an Acceptance Notice prior to such date, this Section 2.4 shall become null and void and of no further force or effect and Tenant shall have no further ROFO Options or other rights to lease any ROFO Space pursuant to this Section 2.4. In such event, all of the obligations of Landlord to offer any ROFO Space to Tenant shall be considered to have been fully and completely satisfied, and neither Landlord nor Tenant shall have any further rights, liabilities or obligations under this Section 2.4.

(h) Time is of the essence of this Section 2.4.

2.5 Guaranty. Concurrent with the execution of this Lease, Guarantor has executed and delivered to Landlord the Guaranty (the "Guaranty") in the form attached

hereto as Exhibit G. The Guaranty shall remain in full force and effect throughout the Term.

ARTICLE 3
Condition of Premises; Tenant's Work

3.1 Condition of Premises. Landlord shall deliver possession of the Premises to Tenant on the Commencement Date free of all tenants and occupants and otherwise in compliance with this Lease. Tenant has inspected the Premises and agrees (a) to accept possession of the Premises in the condition existing as of the Commencement Date, in "as is" condition, excepting only Latent Defects, (b) that neither Landlord nor any of Landlord's agents have made any representations or warranties with respect to the Premises or the Building, and (c) except for payment of the Allowance and the Landlord's Contribution, Landlord has no obligation to perform any work, supply any materials, incur any expense or make any alterations, additions or improvements to the Premises to prepare the Premises for Tenant's use and occupancy. Tenant shall notify Landlord promptly after it becomes aware of any Latent Defects. If Tenant does not notify Landlord, of a Latent Defect within one hundred twenty (120) days after the Commencement Date, then Landlord shall have no further liabilities or obligations of any kind, in connection therewith. Latent Defects shall include only defects in the Premises, and in no event shall Latent Defects include defects of any kind or description in or with respect to the Building and/or the Building systems. Promptly after the Commencement Date, Tenant shall, at its own cost and expense, in accordance with and subject to the terms and provisions of this Lease, perform or cause to be performed any and all work necessary to prepare the Premises for Tenant's initial occupancy, The Building is equipped with telecommunications systems for RCN and Verizon. Landlord shall provide Tenant and/or Tenant's telecommunications companies with the access to the existing conduits and chases of the Building for the installation and operation of Tenant's telecommunication systems, including but not limited to voice, video, data and other telecommunications services; provided, however, that any such access, installation and operation shall be subject to Landlord's prior approval in each case, which approval will not be unreasonably withheld, conditioned or delayed. Tenant's occupancy of any part of the Premises shall be conclusive evidence, that Tenant has accepted possession of the Premises in its then-current condition, and that at the time such possession was taken, the Premises and the Building were in a good and satisfactory condition as required by this Lease.

3.2 Tenant's Work; Landlord's Contribution. The "Tenant's Work" shall mean all alterations and improvements performed by Tenant in connection with the initial build-out of the Premises, excluding the Stairway/Common Area Work which shall be designed by Landlord's architect and engineers and performed by Tenant's contractor subject to reimbursement by Landlord as provided below. Landlord has provided Tenant with the architectural and engineering plans listed on the schedule attached hereto as Exhibit J (the "Stairway/Common Area Work Plans") for the following work (collectively, the "Stairway/Common Area

Work"): (i) the removal of the interior stairway between the sixth (6th) and seventh (7th) floors of the Building, (ii) the construction of the demising walls and common corridors separating the Premises from the remaining balance of the sixth (6th) floor, (iii) the stubbing of utilities and other systems as necessary to separately demise the remainder of the sixth floor from the Premise, and (iv) the construction of the common elevator lobby area on the sixth (6th) floor of the Building. Tenant shall engage in a competitive bidding process for general contractors to perform the Stairway/Common Area Work, share on an "open-book" basis the results of the bidding process with Landlord and, after approval of the bid therefor by Landlord (such approval not to be unreasonably withheld, conditioned or delayed), have Tenant's contractor perform the Stairway/Common Area Work concurrent with the performance of the Tenant's Work in accordance with the provisions of this Article 3 (subject to the obligation of Landlord to provide the Landlord's Contribution as hereinafter defined). The "Landlord's Contribution" shall mean the sum of (i) the hard construction costs of performing the Stairway/Common Area Work, as set forth on the bid therefore approved by Landlord, (ii) the fees payable to any mechanical, electrical, plumbing and/or structural engineers designated by Landlord to assist in the performance of the Stairway/Common Area Work to the extent not paid directly by Landlord, and (iii) the Landlord's Share of the General Conditions Charges (as hereinafter defined). The "Landlord's Share of the General Conditions Charges" shall mean the general conditions and overhead and profit charges imposed by the Tenant's contractor in connection with the performance of both the Tenant's Work and the Stairway/Common Area Work, as set forth on the bid therefore approved by Landlord, multiplied by a fraction, the numerator of which is the hard construction costs of performing the Stairway/Common Area Work (as set forth on said approved bid) and the denominator of which is the total hard construction cost of performing both the Tenant's Work and the Stairway/Common Area Work (as set forth on said approved bid); provided, however, if Landlord requests changes to the Stairway/Common Area Work as shown on the Stairway/Common Area Work Plans after the date of delivery of the Stairway/Common Area Work Plans to Tenant for inclusion in the Tenant's competitive bidding process (a "Stairway/Common Area Work Change"), then Landlord shall pay for the full amount of the general conditions and overhead and profit charges imposed by the Tenant's contractor in connection with the performance of such Stairway/Common Area Work Change. If Tenant requests a Change Order (as defined below), then Tenant shall pay for the full amount of the general conditions and overhead and profit charges imposed by the Tenant's contractor in connection with the performance of such Change Order. The Stairway/Common Area Work is to be performed by Tenant's contractor and reimbursed by Landlord, but such Stairway/Common Area Work shall be without any warranty by Tenant.

3.3 Plans and Specifications. (a) Landlord has approved the final construction documents for the Tenant's Work which are listed on the schedule attached hereto as Exhibit I (such documentation and the constituent items thereof are referred to herein collectively as the "Construction Documents"). Landlord has also

approved PHP Partners as Tenant's Architect. Tenant has submitted to Landlord and Landlord's architect (i) four (4) sets of paper versions of the Construction Documents, and (ii) electronic versions of the Construction Documents in AutoCad (dwg) format prepared by Tenant's Architect. The Tenant's Work shall be performed in accordance with the Construction Documents and the "Standard Tenant Fit-Out Specifications for 255 State Street" attached hereto as Exhibit F and incorporated herein by this reference (as the same may be updated, amended, modified and supplemented by Landlord from time-to-time, the "Standard Tenant Fit-Out Specifications"). There shall be no requirement for Tenant to use any particular building standard materials or items; however, the Tenant's Work shall be first-class in all respects and shall be consistent with and complementary to the first-class standards of the Building. Landlord has retained, at its sole cost and expense, the services of the mechanical, electrical, plumbing and structural engineers designated by Landlord ("Landlord's Engineers") to assist in the performance of the Stairway/Common Area Work. Tenant shall cause Tenant's Architect to perform all architectural services typically and reasonably required under typical construction contracts for similar leasehold improvements. Such services shall include, without limitation, all certifications typically and reasonably required to be provided by the architect for similar leasehold improvements in order to obtain a certificate of occupancy for the Premises. Tenant shall be solely responsible for the cost of all architectural and engineering services required for the Tenant's Work. The Construction Documents for Tenant's Work shall comply with all applicable laws, ordinances and regulations (including, without limitation, the applicable requirements of the Americans with Disabilities Act of 1990, as amended from time to time, and the regulations promulgated thereunder (collectively, the "ADA")) and shall be in a form satisfactory to appropriate governmental authorities responsible for issuing the permits, approvals and licenses required for construction of Tenant's Work. Landlord shall cause Landlord's architect and engineers to be available for meetings as reasonably necessary in connection with matters relating to the Stairway/Common Area Work. Landlord shall be solely responsible for the cost of all architectural and engineering services required for the Stairway/Common Area Work. Landlord's Architect shall be solely responsible for causing the design of the Stairway/Common Area Work to comply with all applicable laws, ordinances and regulations (including, without limitation, the applicable requirements of the ADA) and, to the extent applicable, to be in a form satisfactory to appropriate governmental authorities responsible for issuing the permits, approvals and licenses required for construction of the Stairway/Common Area Work. Tenant's interior furnishings (i.e., specifications, coordination, supply and installation of furniture, furnishings, telephone and moveable equipment) will be the responsibility of Tenant. Tenant will be responsible for obtaining all permits and approvals for the Tenant's Work, including, without limitation, a building permit and all applicable electrical and plumbing permits from the City of Boston Department of Inspectional Services.

(b) All requests for amendments, changes, change orders, or alterations to the Construction Documents (each, a "Change Order") shall require Landlord's

approval, which approval shall not be unreasonably withheld or conditioned and shall be given within the timeframe set forth below (it being understood that any denial shall state Landlord's objections with specificity so that they may be addressed by Tenant). Landlord's approval process for a requested Change Order will also include review of Tenant's fire protection design by Factory Mutual Global representing Landlord's insurance underwriter. Landlord will give Tenant notice (a "Landlord Plan Notice") of any objections it may have with respect to any requested Change Order within five (5) business days after receipt by Landlord and Landlord's Architect of four (4) sets of paper versions of the applicable Construction Documents affected by such Change Order and an electronic version of such Construction Documents. Landlord shall not be deemed unreasonable for withholding approval of any such Change Order which (i) involve or are reasonably anticipated to affect any structural or exterior element of the Building or any portion thereof, (ii) are anticipated to, in Landlord's reasonable opinion, materially adversely affect the value of the Building or any portion thereof, (iii) are reasonably anticipated to materially adversely affect the proper functioning of the building systems or other facilities, (iv) will materially increase the cost of construction or insurance on the Building or any portion thereof, or may materially increase the Operating Costs or Taxes, or (v) do not incorporate any changes requested by Factory Mutual Global and contained in the Landlord Plan Notice. Concurrently with its review of proposed Change Orders, Landlord will notify Tenant as to which of the proposed installations and improvements shown on the applicable Change Order constitute Specialty Alterations (as defined in Section 1.3) which Tenant will be required to remove at the expiration of the Term.

(c) Tenant shall cause the Change Order and any affected Construction Documents to be revised in a manner sufficient to remedy Landlord's objections and/or respond to Landlord's concerns and to be redelivered to Landlord as soon as reasonably possible after Tenant is given a Landlord Plan Notice, Tenant shall exercise diligent efforts to revise the applicable Construction Documents to address the objections contained in each Landlord Plan Notice.

(d) Landlord's approval of any plans and specifications with respect to Tenant's Work furnished to and approved by Landlord, or of any changes thereto, shall in no way be deemed an agreement by Landlord that the work contemplated therein fulfills the requirements of Section 3.3(a) hereof. Tenant shall be responsible for the design of the Tenant's Work. Landlord shall be responsible for the design of the Stairway/Common Area Work.

3.4 Performance of TIW; Tenant's Contractor. Tenant agrees to employ for the Tenant's Work a responsible general contractor approved by Landlord, which general contractor shall (1) employ and hire subcontractors who employ union labor to do all union trade work, (2) employ and hire subcontractors who employ labor which will work without interference with other labor working in the Building for any work that is not union trade work, and (3) obtain and maintain the insurance required by Section 6.2.5 of this Lease. Landlord hereby consents

to Tenant's selection of any of Structuretone, Turner Construction, Jones Lang LaSalle or Commodore Construction as Tenant's general contractor, Tenant shall submit certificates evidencing such insurance coverage to Landlord prior to the commencement of the Tenant's Work. Tenant shall obtain all necessary governmental licenses, approvals and permits therefor and deliver to Landlord the statements and insurance certificates required hereunder and under 6.2.5 of this Lease on or before the commencement of the Tenant's Work. Promptly thereafter (subject to delays to the extent caused by Force Majeure Events, provided that tenant uses diligent efforts to minimize the duration and extent of the affect of such Force Majeure Event), Tenant shall commence and diligently prosecute to completion the Tenant's Work in accordance with the Construction Documents in a good and workmanlike manner employing materials of good quality and in compliance with all applicable zoning, building, fire, health and other codes, regulations, ordinances and laws. Tenant shall be responsible for all costs and expenses of performing Tenant's Work, subject to the obligations of Landlord to provide the Landlord's Contribution and the Allowance. The Tenant's Work shall otherwise be performed in accordance with the applicable provisions of this Lease, including, without limitation, the provisions of Section 6.2.5; provided, however, in the event of any conflict or inconsistency between the provisions of this Section 3.4 and Section 6.2.5 of this Lease the terms Of this Section 3.4 shall govern and control. Tenant shall provide a project manager who will be the point of contact with Landlord's Project Manager for all matters dealing with the design and construction of the Tenant's Work. Landlord hereby designates Tom Walsh as "Landlord's Project Manager."

3.5 Funding of Landlord's Contribution and Allowance.

(a) Landlord agrees to pay to Tenant (a) the Landlord's Contribution and (b) the Allowance, in accordance with and subject to the requirements and conditions of this Section 3.5; provided, however, as of the date on which Landlord is required to make payment of the Allowance no Event of Default shall have occurred and remains uncured under this Lease. The Landlord's Contribution shall be applied against the costs of performing the Stairway/Common Area Work and the Allowance shall be applied against the costs of performing the Tenant's Work. The costs of the Tenant's Work payable from the Allowance shall include the costs incurred by Tenant for constructing the Tenant's Work; provided, however, up to 20% of the Allowance, may be used for "soft costs," including reasonable architectural, consulting, and engineering fees, moving fees, and for the purchase and installation of telecommunications equipment and cabling, and furniture, trade fixtures and other equipment.

(b) Tenant shall reimburse to Landlord, promptly after receipt of invoices therefor, the costs actually incurred by Landlord in connection with providing supplemental or additional security if reasonably required as a result of the Tenant's Work. In no event shall Landlord be required to disburse the Landlord's Contribution or the Allowance more frequently than monthly. Notwithstanding anything herein to the contrary, Landlord shall not be obligated to disburse any

portion of the Allowance during the continuance of an uncured Event of Default under this Lease, and Landlord's obligation to disburse the Allowance shall resume only when and if such Event of Default is cured.

(c) The Allowance and Landlord's Contribution shall be paid to Tenant or, at Tenant's option, to the order of the Tenant's general contractor, in periodic disbursements within fifteen (15) days after receipt of the following: (i) an application for payment and sworn statement of the contractor substantially in the form of AIA Document G702 covering all work for which disbursement is to be made to a date specified therein; (ii) a certification from the Tenant's Architect substantially in the form of the Architect's Certificate for Payment which is contained in AIA Document G702; (iii) Contractor's, subcontractor's and material supplier's partial waivers of liens covering all Tenant's Work for which disbursement is being requested, together with such invoices, contracts, and other supporting data as Landlord may reasonably require; (iv) to the extent not previously delivered to Landlord, copies of all construction contracts for the Tenant's Work, together with copies of all change orders, if any; and (v) a request from Tenant to disburse the Landlord's Contribution or Allowance, as applicable; provided, however, the final requisition of the Landlord's Contribution and/or the Allowance, as applicable shall not be paid until fifteen (15) days after Landlord's receipt of all of the foregoing, together with the following: (i) a written statement from Tenant's Architect that the Tenant's Work has been completed in accordance with the Construction Documents and in accordance with all applicable laws, codes, and regulations, (ii) final lien waivers executed by Tenant's general contractor and by all subcontractors and suppliers, (iii) a complete set of "as-built" plans and specifications for the Tenant's Work, prepared using electronic AutoCad format, and (iv) a temporary or final unconditional certificate of occupancy for the Premises and all other required governmental approvals for the Tenant's Work; provided, however, if a temporary or conditional certificate of occupancy is delivered, then thereafter Tenant shall exercise diligent efforts to obtain and deliver to Landlord promptly thereafter, a final, unconditional certificate of occupancy for the Premises.

(d) Without limiting Landlord's rights and remedies or Tenant's obligations on account thereof, if arising out of or in connection with the Tenant's Work any lien or encumbrance is filed against the Property or any part or interest therein, and such lien or encumbrance is not discharged, insured or bonded over or otherwise disposed of to the satisfaction of Landlord within ten (10) days after the filing or establishment thereof, then Landlord shall have no further obligation to make any further disbursements of the Allowance unless and until the same is so discharged or otherwise disposed.

(e) Notwithstanding the foregoing, if Tenant submits a valid and proper requisition for payment of the Landlord's Contribution and/or the Allowance, and all of the conditions thereto as set forth above have been timely, fully and completely satisfied in full, and Landlord shall fail timely to pay the amount requested and such failure shall continue for ten (10) days after Tenant provides a

written notice to Landlord which expressly and specifically identifies such failure to pay the amount requested and specifically references this Section 3.5(d), then Tenant shall have the right to set-off such unpaid amount, together with interest at the Default Rate for the period from the date such payment was due until the date of such set-off, against the next monthly installments of Rent payable under this lease.

3.6 Mechanic's Liens. Tenant hereby indemnifies and holds harmless Landlord from and against any liabilities and/or obligations for any and all liens or encumbrances filed against the Property or any part thereof or interest therein arising out of or resulting from the Stairway/Common Area Work (excepting only liens filed by architects or engineers retained by Landlord in connection with the Stairway/Common Area Work), the Tenant's Work or any other work performed by Tenant under this Lease. Tenant, at its expense, shall procure the discharge of all such liens and encumbrances within ten (10) days after the filing of any such lien or encumbrance against the Premises and/or the Property or any part thereof. If Tenant shall fail to cause any such lien or encumbrance to be discharged within such ten (10) day period, then, in addition to any other right or remedy, Landlord may, but shall not be obligated to, discharge the same either by paying the amount claimed to be due or by deposit or bonding proceedings, and in any such event Landlord shall be entitled, if it elects, to compel the prosecution of an action for the foreclosure of such lien and to pay the amount of the judgment in favor of the lien with interest, costs and allowances. Without limiting the foregoing, any amount so paid by Landlord, and all costs and expenses incurred by Landlord in connection therewith, shall constitute Additional Rent under this Lease and shall be paid by Tenant to Landlord on demand. In addition, without limiting the foregoing, if (i) Tenant bonds over or discharges a lien, and (ii) it is subsequently determined in an action or arbitration proceeding, that the lien was filed solely as a result of a failure of Landlord to pay the Landlord's Contribution when due, then, without limitation and in addition to any other remedy available to Tenant as a result thereof, Landlord shall reimburse Tenant for all costs and expenses incurred by Tenant in connection with bonding or discharging said lien, together with interest at the Default Rate from the date such payment was due until the date that Landlord pays such amount to Tenant.

ARTICLE 4
Rent

4.1 Payment of Rent: Fixed Rent. (a) Tenant covenants and agrees to pay to Landlord, without notice or demand and without abatement, offset, deduction or counterclaim, at the Original Address of Landlord, or at such other place or to such other person or entity as Landlord may from time-to-time direct in writing: (i) Fixed Rent at the Annual Fixed Rent Rate, in equal monthly installments at the Monthly Fixed Rent Rate (which is l/12th of the Annual Fixed Rent Rate), (and for any portion of a calendar month following the Rent Commencement Date or at the end of the Term, at that rate prorated on a daily basis payable for such portion), in advance, on the first day of each calendar month during the Term,

commencing on the Rent Commencement Date; and (ii) Additional Rent, in the amounts, at the times and in the manner set forth in this Lease. The Fixed Rent and Additional Rent payable hereunder sometimes are referred to in this Lease collectively as the "Rent."

(b) If Landlord shall give notice to Tenant that all Rent and other payments due hereunder are to be made to Landlord by electronic funds transfers or by similar means, then Tenant shall make all such payments as shall be due after receipt of such notice by means of such electronic funds transfers or such similar means as designated by Landlord.

4.2 Additional Rent. Tenant covenants and agrees to pay the following, as Additional Rent:

4.2.1 Real Estate Taxes. (a) If for any Tax Year during the Term the Taxes exceed Base Taxes then Tenant shall reimburse Landlord, as Additional Rent, for Tenant's Percentage of such excess. The Additional Rent payable by Tenant under the preceding two sentences is referred to herein collectively as the "Tax Excess." Tenant shall remit to Landlord, on the first day of each calendar month, estimated payments on account of Tax Excess, such monthly amounts to be sufficient to provide Landlord, by the time real estate tax payments are due and payable to any governmental authority responsible for collection of same, a sum equal to the Tax Excess, as reasonably estimated by Landlord from time-to-time on the basis of the most recent tax data available. If the total of such monthly payments for any Tax Year is greater than the actual Tax Excess for such Tax Year, then promptly after the expiration of such Tax Year and the determination of the actual amount of Tax Excess for such Tax Year, Landlord shall pay to Tenant, or credit against the next accruing payments to be made by Tenant pursuant to this subsection 4.2.1, the difference; if the total of such payments is less than the actual Tax Excess for such Tax Year, then Tenant shall pay the difference to Landlord not more than ten (10) days after Landlord delivers to Tenant an itemized statement of the Tax Excess.

(b) If, after Tenant shall have made reimbursement to Landlord pursuant to this subsection 4.2.1, Landlord shall receive a refund of any portion of Taxes paid by Tenant with respect to any Tax Year during the Term hereof, whether as a result of an abatement of such Taxes by legal proceedings, settlement or otherwise (without Landlord having any obligation to undertake any such proceedings), Landlord shall promptly pay to Tenant, or credit against the next accruing payments to be made by Tenant pursuant to this subsection 4.2.1, the Tenant's Percentage of the refund (less the proportional pro rata expenses, including, without limitation, attorneys' fees and appraisers' fees, incurred in connection with obtaining any such refund.

(c) If the Term of this Lease shall commence, or shall end (by reason of expiration of the Term or earlier termination pursuant to the provisions hereof), on any date other than the first or last day of the Tax Year, or should the Tax Year or

period of assessment of real estate taxes be changed or be more or less than one (1) year, as the case may be, then the amount of Tax Excess payable by Tenant for such year shall be appropriately apportioned on the basis of daily prorations and adjusted accordingly.

(d) The term "Taxes" shall mean all ad valorem real estate and personal property taxes, assessments, betterments and other charges and impositions (including, but not limited to, fire protection service fees and similar charges) levied, assessed or imposed at any time and from time-to-time during the Term by any governmental authority upon or against the Property and/or any part thereof, or taxes in lieu thereof, and in the case of personal property taxes, those taxes payable with respect to personal property located at and used in connection with the maintenance and operation of the Property. "Taxes" shall also include all taxes and payments assessed, levied, imposed or otherwise payable in lieu of the foregoing, all costs and expenses (including reasonable attorneys fees) incurred in contesting any of the foregoing, and all other additional types of taxes assessments, levies, impositions, fees and charges however described or imposed upon the Property and/or the Landlord with respect to the Property. If, at any time during the term of this Lease, any tax or excise on rents or other taxes, however described, are levied or assessed against Landlord with respect to the Rent reserved hereunder and/or the ownership of the Property, either wholly or partially in substitution for, or in addition to, ad valorem real estate taxes assessed or levied on the Property and/or any part thereof, such tax or excise on rents shall be included in Taxes; provided however, Taxes shall not include franchise, estate, inheritance, succession, capital levy, transfer, net income or excess profits taxes assessed on Landlord. Taxes shall include any estimated payment made by Landlord on account of a fiscal tax period for which the actual and final amount of taxes for such period has not been determined by the governmental authority as of the date of any such estimated payment.

4.2.2 Personal Property Taxes. Tenant shall pay all taxes, assessments, betterments and other charges and impositions charged, assessed or imposed upon the personal property, fixtures and equipment of Tenant in or upon the Premises prior to the due date thereof.

4.2.3 Operating Costs. (a) If for any calendar year during the Term the Operating Costs exceed the Base Operating Costs, then Tenant shall reimburse Landlord, as Additional Rent, for Tenant's Percentage of such excess (such amount being hereinafter referred to as the "Operating Costs Excess"). Tenant shall remit to Landlord, on the first day of each calendar month, estimated payments on account of Operating Costs Excess, in monthly amounts reasonably estimated by Landlord from time-to-time to be sufficient to provide Landlord, by the end of the calendar year, a sum equal to the Operating Costs Excess for such calendar year. If, at the expiration of any respective calendar year the total of such monthly payments made by Tenant is greater than the actual Operating Costs Excess for such year, then promptly after the expiration of such calendar year and the determination of the actual amount of Operating Costs Excess, Landlord shall pay to Tenant or

credit against the next accruing payments to be made by Tenant pursuant to this subsection 4.2.3, the difference; if the total of such payments is less than the Operating Costs Excess for such year, then Tenant shall pay the difference to Landlord within not more than thirty (30) days after the date Landlord furnishes to Tenant an itemized statement of the Operating Costs Excess. Landlord shall deliver the annual statement of actual Operating Costs Excess not later than one hundred eighty (180) days after the expiration of the respective calendar year. Any reimbursement for Operating Costs due and payable by Tenant with respect to periods of less than twelve (12) months shall be equitably prorated.

(b) The term "Operating Costs" shall mean all costs or expenses of every kind and nature paid or incurred by Landlord in connection with the operation, cleaning, management, maintenance, repair and upkeep of the Property, including, without limitation, all costs of maintaining and repairing the Property (including snow removal, security, operation and repair of heating and air-conditioning equipment, elevators, lighting and any other building equipment or systems) and of all repairs and replacements (other than repairs or replacements for which Landlord has received full reimbursement from contractors, other tenants of the Building or from others) required or desirable in order to keep the Property in good working order, repair; appearance and condition; all costs, including material and equipment costs, for cleaning and janitorial services to the Building (including window cleaning of the Building); all premiums and costs of insurance carried by Landlord relating to the Property; all costs related to provision of heat (including oil, electric, steam and/or gas), air-conditioning, ventilation, and water (including sewer charges) and other utilities to the Building (exclusive of reimbursement to Landlord for any of same received as a result of direct billing to any tenant); payments under all service contracts relating to the foregoing; all compensation, fringe benefits, payroll taxes and worker's compensation insurance premiums related thereto with respect to any employees (but not above the grade of general manager) of Landlord or its affiliates or manager engaged in security and maintenance of the Property; attorneys' fees and disbursements (exclusive of any such fees and disbursements incurred in tax abatement proceedings or the preparation of leases or disputes with tenants) and auditing and other professional fees and expenses; shuttle services; management fees not in excess of 3% of gross rent receipts for the Building for the applicable year; fire protection service fees and similar governmental charges not included in Taxes; and the portion fairly allocable to the Property of any and all of the foregoing costs incurred with regard to the operation, maintenance and repair of any facilities shared by the Property with any other properties.

(c) There shall not be included in such Operating Costs the following: (1) brokerage fees (including rental fees) related to the operation of the Building; (2) interest and depreciation charges incurred on the Property; (3) expenditures made by Tenant with respect to (a) cleaning, maintenance and upkeep of the Premises, or (b) the provision of electricity to the Premises; (4) any ground lease rent; (5) costs of leasing space, including advertising and leasing commissions; (6) costs of services provided by affiliates of Landlord (other than the management fees set

forth above) to the extent such costs exceed market competitive costs for such services for owner managed buildings; (7) Capital Expenditures (as hereinafter defined) which are required in order to cause the Building to comply with Requirements that are effective and applied to the Building (whether through adoption, promulgation, application, interpretation or otherwise) as of the date of this Lease and rent for items which if purchased, rather than rented, would not be includable in Operating Expenses pursuant to Section 4.2.3(d); (8) bad debt expenses and payments of principal, interest or mortgage charges, or other costs of financing or refinancing or brokerage commissions, or the costs of selling, syndicating, financing, mortgaging or hypothecating Landlord's interest in the Property, or the costs of defending any lawsuits with mortgagees; (9) the cost of repairs or other work caused by any insured casualty or the exercise of the right of eminent domain, to the extent the Landlord is reimbursed by insurance awards, rebates or condemnation proceeds; (10) leasing commissions, brokerage fees, legal fees, advertising costs and disbursements and other expenses incurred in connection with negotiations or disputes with other tenants or occupants, or prospective tenants or occupants; (11) the costs of renovating or otherwise improving, decorating, painting or redecorating premises for other tenants or other occupants of the Building; (12) any fines or penalties incurred by Landlord as a result of a violation by Landlord of applicable laws or governmental rule or authority; (13) costs of installing sculpture, paintings or other objects of art in common areas, except to the extent required to maintain the Building in first-class condition; (14) wages, salaries or other compensation paid to any executive employees above the grade of general manager, except that if any such employee performs a service which would have been performed by an outside consultant, the compensation paid to such employee for performing such service shall be included in Operating Costs; (15) costs or fees relating to the defense of the title or interest of Landlord in the Property; (16) income, excess profits, franchise taxes or other taxes assessed on the income of the Landlord from the Property; (17) costs of maintaining the legal entity constituting the Landlord; (18) costs of the charitable or political contributions of the Landlord; (19) costs incurred by Landlord to the extent that Landlord is reimbursed by third parties; (20) third-party management fees in excess of the percentage set forth in Section 4.2.3(b) and management fees paid or charged by affiliates of Landlord in excess of 3% of gross rent receipts; or (21) fines, penalties or interest to the extent caused by the negligence or willful misconduct of Landlord or its agents or employees.

(d) If, during the Term of this Lease, Landlord shall replace any capital items or make any capital expenditures (collectively, "Capital Expenditures"), then the "annual charge-off" of such Capital Expenditure shall be included in Operating Costs for each calendar year in which such Capital Expenditure is made, and for each subsequent calendar year only if (i) the Capital Expenditure is reasonably intended to effect savings in Operating Costs, or (ii) is made to comply with a Requirement which becomes effective (whether through adoption, promulgation, application, interpretation, or otherwise) after the date of this Lease. The "annual charge-off" shall be determined by (i) dividing the original cost of the Capital Expenditure by the number of years of useful life thereof (which useful life shall

be determined by Landlord in accordance with generally accepted accounting principles and practices in effect at the time of acquisition of the capital item or making of a capital expenditure); and (ii) adding to such quotient an interest factor computed on the unamortized balance of such Capital Expenditure based upon an interest rate reasonably determined by Landlord as being the interest rate then being charged for long-term mortgages by institutional lenders on similar properties within the locality in which the Building is located; provided, however, if Landlord reasonably concludes on the basis of engineering estimates that such Capital Expenditure will effect savings in Operating Costs and that such annual projected savings will exceed the annual charge-off of such Capital Expenditure computed as aforesaid, then the annual charge-off shall be determined by (i) dividing the original cost of such Capital Expenditure by the number of years over which the projected amount of such savings shall fully amortize the cost of such Capital Expenditure; and (ii) by adding the interest factor, as aforesaid.

(e) If during all or any portion of any year for which Operating Costs are being computed, less than 95% of the rentable area of the Building is occupied by tenants, or Landlord does not furnish any particular item(s) of work or service (which would otherwise constitute an Operating Cost) to any leasable areas of the Building, then for purposes of calculating Operating Costs for such year, the actual Operating Costs incurred for such year or portion thereof shall be reasonably extrapolated by Landlord to be the estimated Operating Costs that would have been incurred if 95% of the rentable area of the Building had been occupied by tenants and such item(s) of work and services were being supplied to tenants occupying 95% of the rentable area of the Building, and for the purposes of this Section 4.2.3, such extrapolated amount shall be deemed to be the Operating Costs for such year or portion thereof.

(f) Each statement of Operating Costs delivered to Tenant shall constitute an account stated between Landlord and Tenant and shall be conclusively binding upon Tenant, unless Tenant (i) pays to Landlord when due the amount set forth in such statement, without prejudice to Tenant's right to dispute such statement, and (ii) within one hundred eighty (180) days after such statement is sent, sends a written notice to Landlord objecting to such statement and specifying the reasons therefor, in which event, upon request, Tenant may, at its sole cost and expense, audit the books and records pertaining to the Operating Costs for the subject year. Said audit shall be performed either (i) at a mutually satisfactory time at Landlord's offices in Boston, Massachusetts, or (ii) after physical or electronic delivery to Tenant of the relevant documents. Tenant agrees that Tenant will not employ, in connection with any such audit or any dispute under this Lease, any person or entity who is to be compensated in whole or in part, on a contingency fee basis. In connection with any such audit, Tenant, such accountants and all consultants and agents of Tenant shall keep all information confidential and shall execute and deliver to Landlord a commercially reasonable and mutually acceptable confidentiality agreement, whereby such parties agree not to disclose to any third party any of the information obtained in connection with such audit. Tenant shall pay the fees and expenses relating to such audit, unless it is

conclusively determined that Landlord overstated Operating Costs by more than 5% for such year, in which event Landlord shall reimburse Tenant for the reasonable out-of-pocket costs incurred by Tenant in such audit.

4.2.4 Insurance. Tenant shall, at its cost and expense, obtain and maintain throughout the Term, the following insurance protecting Landlord and all Landlord Affiliates, as requested by Landlord from time-to-time:

4.2.4.1 Commercial general liability insurance, in the broadest and most comprehensive form generally available from time-to-time, naming Tenant as insured, and Landlord, Landlord's managing agent, the Landlord Affiliates (of which Tenant has been given notice), and any mortgagee of which Tenant has been given notice as additional insureds, and indemnifying the parties so named on an occurrence basis against all claims and demands for death or any injury to persons or damage to property which may be claimed to have occurred on the Premises (or the Property, insofar as used by customers, employees, servants or invitees of the Tenant), in amounts which shall, at the beginning of the Term, be at least equal to the limits set forth in Section 1.1, and, which, from time to time during the Term, shall be for such higher limits, if any, as Landlord determines in its reasonable discretion as are customarily carried in the area in which the Premises are located on property similar to the Premises and used for similar purposes.

4.2.4.2 Insurance against loss or damage by fire, and such other risks and hazards as are insurable under then available standard forms of "all risk" property insurance policies with extended coverage, insuring all of Tenant's furniture, furnishings, fixtures, and equipment, for the full insurable value thereof or replacement cost value thereof, having a deductible amount, if any, of not greater than $25,000.00 per annum;

4.2.4.3 During the performance of any Alterations (including the Tenant's Work), until completion thereof, builder's risk insurance on an "all risk" basis and on a completed value form, for full replacement value covering the interests of Landlord and Tenant (and their respective contractors and subcontractors), any superior mortgagee and any superior lessor in all work incorporated in the Building and all materials and equipment in or about the Premises;

4.2.4.4 Workers' compensation insurance, in amounts and with coverages as required by law;

4.2.4.5 Business interruption insurance, which may be included within a blanket limit covering multiple office locations including the Premises, in commercially reasonable amounts; and

4.2.4.6 Such other insurance, in such amounts and with such coverages as Landlord may reasonably require from time to time, provided that such coverages are consistent with coverages then customarily being required by other landlords of comparable buildings in Boston, Massachusetts.

4.2.4.7 All such policies shall be obtained from insurance companies with A.M. Best ratings of "A-" or better, Class VIII or larger, and with S&P ratings of "AA" or better. All such insurance companies shall be qualified to do business and in good standing in the Commonwealth of Massachusetts. All such insurance companies and the amount of insurance allocated thereto shall be subject to Landlord's approval, which approval shall not be unreasonably withheld. Tenant agrees to furnish Landlord with certificates evidencing all such insurance prior to the beginning of the Term hereof and evidencing renewal thereof at least thirty (30) days prior to the expiration of any such policy. Each such policy shall be non-cancelable with respect to the interest of Landlord without at least ten (10) days prior written notice thereto. In the event provision for any such insurance is to be by a blanket insurance policy, the policy shall allocate a specific and sufficient amount of coverage to the Premises.

4.2.4.8 All insurance which is carried by either party with respect to the Building, the Premises or furniture, furnishings, fixtures, or equipment therein or alterations or improvements thereto, whether or not required, shall include provisions which either designate the other party as one of the insured or deny to the insurer acquisition by subrogation of rights of recovery against the other party to the extent such rights have been waived by the insured party prior to occurrence of loss or injury. In the event that extra premium is payable by either party as a result of this provision, the other party shall reimburse the party paying such premium the amount of such extra premium. If at the request of one party, this non-subrogation provision is waived, then the obligation of reimbursement shall cease for such period of time as such waiver shall be effective, but nothing contained in this subsection shall derogate from or otherwise affect releases elsewhere herein contained of either party for claims. Each party shall be entitled to have certificates of any policies containing such provisions. Each party hereby waives all rights of recovery against the other for loss or injury against which the waiving party is protected by insurance containing such provisions, reserving, however, any rights with respect to any excess of loss or injury over the amount covered by such insurance. Tenant shall not acquire as insured under any insurance carried by or on behalf of the Landlord with respect to the Premises any right to participate in the adjustment of loss or to receive insurance proceeds and agrees upon request promptly to endorse and deliver to Landlord any checks or other instruments in payment of loss in which Tenant is named as payee.

4.2.5 Utilities. Tenant shall pay to Landlord, as Additional Rent, the Condenser Water Charge for condenser water supplied by Landlord pursuant to Section 5.1.1, the

Overtime HVAC Charge for the Overtime HVAC service provided by Landlord pursuant to Section 5.1.2, and all charges for electricity supplied by Landlord to the Premises, if any (which may include electricity for ventilation and cooling, including reheat coils, fan boxes, compressors and refrigerating units serving the Premises). Tenant shall also pay, to the appropriate third party, all charges for telephone and other utilities or services not supplied by Landlord pursuant to Sections 5.1, whether designated as a charge, tax, assessment, fee or otherwise, all such charges to be paid as the same from time to time become due. Except as otherwise provided in Article 5, it is understood and agreed that Tenant shall make its own arrangements for the installation or provision of all such utilities and that Landlord shall be under no obligation to furnish any utilities to the Premises and shall not be liable for any interruption or failure in the supply of any such utilities to the Premises.

4.3 Late Payment of Rent. If Tenant shall fail to pay any installment of Rent more than two (2) days after the date that such Rent was due, and if on a prior occasion in the twelve (12) month period immediately preceding such date Tenant also failed to pay any installment of Rent more than two (2) days after the date that such Rent was due, then in addition to the outstanding amounts, Tenant shall pay Landlord a late payment fee equal to 5% percent of the overdue payment.

ARTICLE 5
Landlord's Covenants

5.1 Affirmative Covenants. Landlord covenants with Tenant:

5.1.1 Condenser Water. To furnish condenser water and a condenser water connection to the heat pump and related equipment which are to be installed by Tenant at its sole cost and expense. Tenant shall pay to Landlord the "Condenser Water Charge." The "Condenser Water Charge" is currently $650.00 per ton per annum and is subject to increase by Landlord from time to time.

5.1.2 Overtime HVAC. To furnish heating, ventilation and cooling services both during Normal Business Hours and upon notice from Tenant as provided below, at times other than during Normal Business Hours ("Overtime HVAC Services"). For Overtime HVAC Services Tenant shall pay to Landlord the "Overtime HVAC Charge." The "Overtime HVAC Charge" is currently $80.00 per hour per floor and is subject to increase by Landlord from time to time. Overtime HVAC Services shall be provided for a minimum of two (2) hours and Tenant shall submit a request to Landlord not less than twenty four (24) hours prior to the commencement of said Overtime HVAC Services, which request may be made via telephone or email to the Building manager.

5.1.3 Electricity. To furnish electrical service to the Premises. Tenant shall contract directly with the electricity company furnishing electric service to the Building for electric service to the Premises. Landlord has installed a separate meter in the Premises to measure Tenant's consumption of electricity. Tenant shall pay all

amounts payable to the utility company, on a timely basis, and in all events prior to the due date thereof. Landlord shall maintain the meter in good working order and repair. If Tenant fails to pay such charges on a timely basis, then Landlord may pay such charges directly to the utility company and Tenant shall reimburse Landlord as additional rent for all amounts expended by Landlord in connection therewith within ten (10) days after receipt of a bill therefor. Tenant shall at all times comply with the rules and regulations of the utility company supplying electricity to the Building. Tenant shall not use any electrical equipment which, in Landlord's reasonable judgment, would exceed the capacity of the electrical equipment serving the Premises.

5.1.4 Cleaning. To provide cleaning to the Premises (excluding any portions thereof used for the storage, preparation, service or consumption of food) and the common areas of the Building substantially in accordance with the Cleaning Specifications attached hereto as Exhibit D and incorporated herein by this reference. Notwithstanding the foregoing, Tenant, at Tenant's expense, shall cause any portions of the Premises used for the storage, preparation, service or consumption of food or beverages to be cleaned daily in a manner reasonably satisfactory to Landlord, and to be treated against infestation by vermin, roaches or rodents, on a regular basis. Without limiting the foregoing, except as set forth above, in no event shall any portion of the Premises (other than a kitchenette area) be used for the storage, preparation, service or consumption of food or beverages.

5.1.5 Water. To furnish water to the Premises for ordinary cleaning, lavatory and toilet facilities.

5.1.6 Passenger Elevator Service. To furnish passenger elevator service from the lobby to the Premises.

5.1.7 Security and Access. To furnish at least one (1) attendant in the Building during Normal Business Hours, and a card access control system for access to the Building and Premises after Normal Business Hours, including, without limitation, elevator access cards if needed for elevator access to floors. Tenant understands that except as expressly set forth in this Section 5.1.7, Landlord will not provide Tenant with any security guards or alarm or security systems of any kind or nature. Notwithstanding the foregoing, in no event shall Landlord have any liability or obligation to Tenant arising from any claims for loss, injury or damage to persons or property in connection therewith. Subject to reasonable security measures and Force Majeure Events, or when precluded by casualties or eminent domain events, Tenant and its employees shall have access to the Building and Premises twenty-four (24) hours per day, seven (7) days per week, three-hundred-sixty-five (365) days per year during the Term, as the same may be extended in accordance with Section 2.3 of this Lease.

5.1.8 Repairs. Except as otherwise expressly provided herein, to make such repairs and replacements to the roof, exterior walls, exterior windows, floor slabs and other structural components of the Building, and to the common areas, facilities and

plumbing, electrical, heating, ventilating and air-conditioning systems of the Building (including without limitation such base building electrical, heating, ventilating and air-conditioning systems that serve the Building and the Premises) as may be necessary, to keep them in good repair and condition (exclusive of equipment installed by Tenant and except for those repairs required to be made by Tenant pursuant to Section 6.1.3 hereof, and repairs or replacements occasioned by any negligence of Tenant, its servants, agents, customers, contractors, employees, invitees, or licensees).

5.1.9 Telecommunications. To permit Tenant, at its sole cost and expense, to install in a riser location (or locations) designated by Landlord in its reasonable discretion, its telecommunications lines, cables and equipment ("Tenant's Telecommunications Equipment"). Except with respect to Tenant's Telecommunications Equipment installed as part of the Tenant's Work, which shall be subject to prior approval by Landlord pursuant to Section 3.3, the capacity, size, location and dimensions of such risers and of each element of the Tenant's Telecommunications Equipment shall be subject to Landlord's approval, which approval will not be unreasonably withheld, conditioned or delayed. Tenant's Telecommunications Equipment shall be considered to be an Alteration for all purposes under this Lease, and shall comply with the provisions of Section 6.2.5 and all of the other provisions of this Lease. Tenant shall remove the Tenant's Communication Equipment upon the expiration or earlier termination of this Lease.

5.1.10 Property Insurance. To maintain throughout the Term, as the same may be extended pursuant to section 2.3 of this Lease, property insurance insuring the Building against loss or damage by fire and other perils covered under so-called "all risk," vandalism, malicious mischief coverage, boiler and machinery coverage and such other insurable hazards and contingencies as are from time to time normally insured against by owners of comparable first-class multi-tenant office buildings in the City of Boston, in an amount approximately equal to the full replacement cost thereof, including, without limitation, builder's risk coverage for the Stairway/Common Area Work and Tenant's Work (subject to such commercially reasonable deductibles as Landlord may elect from time to time). From time to time upon the reasonable request of Tenant Landlord shall deliver to Tenant certificates evidencing all such insurance. All policies of insurance maintained by Landlord shall contain the same waiver of subrogation provisions for the benefit of Tenant as Tenant is required to obtain in its insurance policies for the benefit of Landlord.

5.1.11 Representations of Landlord. Landlord represents and warrants to Tenant as follows: (i) Landlord is the fee simple and record owner of the Property and the Building, and has the full right, power and authority to execute, deliver and perform its obligations under this Lease and has obtained all consents and taken all actions necessary in connection therewith; (ii) there are no mortgages or ground leases affecting the Property and/or the Building or any portion thereof,

except the mortgage granted to FMR LLC; and (iii) the person executing this Lease on behalf of Landlord is authorized to do so.

5.2 Interruption. Except as otherwise expressly provided below in this Section 5.2, Landlord shall have no responsibilities, obligations, or liabilities for any failure or interruption of any of the above-described services, or for any failure or inability to make any repairs or replacements, if such failure, interruption or inability arises out of or results from emergencies, breakage, accidents, strikes, repairs, inability to obtain supplies, labor or materials, or any other causes beyond the reasonable control of the Landlord. Without limiting the foregoing, in no event shall Landlord ever be liable to Tenant for any lost profits, or for any indirect or consequential damages. No failure or omission on the part of the Landlord to furnish any of the services described in Section 5.1 shall be construed as an eviction of Tenant, actual or constructive, nor entitle Tenant to an abatement or reduction of, or offset against, Rent, nor render the Landlord liable in damages, nor release Tenant from prompt fulfillment of any of its obligations and covenants under this Lease.

Notwithstanding anything to the contrary contained in this Lease, if Tenant is unable despite its good faith commercially diligent efforts to use the Premises for the ordinary conduct of Tenant's business due solely to (a) an interruption of an Essential Service (as hereinafter defined) which Landlord is required to provide hereunder, or (b) Landlord's breach of an obligation under this Lease to perform repairs or replacements which results in Landlord's failure to provide an Essential Service, in each case other than as a result of casualty or condemnation and subject to the provisions of Section 11.5, and such condition continues for a period of longer than ten (10) consecutive business days after Tenant furnishes a notice to Landlord (the "Abatement Notice") identifying the condition and Essential Service which has been interrupted and stating that Tenant's inability to use the Premises is solely due to such condition, provided that (i) Tenant does not actually use or occupy the Premises during such ten (10) consecutive Business Day period, (it being understood that entry by Tenant's employees solely to retrieve files, data, laptops and other equipment shall not be deemed occupancy hereunder), and (ii) such condition has not resulted from the negligence or misconduct of Tenant or any Tenant Party, then Fixed Rent payable on account of the Premises shall be abated on a pro rata per diem basis for the period (the "Abatement Period") commencing on the eleventh (11th) Business Day after Tenant delivers the Abatement Notice to Landlord and ending on the earlier of (x) the date Tenant reoccupies the Premises, or (y) the date on which such condition is substantially remedied. "Essential Service" shall mean the following services, but only to the extent that Landlord is required to provide such services to Tenant pursuant to the terms of this Lease and if not provided the absence of such service shall materially and adversely affect the use of the Premises for the ordinary conduct of Tenant's business: HVAC service; electrical service; passenger elevator service; and water and sewer service. The foregoing rent abatement shall be the sole and exclusive remedy of Tenant on account of an interruption or lack of an Essential Service for ten (10) consecutive business days

or longer after notice from Tenant as set forth in this Section 5.2, and Landlord shall have no further liabilities or obligations to Tenant on account thereof.

5.3 Outside Services. If Tenant wishes to obtain "Outside Services" for the Premises, i.e. services in addition to, or in excess of, the services to be provided by Landlord as set forth herein, then Tenant shall first obtain the prior written approval of Landlord (which approval shall not be unreasonably withheld) for the installation and/or utilization of such Outside Services. For purposes of this Lease, "Outside Services" shall include, but shall not be limited to, cleaning services, television, so-called "canned music" services, security services, and the like. In the event Landlord approves the installation and/or utilization of such Outside Services, such installation and utilization shall be at Tenant's sole cost, risk and expense, and Landlord shall have no obligations or liabilities in connection therewith.

5.4 Discontinuance of Electrical Service. Notwithstanding any provision to the contrary contained in this Article 5, Landlord reserves the right to discontinue furnishing electricity to Tenant in the Premises on not less than sixty (60) days notice to Tenant; provided, that, either (a) Landlord discontinues furnishing electricity to tenants (including Tenant) leasing an aggregate of at least 60% of the rentable area of the Building, or (b) Landlord is required to do so by the public utility or pursuant to applicable laws, codes, regulations, or requirements. If Landlord discontinues furnishing electricity to Tenant, then this Lease shall continue in full force and effect and shall be unaffected thereby, except that from and after the effective date of such discontinuance, Landlord shall not be obligated to furnish electricity to Tenant hereunder. If Landlord so discontinues furnishing electricity, then Tenant shall arrange to obtain electricity directly from a utility company serving the Building. All equipment that may be required to obtain electricity of substantially the same quantity, quality and character shall be installed by Landlord at the sole cost and expense of (a) Landlord, if Landlord voluntarily discontinues such service, or (b) Tenant, if Landlord is compelled to discontinue such service by the public utility or pursuant to applicable laws, codes, regulations, or requirements. Landlord shall not voluntarily discontinue furnishing electricity to Tenant until Tenant is able to receive electricity directly from a utility company servicing the Building, unless the utility company is not prepared to furnish electricity to the Premises on the date required as a result of Tenant's delay or negligence in arranging for service or Tenant's refusal to provide the utility company with a deposit or other security requested by the utility company, or Tenant's refusal to take any other action reasonably requested by the utility company.

ARTICLE 6
Tenant's Additional Covenants

6.1 Affirmative Covenants. Tenant covenants at all times during the Term and for such additional time (prior or subsequent thereto) as Tenant occupies the Premises or any part thereof:

6.1.1 Perform Obligations. To perform promptly all of the obligations of Tenant set forth in this Lease; and to pay when due the Fixed Rent, the Additional Rent, and all other charges, rates and other sums which by the terms of this Lease are to be paid by Tenant.

6.1.2 Use. To use the Premises only for the Permitted Uses (and for no other purpose or purposes), and to obtain and maintain at all times all licenses and permits necessary or required therefor, at Tenant's sole expense. Without limiting the foregoing, Tenant shall deliver to Landlord for its review, copies of all, applications for all such licenses and permits that are issued in connection with the use and occupancy of the Premises or Alterations proposed by Tenant in or to the Premises, prior to submission thereof to the applicable governmental authorities.

6.1.3 Repair and Maintenance. To maintain the Premises in first-class, good and neat order, condition and repair; to perform all routine and ordinary repairs to the Premises and to any plumbing, heating, electrical, ventilating and air-conditioning systems located within the Premises, in order to maintain such systems in good working order, appearance and condition, in all cases reasonable use and wear thereof and damage by fire or casualty only excepted; to keep all glass in windows and doors of the Premises (except glass in the exterior windows of the Building) whole and in good condition with glass of the same quality as that injured or broken; and to make all necessary repairs to the Premises and/or the Property arising out of or resulting from misuse or damage by, or neglect or improper conduct of, Tenant or Tenant's servants, employees, agents, invitees or licensees or otherwise, damage by fire or casualty excepted. All repairs and replacements performed by Tenant shall be in quality and class equal to the original work. If Tenant fails to perform such obligations and the failure continues for thirty (30) days after delivery of prior notice to Tenant (except in the event of an emergency when such notice may be delivered concurrently), then Landlord may elect, at the expense of Tenant, to perform all such cleaning and maintenance, and to make any such repairs or to repair any damage or injury to the Premises and/or the Property caused by moving property of Tenant into or out of the Premises, or by the installation or removal of furniture or other property, or by misuse by, or neglect, or improper conduct of, Tenant or Tenant's servants, employees, agents, contractors, customers, patrons, invitees, or licensees.

6.1.4 Compliance with Law. To make all repairs, alterations, additions or replacements to the Premises required by any law, code, ordinance, order, or regulation of any public or governmental authority; to keep the Premises equipped with all safety appliances so required; and to comply with the orders and regulations of all governmental authorities with respect to zoning, building, fire, health and other codes, regulations, ordinances or laws applicable to the Premises, except that Tenant may defer compliance so long as the validity of any such law, ordinance, order or regulations shall be contested by Tenant in good faith and by appropriate legal proceedings, if Tenant first gives Landlord appropriate assurance or security against any loss, cost or expense on account thereof; provided, however, that

Tenant shall not be obligated to make any structural Alterations or Alterations to the building systems unless the need for such Alterations arises out of or results from (i) the specific manner and nature of Tenant's use or occupancy of the Premises, as distinguished from general office use, (ii) Alterations made by Tenant, or (iii) a breach by Tenant of any of the provisions of this Lease. Without limiting the foregoing, within the Premises, and with respect to all means of access and egress to and from the Premises (including all entrances and doorways), Tenant shall be responsible for compliance with the ADA.

6.1.5 Indemnification. To the maximum extent permitted by law, to indemnify and hold harmless Landlord and all Landlord Affiliates, and to exonerate, indemnify and hold harmless Landlord and all Landlord Affiliates from and against any and all claims, actions, proceedings, judgments, obligations, liabilities, costs, expenses (including, without limitation, reasonable attorneys' fees), and penalties (collectively, "Claims") asserted by or on behalf of any person, firm, corporation or public authority (i) arising out of or resulting from any injury, death, damage or loss to any person or property in or upon the Premises and/or the Property (or any part thereof), which Claims arise out of or result from the use or occupancy of the Premises by Tenant or by any person claiming by, through or under Tenant (including, without limitation, all contractors, agents, patrons, employees, invitees, and customers of Tenant), or (ii) arising out of or resulting from (a) any delivery to or service supplied to the Premises other than services supplied by or on behalf of Landlord, or (b) anything whatsoever done on the Premises, excepting, in each case, only to the extent caused by the negligence or willful misconduct of Landlord, its agents, servants or employees. Without limiting the foregoing, if any action or proceeding is brought against Landlord and/or any Landlord Affiliates by reason of any such Claim, upon notice from Landlord and at Tenant's expense, Tenant shall resist or defend all such actions or proceedings and employ counsel therefor reasonably satisfactory to and approved in advance by Landlord, such approval not to be unreasonably withheld, conditioned or delayed.

6.1.6 Landlord's Right to Enter. To permit Landlord and its agents to enter into and examine the Premises at reasonable times and to make repairs to the Premises and/or the Building, and during the last fifteen (15) months of the Term, to show the Premises and/or the Building. Landlord shall provide reasonable prior notice of such entry (which notice may be verbal), except in the event of emergencies when no such prior notice shall be required but notice shall be provided to Tenant as soon as reasonably practicable following such entry. Tenant shall provide Landlord with copies of keys and a means of access to Tenant's security system as may be necessary for such entry by Landlord.

6.1.7 Personal Property at Tenant's Risk. All of the furnishings, fixtures, equipment, effects and property of every kind, nature and description of Tenant and of all persons claiming by, through or under Tenant which, during the continuance of this Lease or any occupancy of the Premises by Tenant or anyone claiming by, through or under Tenant, may be on the Premises, shall be at the sole risk and

hazard of Tenant or such other person, excepting only to the extent such damage is caused by the negligence or misconduct of Landlord. If the whole or any part of such personal property shall be destroyed or damaged by fire, water or otherwise, or by the leakage or bursting of water pipes, steam pipes, or other pipes, or by theft or from any other cause, then to the maximum extent permitted by law, Landlord shall have no liabilities or obligations as a result thereof and no part of such loss or damage is to be charged to or to be borne by Landlord, excepting only to the extent such damage is caused by the negligence or misconduct of Landlord.

6.1.8 Payment of Landlord's Costs of Enforcement. To pay on demand all reasonable expenses (including, without limitation, reasonable attorneys' fees) incurred from time-to-time by Landlord, in enforcing any obligation of Tenant under this Lease, or in curing any breach or default by Tenant under this Lease.

6.1.9 Yield Up. (a) To yield up and surrender possession of the Premises to Landlord at the expiration of the Term or earlier termination of this Lease; to surrender all keys to the Premises; to remove all of its trade fixtures and personal property from the Premises; to remove all Tenant's Telecommunications Equipment and wires and cables installed by or on behalf of Tenant; to remove such Specialty Alterations as Landlord may request and all Tenant's signs wherever located; to repair all damage caused by such removal and to yield up the Premises (including all installations and improvements made by Tenant, except for trade fixtures and such of such installations or improvements as Landlord shall request Tenant to remove), broom-clean and in the same good order and repair in which Tenant is obliged to keep and maintain the Premises by the provisions of this Lease. Any property not so removed shall be deemed abandoned and, if Landlord so elects, deemed to be Landlord's property, and may be retained or removed and disposed of by Landlord in such manner as Landlord shall determine. Tenant shall reimburse Landlord for the entire cost and expense incurred by it in effecting the removal and disposition of property which was required to be removed by Tenant pursuant to this Lease, and in making any repairs and replacements to the Premises after surrender thereof by Tenant.

Without limiting the foregoing, concurrent with the review of the applicable Construction Documents in connection with a Change Order or, upon request of Tenant, concurrent with the review of other plans and specifications in connection with any Alterations, Landlord will notify Tenant as to which of the proposed installations and improvements constitute Specialty Alterations which Tenant will be required to remove at the expiration of the Term provided that Tenant shall include the following legend in capitalized and bold type displayed prominently on the top of the first page of Tenant's notice delivered concurrently with such plans and specifications: **"IF LANDLORD FAILS TO NOTIFY TENANT AT THE TIME LANDLORD APPROVES THESE PLANS AND SPECIFICATIONS THAT ANY ALTERATIONS SHOWN THEREON ARE SPECIALTY ALTERATIONS (AS DEFINED IN THE LEASE), LANDLORD MAY NOT REQUIRE TENANT TO REMOVE SUCH**

SPECIALTY ALTERATIONS AT THE END OF THE TERM OF THE LEASE."

(b) If the Tenant remains in the Premises beyond the expiration of the Term or earlier termination of this Lease, such holding over shall be without right and shall not be deemed to create any tenancy, but the Tenant shall be a tenant at sufferance only at the rent set forth in this Section 6.1.9(b) and otherwise upon the terms and conditions set forth in this Lease. If possession of the Premises (or any part thereof) is not surrendered to Landlord on the expiration or earlier termination of this Lease, then (i) Tenant shall pay to Landlord for each month (or any portion thereof) prior to the date on which Tenant actually surrenders possession of the Premises, a sum equal to one hundred and fifty percent (150%) of the Fixed Rent, Additional Rent, and other charges payable under this Lease as of the day immediately preceding the date of expiration or earlier termination of this Lease, and (ii) if possession of the Premises (or any part thereof) is not surrendered to Landlord by the date which is ninety (90) days after the expiration or earlier termination of this Lease, then Tenant also shall indemnify and hold harmless Landlord from and against all damages (direct, consequential, or indirect) arising out of or resulting from such holding over.

6.1.10 Rules and Regulations. To comply with the Rules and Regulations set forth in Exhibit E and with all reasonable Rules and Regulations as may be adopted from time-to-time by Landlord (the "Rules and Regulations") and of which Tenant has received notice. Landlord agrees to enforce such Rules and Regulations in a nondiscriminatory fashion, except where differing circumstances justify different treatment; however, Landlord shall not be liable to Tenant for the failure of any other tenant(s) of the Building to comply with such Rules and Regulations. In the event of any conflict or inconsistency between the Rules and Regulations (whether included in Exhibit E or later adopted) and the terms and conditions of this Lease, the terms and conditions of this Lease shall govern and control.

6.1.11 Estoppel Certificates. Within not more than fifteen (15) days after request by Landlord, to execute, acknowledge and deliver to Landlord an estoppel certificate in writing in the form reasonably required by Landlord, certifying as to all or any of the following: (i) that this Lease is unmodified and in full force and effect (or, if there have been any modifications stating such modifications), (ii) whether the Term has commenced and Fixed Rent and Additional Rent have become payable hereunder and, if so, the dates to which they have been paid, (iii) whether or not, to Tenant's knowledge, Landlord is in default in performance of any of the terms of this Lease, and, if so, specifying such defaults, (iv) whether Tenant has accepted possession of the Premises, (v) whether Tenant has made any claim against Landlord under this Lease and, if so, the nature thereof and the dollar amount, if any, of such claim, (vi) whether Tenant claims any offsets or defenses against enforcement of any of the terms of this Lease, and, if so, setting them forth in reasonable detail, and (vii) such further information with respect to Lease and/or the Premises as Landlord may reasonably request and is customary in estoppel certificates provided to landlords, buyers and/or lenders. Any such

statement delivered pursuant to this subsection 6.1.11 may be relied upon by Landlord, any prospective purchaser or mortgagee of the Premises, or any prospective assignee of such mortgage. Tenant shall also deliver to Landlord such financial information as may be reasonably required by Landlord to be provided to any mortgagee or prospective purchaser of the Property; provided, however, Landlord shall exercise good faith reasonable efforts to keep such financial information confidential and, prior to the delivery of any of Tenant's financial information to such prospective purchasers, mortgagees or assignees of any mortgage, require such prospective purchasers, mortgagees or assignees of any mortgage to sign a commercially reasonable confidentiality agreement with respect to such confidential information.

6.1.12 Landlord's Expenses Re Consents. To reimburse Landlord promptly upon demand for all reasonable legal fees and expenses incurred by Landlord in connection with all requests made by Tenant for consents or approvals hereunder.

6.1.13 Outside Sales, etc. Not to (i) solicit sales, place signs, place or maintain any articles in any area of the Property outside of the Premises, or in the lobbies or on the sidewalks, corridors or other common areas of the Building, nor (ii) receive or ship articles of any kind outside the designated loading areas for the Premises, nor (iii) permit the parking of vehicles so as to interfere with the use of any driveway, corridor, footwalk, parking area, street or other common area of the Building.

6.1.14 Fire Extinguishers, etc. To install and maintain automatic, non-toxic, dry chemical fire extinguishing devices approved by the Fire Insurance Rating Organization having jurisdiction over the Premises, and if gas is used in the Premises, suitable gas cut-off devices (manual and automatic).

6.1.15 Receipt and Delivery. To receive and deliver goods and merchandise only through the loading dock designated from time to time by Landlord, during ordinary weekday business hours (except for Saturday deliveries by overnight courier firms such as Federal Express), and to cause all messenger and small scale deliveries to be made through the Building security desk, all in accordance with Landlord's rules and regulations therefor. Without limitation, no "hand trucks" shall be used in the lobby areas of the Building.

6.1.16 Security Measures. To maintain order and decorum in and around all portions of the Premises, and if auxiliary security personnel shall reasonably be required to maintain such order and decorum the same shall be provided by and at the expense of Tenant whenever requested by Landlord.

6.2 Negative Covenants. Tenant covenants and agrees, at all times during the Term and during such additional times (prior or subsequent thereto) as Tenant occupies the Premises or any part thereof:

6.2.1 Assignment and Subletting. (a) Not to assign, transfer, mortgage or pledge this Lease or to sublease (which term shall be deemed to include the granting of

concessions and licenses and the like) all or any part of the Premises or suffer or permit this Lease or the leasehold estate hereby created or any other rights arising under this Lease to be assigned, transferred or encumbered, in whole or in part, whether voluntarily, involuntarily or by operation of law, or permit the occupancy of the Premises by anyone other than Tenant, without the prior written consent of Landlord in each instance. In the event Tenant desires to assign this Lease or sublet any portion or all of the Premises, Tenant shall notify Landlord in writing of Tenant's intent to so assign this Lease or sublet the Premises, which notice shall be accompanied by (a) with respect to an assignment of this Lease, the date Tenant desires the assignment to be effective, and (b) with respect to a sublet of all or a part of the Premises, (i) the material business terms on which Tenant would sublet such premises, and (ii) a description of the portion of the Premises to be sublet. Each such notice shall be deemed an offer from Tenant to Landlord whereby Landlord shall be granted the right, at Landlord's option, (1) to suspend this Lease with respect to such space as Tenant proposes to sublease (the "Partial Space"), upon the terms and conditions hereinafter set forth, or (2) if the proposed transaction is an assignment of this Lease or a subletting of fifty percent (50%) or more of the rentable square footage of the Premises for a sublease term that expires later than twelve (12) months prior to the Expiration Date, to terminate this Lease with respect to the entire Premises. Such option may be exercised by notice from Landlord to Tenant within ten (10) business days after Landlord's receipt of Tenant's notice. If Landlord exercises its option to terminate this Lease as to the entire Premises, or to suspend this Lease as to a Partial Space, pursuant to the foregoing provisions, then (a) this Lease shall end and expire, or be suspended, with respect to all or a portion of the Premises, as the case may be, on the date that such assignment or sublease was to commence (as if such date were the expiration date of the Term hereof), (b) Rent shall be apportioned, paid or refunded as of such date and Tenant's Percentage shall be appropriately adjusted, (c) Tenant, upon Landlord's request, shall enter into an amendment of this Lease ratifying and confirming such termination or suspension, and setting forth any appropriate modifications to the terms and provisions hereof, (d) Landlord shall be free to lease the Premises, or the portion thereof as to which such termination or suspension shall be effective, or any part thereof, to any person or persons, including, without limitation, to Tenant's prospective assignee or subtenant, and (e) if the termination is only as to a Partial Space, Tenant shall be liable for all costs and expenses of segregating the Partial Space from the remaining Premises, and for the costs of separately demising the Partial Space from the remaining Premises. If Landlord does not elect to terminate or suspend this Lease as aforesaid, then Landlord's consent shall not be unreasonably withheld to such assignment or subletting, provided that the following conditions are met:

(i) the Guaranty remains in full force and effect and the Guarantor remains fully and completely liable for all of its obligations thereunder, excepting only if, and only if Landlord elects, in its sole and unfettered discretion, to release Guarantor from its obligations under the Guaranty from and after an assignment or subletting and a substitute guaranty from a guarantor satisfactory to Landlord in its sole discretion is provided in form and substance satisfactory to Landlord

in its sole and unfettered discretion at the time of such assignment or subletting;

(ii) the proposed assignee or subtenant is not then, and has not within the twelve (12) months immediately preceding such request, been a tenant in the Building or an entity with whom Landlord is dealing or has dealt within such twelve (12) month period regarding the possibility of leasing space in the Building;

(iii) Tenant is not in default under this Lease beyond any applicable grace period;

(iv) the assignee or subtenant shall use the Premises only for the Permitted Uses; and

(v) the form and substance of the proposed sublease or instrument of assignment is reasonably satisfactory to Landlord.

Tenant shall furnish Landlord with any information reasonably requested by Landlord to enable Landlord to determine whether the proposed assignment or subletting complies with the requirements contained herein, including, without limitation, financial statements relating to the proposed assignee or subtenant, which Landlord shall keep confidential.

(a) Tenant shall, promptly after Landlord's request therefor, reimburse Landlord, as Additional Rent, for all reasonable legal fees and expenses incurred by Landlord in connection with any request by Tenant for such consent provided, however, with respect to each proposed sublease or assignment Tenant shall not be obligated to reimburse Landlord for more than $3,500.00 on account of such costs and expenses, unless such sublease or assignment does not occur in the ordinary course of business (e.g. is in connection with a bankruptcy or reorganization of Tenant) or involves an amendment to this Lease or other additional documentation (other than a customary Landlord's consent to sublease or assignment agreement), or if Landlord provides unusual or extraordinary services in connection therewith. If Landlord consents thereto, no such subletting or assignment shall in any way impair the continuing primary liability of Tenant hereunder, and no consent to any subletting or assignment in a particular instance shall be deemed to be a waiver of the obligation to obtain the prior written consent of Landlord for any other subletting or assignment. If Tenant has not executed and delivered to Landlord an assignment or sublease within one hundred eighty (180) days after Landlord's election not to terminate or suspend the Term hereof pursuant to the provisions of Section 6.2.1(a) above, then Tenant shall submit an additional notice to Landlord, and Landlord shall again have the right to terminate the Term in the case of a proposed assignment or to suspend this Lease pro tanto for the period and with respect to the space involved in the case of a proposed subletting, in accordance with the provisions of Section 6.2.1(a) as if Landlord's prior election not to do so had not been made.

(b) If Tenant shall enter into any assignment of this Lease or any sublease of all or any portion of the Premises, and in connection with any such assignment or sublease Tenant receives rent or other consideration, either initially or over the term of the assignment or sublease, in excess of the Rent payable by Tenant hereunder, or in case of any sublease of part of the Premises in excess of the Rent fairly allocable, to such part of the Premises (after first deducting Tenant's reasonable actual out-of-pocket costs for construction of improvements in connection with said sublease the reasonable third-party fees and expenses for brokerage, advertising, architectural, and legal services actually incurred by Tenant in connection with such assignment or sublease), amortized over the term of the assignment or sublease, then Tenant shall pay to Landlord, promptly after receipt thereof, as Additional Rent, fifty percent (50%) of the excess of each such payment of rent or other consideration received by Tenant. Within sixty (60) days after Landlord's consent to such assignment or sublease (or if Landlord's consent is not required hereunder, within such sixty (60) days after the date of such assignment or sublease), Tenant shall deliver to Landlord a complete list of Tenant's reasonable third-party brokerage fees, legal fees and architectural fees paid or to be paid in connection with such transaction, together with a list of all of Tenant's personal property to be transferred to such assignee or sublessee. Tenant shall deliver to Landlord evidence of the payment of such fees promptly after the same are paid.

(c) If Tenant is a corporation, the transfer by one or more transfers, directly or indirectly, by operation of law or otherwise, of a majority of the stock of Tenant shall be deemed a voluntary assignment of this Lease; provided, however, that the provisions of this subsection (d) shall not apply to the transfer of shares of stock of Tenant if and so long as the voting of stock of Tenant is publicly traded on a nationally recognized stock exchange. For purposes of this subsection (d) the term "transfers" shall be deemed to include the issuance of new stock or of treasury stock which results in a majority of the stock of Tenant being held by a person or persons that do not hold a majority of the stock of Tenant on the date hereof. If Tenant is a partnership, the transfer (by one or more transfers) of a majority interest in the partnership shall be deemed a voluntary assignment of this Lease. If Tenant is a limited liability company, trust, or any other legal entity, the transfer (by one or more transfers) of a majority of the beneficial ownership interests in, or the right(s) to manage and/or direct the operations of, such entity, however characterized, shall be deemed a voluntary assignment of this Lease.

(d) Any assignment or transfer, whether made with Landlord's consent or without Landlord's consent because Landlord's consent is not required pursuant to the applicable provisions of this Section 6.2.1, if and to the extent permitted hereunder, shall not be effective unless and until the assignee or transferee executes, acknowledges and delivers to Landlord an agreement in form and substance satisfactory to Landlord whereby the assignee (A) assumes Tenant's obligations under this Lease (including, without limitation, the obligation to continue to operate for the Permitted Use), and (B) agrees that, notwithstanding

such assignment or transfer, the provisions of this Section 6.2.1 shall be binding upon it with respect to all future assignments and transfers.

(e) Notwithstanding the foregoing provisions, Landlord's prior consent shall not be required for an assignment of this Lease in connection with transactions with an entity which acquires all or substantially all of the assets of or ownership interests in Tenant, or into or with which Tenant is merged or consolidated so long as: (i) such entity shall agree with Landlord to be bound by all of the obligations of Tenant hereunder; (ii) such assignment shall not relieve Tenant of any of its obligations hereunder; (iii) such transfer was made for a legitimate independent business purpose and not for the purpose of transferring this Lease, and (iv) the Guarantor covenants and agrees, pursuant to a reaffirmation agreement prepared by Landlord, that the Guaranty remains in full force and effect notwithstanding said assignment, unless Landlord elects, in its sole and unfettered discretion as set forth in Section 6.2.1(a)(i), to release Guarantor and accept a substitute guaranty.

(f) Notwithstanding the foregoing provisions, Landlord's prior consent shall not be required for an assignment of this Lease or a sublease of all or a portion of the Premises to an Affiliate of Tenant (but only for such period of time as such Person remains an Affiliate of Tenant), it being agreed that the subsequent transfer of control, or any other transaction(s) having the overall effect that such Person ceases to be such an Affiliate of Tenant, shall be treated as if such transfer or transaction(s) were, for all purposes, an assignment of this Lease to a third party not an Affiliate of Tenant governed by the provisions of subsection (a). "Affiliate" shall mean any entity (i) of which Wilmer Cutler Pickering Hale and Dorr LLP or Tenant possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such entity, or (ii) of which Wilmer Cutler Pickering Hale and Dorr LLP or Tenant owns not less than fifty percent (50%) of the ownership interests; provided, however, the subsequent sale or transfer of stock or ownership interests having the overall effect that Wilmer Cutler Pickering Hale and Dorr LLP or Tenant no longer holds fifty percent (50%) or more of the ownership interests of such entity shall be treated as if such sale, transfer or other transactions) were for all purposes, an assignment of this Lease. Any assignee or sublessee pursuant to a transaction described in Section 6.2.1(f) or (g) shall be a "Permitted Assignee."

(g) The joint and several liability of Tenant and any successors-in-interest of Tenant and the due performance of Tenant's obligations under this Lease shall not be discharged, released or impaired by any agreement or stipulation made by Landlord, or any grantee or assignee of Landlord, extending the time, or modifying any of the terms and provisions of this Lease, or by any waiver or failure of Landlord, or any grantee or assignee of Landlord, to enforce any of the terms and provisions of this Lease. The listing of any name other than that of Tenant on the doors of the Premises, the Building directory or elsewhere shall not vest any right or interest in this Lease or in the Premises, nor be deemed to constitute Landlord's consent to any assignment or transfer of this Lease or to any sublease of the Premises or to the use or occupancy thereof by others. Any such

listing shall constitute a privilege revocable in Landlord's discretion by notice to Tenant.

(h) Notwithstanding the foregoing, the prior consent of Landlord shall not be required with respect to, and the provisions of Section 6.2.1 shall not apply to, occupancy agreements entered into by Tenant with its clients and customers ("Approved Users") for the temporary occupancy of space within the Premises, provided that (a) Tenant does not separately demise such space and the Approved Users utilize, in common with Tenant, common entryways to the Premises as well as shared central services, such as reception, photocopying and the like; (b) the Approved Users shall not occupy, in the aggregate, more than 20% of the Rentable Area in the Premises; (c) the Approved Users occupy space in the Premises for the Permitted Uses and for no other purpose; and (d) if requested by Landlord, Tenant notifies Landlord, in writing, of the identity of any such Approved Users prior to occupancy of the Premises by such Approved Users. If any Approved Users occupy any portion of the Premises as described herein, (i) the Approved Users shall comply with all provisions of this Lease, and a default by any Approved User shall be deemed a default by Tenant under this Lease; (ii) all notices required to be provided by Landlord under this Lease shall be forwarded only to Tenant in accordance with the terms of this Lease and in no event shall Landlord be required to send any notices to any Approved Users; (iii) in no event shall any use or occupancy of any portion of the Premises by any Approved User release or relieve Tenant from any of its obligations under this Lease; (iv) the Approved Users shall be deemed to be contractors of Tenant for purposes of Tenant's indemnification obligations set forth in this Lease; and (v) in no event shall the occupancy of any portion of the Premises by Approved Users be deemed to create a landlord/tenant relationship between Landlord and such Approved Users, and, in all instances, Tenant shall be considered the sole tenant under this Lease notwithstanding the occupancy of any portion of the Premises by the Approved Users.

6.2.2 Nuisance. Not to permit or cause any offensive odors or vibrations to be emitted from the Premises. Not to injure, deface or otherwise harm the Premises or the Property (or any part thereof), nor to commit any nuisance; nor permit in the Premises any vending machine (except as used for the sale of merchandise to employees and guests of Tenant) or kerosene, gasoline, or inflammable or combustible or explosive fluid or chemical substance (other than limited quantities of such materials or substances reasonably necessary for the operation or maintenance of office equipment or limited quantities of cleaning fluids and solvents required in Tenant's normal operations in the Premises); nor permit any cooking to such extent as requires special exhaust venting or in violation of the Rules and Regulations; nor permit the emission of any objectionable noise or odor; nor permit use of any telecommunications or other equipment which interferes with the use and enjoyment by any other tenant of the Building of its demised premises; nor make, allow or suffer any waste; nor make any use of the Premises which is improper, offensive or contrary to any law or ordinance or which will invalidate any of Landlord's insurance or cause any increase above

normal insurance premiums on the Building; nor conduct any auction, fire, "going out of business" or bankruptcy sales.

6.2.3 Hazardous Wastes and Materials. Not to cause or permit any Hazardous Materials to be used, handled, generated, stored or disposed of on, under or above, or transported to or from, the Premises and/or the Property (collectively, "Hazardous Materials Activities"). Nothing contained herein shall be deemed to prevent Tenant from using de minimus quantities of commercially available cleaners and office supplies which are customarily used in the ordinary course of first-class business office operations, which cleaners and/or office supplies contain Hazardous Materials; provided that, Tenant shall use such cleaners and/or office supplies in strict compliance (at Tenant's sole cost and expense) with all applicable laws, and shall use all necessary and appropriate precautions to prevent any spill, discharge, release or exposure to persons or property. Landlord shall not be liable to Tenant for any loss, cost, expense, claim, damage or liability arising out of any Hazardous Materials Activities by Tenant, or by Tenant's employees, agents, contractors, licensees, customers or invitees, whether or not consented to by Landlord. Tenant shall indemnify, defend with counsel acceptable to and approved by Landlord, and hold Landlord and all Landlord Affiliates harmless from and against any and all losses, costs, expenses (including, without limitation, all reasonable attorneys fees), claims, damages, obligations and liabilities arising out of: (i) any Hazardous Materials Activities on the Premises first occurring after the Commencement Date, whether or not consented to by Landlord; (ii) any Hazardous Materials Activities by Tenant, Tenant's employees, agents, contractors, licensees, customers or invitees or anyone claiming by, through or under Tenant, wherever occurring; and (iii) any contamination, claim of contamination, loss or damage, or the like arising out of or resulting from the foregoing. For purposes hereof, "Hazardous Materials" shall include but not be limited to substances defined as "hazardous substances," "toxic substances" or "hazardous wastes" or "oil" in any local, state or federal law, rule, regulation or ordinance (collectively, "Environmental Law(s)"). If Landlord consents to any Hazardous Materials Activities, prior to using, storing or maintaining any Hazardous Materials on or about the Premises, Tenant shall provide Landlord with a list of the types and quantities thereof, and shall update such list from time-to-time as necessary for continued accuracy. Tenant shall also provide Landlord with a copy of any Hazardous Materials inventory statement and any updates thereof required by any applicable Environmental Laws. If Tenant's activities violate or create a risk of violation of any Environmental Law or cause a spill, discharge, release or exposure to any persons or property, Tenant shall cease such activities immediately. Tenant shall immediately notify Landlord both by telephone and in writing of any spill, discharge, release or exposure of Hazardous Materials in or about the Premises, or of any condition in or about the Premises constituting an "imminent hazard" under any Environmental Laws. Landlord, Landlord's representatives and employees may enter the Premises during the Term to inspect Tenant's compliance herewith, and may disclose any spill, discharge, release, or exposure or any violation of any Environmental Laws to any applicable governmental agencies or authorities.

6.2.4 Floor Load; Heavy Equipment. Not to place a load upon any floor of the Premises exceeding the floor load per square foot area which Landlord reasonably determines the floor is adequate to carry, and in no event, in excess of that allowed by law. Landlord reserves the right to reasonably prescribe the weight and position of all heavy business machines and equipment, including safes, which shall be placed so as to distribute the weight. Business machines and mechanical equipment which cause vibration or noise shall be placed and maintained by Tenant at Tenant's expense in settings sufficient to absorb and prevent vibration, noise and annoyance. Tenant shall not move any safe, heavy machinery, heavy equipment, freight or fixtures into or out of the Premises except in such manner and at such time as Landlord shall reasonably authorize in each instance.

6.2.5 Improvements, Alterations and Additions. (a) Not to make any installations, improvements alterations or additions (collectively, "Alterations") in, to or on the Premises, nor the installation or modification of any locks or security devices, without on each occasion obtaining the prior written consent of Landlord. Notwithstanding the foregoing, Landlord's prior written consent shall not be required in connection with usual and customary interior decorative or cosmetic Alterations that satisfy the following criteria: (i) the Alteration is of a decoration or cosmetic nature such as wallpapering, painting, carpeting or installation of artwork, (ii) the Alteration is non-structural and does not affect the Building Systems, (iii) the Alteration affects only the Premises and is not visible from outside of the Premises or the Building, (iv) the Alteration will not adversely affect any service furnished by Landlord to Tenant or to any other tenant of the Building, (v) the Alteration does not require work to be performed inside the walls, above the ceiling, or below the floor of the Premises, and (vi) the Alteration is in compliance with, and does not cause any violations of, all applicable laws, codes, ordinances, by-laws, and requirements. All Alterations (excepting only decorative Alterations) shall be performed pursuant to plans and specifications approved by Landlord in advance in each instance and by contractors approved by Landlord in its reasonable discretion. All Alterations shall be performed in a manner and fashion so as to minimize interference with the other tenants and occupants of the Building, with Landlord and Landlord's operations in the Building and with other labor working on the Premises and/or the Property (or any part thereof). Tenant shall pay promptly when due the entire cost and expense of all Alterations to the Premises undertaken by Tenant and in any event shall cause the Premises at all times to be free of liens for labor and materials. All Alterations performed by Tenant shall be performed in a good and workmanlike manner, employing materials of the highest quality and in compliance with all applicable Requirements. To the maximum extent permitted by law, Tenant shall indemnify and hold harmless Landlord and all Landlord Affiliates from (i) any personal injury, death, damage or loss to any person or property arising out of or resulting from any Alterations undertaken by Tenant, and (ii) any liabilities and/or obligations for any and all liens or encumbrances filed against the Property or any part thereof or interest therein arising out of or resulting from the Alterations performed by Tenant. Tenant, at its expense, shall procure the discharge or

bonding of all such liens and encumbrances within thirty (30) days after the filing of any such lien or encumbrance against the Premises and/or the Property or any part thereof. If Tenant shall fail to cause any such lien or encumbrance to be discharged or bonded within such thirty (30) day period, then, in addition to any other right or remedy, Landlord may, but shall not be obligated to, discharge the same either by paying the amount claimed to be due or by deposit or bonding proceedings, and in any such event Landlord shall be entitled, if it elects, to compel the prosecution of an action for the foreclosure of such lien and to pay the amount of the judgment in favor of the lien with interest, costs and allowances. Without limiting the foregoing, any amount so paid by Landlord, and all costs and expenses incurred by Landlord in connection therewith, shall constitute Additional Rent under this Lease and shall be paid by Tenant to Landlord within ten (10) days after demand.

(b) Prior to commencing any Alterations, Tenant shall, at Tenant's sole cost and expense: (i) secure all licenses, permits and approvals required by any governmental authorities in connection therewith; (ii) deliver to Landlord a statement of the names of all of its contractors and subcontractors, and the estimated costs of all labor and material to be furnished by them; (iii) furnish to Landlord reasonably satisfactory evidence of the insurance coverages maintained by Tenant in accordance with the requirements of Section 4.2.4 of this Lease; and (iv) cause each contractor to carry (A) workers' compensation insurance in statutory amounts and employer's liability insurance with limits of not less than $500,000.00 per accident covering all the contractor's and subcontractor's employees, (B) commercial general liability insurance, including completed operations coverage, for a period of not less than one (1) year beyond completion of the work that the contractor/subcontractor performs, with such limits as Landlord may reasonably require but in no event less than $5,000,000.00 per occurrence, and (C) automobile liability insurance with such limits as Landlord may reasonably require, but in no event less than $1,000,000.00 combined single limit per accident, with liability coverage of not less than $4,000,000.00 (for a total of $5,000,000.00 in an umbrella liability policy). All such insurance coverages (i) shall be written by companies duly licensed in the Commonwealth of Massachusetts and reasonably approved by Landlord, (ii) shall name Landlord, all Landlord Affiliates requested by Landlord, and Tenant as additional insureds, as their respective interests may appear, as well as their respective contractors and subcontractors, (iii) shall contain a waiver of subrogation provision in favor of Landlord and all such Landlord Affiliates, and (iv) shall provide primary coverage as to any other coverage maintained by any insured other than Tenant. Tenant shall deliver to Landlord certificates of all such insurance before Tenant begins any Alterations.

(c) Landlord may inspect the Alterations in progress at reasonable times and from time-to-time; provided, however, Landlord shall, except in case of emergency, (i) give Tenant reasonable prior notice of such inspections, and (ii) conduct such inspections so as to minimize interference with the construction work of Tenant.

(d) At Landlord's request, promptly after such Alterations are completed, Tenant shall provide Landlord with a complete set of "as-built" plans for the portions of the Premises affected by such work, prepared using electronic CAD files in AUTO CAD format.

(e) All Alterations shall be performed (a) in a good and first-class workmanlike manner and free from defects, (b) in accordance with the plans and specifications approved by Landlord, and by contractors approved by Landlord, (c) if requested by Landlord, under the supervision of a licensed architect reasonably satisfactory to Landlord, and (d) in compliance with all applicable laws, by-laws, ordinances, codes, regulations and guidelines, the terms of this Lease, and all procedures and regulations then prescribed by Landlord for coordinating all work performed in the Property.

(f) Tenant shall pay promptly to Landlord or its designee, upon demand, all reasonable out-of-pocket architectural and engineering fees and costs actually incurred by Landlord in connection with the review and supervision of Tenant's Alterations (including the Tenant's Work), including costs incurred in connection with Landlord's review of the Alterations (including review of requests for approval thereof). In addition, if Tenant's Alterations shall cost more than $100,000.00, Tenant shall pay to Landlord or its designee, upon demand, an administrative fee in the amount of three percent (3%) of the total cost of such Alterations; provided, however, no such administrative fee shall be payable in connection with Tenant's Work.

(g) The approval of plans or specifications, or consent by Landlord to the making of any Alterations, does not constitute Landlord's agreement or representation that such plans, specifications or Alterations comply with any laws, codes, ordinances, rules, guidelines or requirements. Landlord shall have no liability to Tenant or any other party in connection with Landlord's approval of any plans and specifications for any Alterations, or Landlord's consent to Tenant's performing any Alterations.

6.2.6 Abandonment. Not to abandon or vacate the Premises during the Term without continuing to pay Rent when due hereunder.

6.2.7 Signs; Building Directory. Not to install or place any signs, displays, curtains, blinds, shades, awnings, aerials, or the like, in any areas that may be visible from outside the Premises, excepting only with the prior written approval of the Landlord in each instance. Landlord will, at Landlord's expense, install the name of the Tenant in the Building lobby directory. Without limiting the foregoing, subject to Landlord's approval and in accordance with the signage standards and specifications adopted by Landlord from time-to-time, Tenant may at its sole cost and expense install identification signage on the entrance doors to the Premises and in the elevator lobby area of the floor on which the Premises are located.

ARTICLE 7
Casualty or Taking

7.1 Termination. In the event that the Premises or the Building and/or any material part thereof, shall be taken by any public authority or for any public use, or shall be destroyed or damaged by fire or other casualty, or by the action of any public authority, then this Lease may be terminated at the election of Landlord. Such election, which may be made notwithstanding the fact that Landlord's entire interest may have been divested, shall be made by the giving of notice by Landlord to Tenant within sixty (60) days after the date of the taking or casualty. In addition to Landlord's right to terminate as provided herein, Tenant shall have the right to terminate this Lease if either (i) more than thirty-five percent (35%) of the Rentable Area of the Premises shall be destroyed or materially damaged by fire or casualty, or (ii) a material portion of the common areas of the Building are destroyed or materially damaged such that Tenant is deprived of reasonable access to the Premises; and as a result thereof, (a) the Premises are not, despite Tenant's commercially reasonable good faith efforts, usable by Tenant in the ordinary course of Tenant's business; and (b) within not more than thirty (30) days after the date of the casualty or damage or of the date of Landlord's notice to Tenant of such taking, Tenant provides Landlord with written notice of its election to terminate this Lease. Subject to the terms of this Section 7.1, if Tenant timely and properly notifies Landlord of its election to terminate this Lease, this Lease shall terminate thirty (30) days after the date such notice is received by Landlord. Notwithstanding anything to the contrary in this Article 7, if any damage during the final 18 months of the Term renders the Premises wholly untenantable, either Landlord or Tenant may terminate this Lease by notice to the other party within 30 days after the occurrence of such damage and this Lease shall expire on the 30th day after the date of such notice. For purposes of this paragraph, the Premises shall be deemed wholly untenantable if Tenant shall be precluded from using more than 35% of the Rentable Area of the Premises for the conduct of its business and Tenant's inability to so use the Premises is reasonably expected to continue for more than 90 days.

7.2 Restoration. Subject to the terms of Section 7.1, if neither Landlord nor Tenant elects to terminate this Lease, then this Lease shall continue in force and, if such taking or damage is of or to the Premises, a just proportion of the Rent reserved, according to the nature and extent of the damages sustained by the Premises, shall be suspended or abated until the Premises, or what may remain thereof, shall be put by Landlord in proper condition for use, which Landlord covenants to do with reasonable diligence (subject to delays which result from any cause beyond the reasonable control of Landlord) to the extent permitted by the net proceeds of insurance recovered or damages awarded for such taking, destruction or damage and subject to zoning and building laws or ordinances then in existence. Should the net proceeds of insurance recovered or damages awarded be insufficient to cover the cost of restoring the Premises, in the reasonable estimate of the Landlord, the Landlord may, but shall have no obligation to, supply the amount of such insufficiency and restore the Premises with all reasonable diligence or the

Landlord may terminate the Lease by giving notice to the Tenant not later than a reasonable time after the Landlord has determined the estimated net proceeds of insurance recovered or damages awarded and the estimated cost of such restoration. In case of damage or destruction, as a result of a risk which is not covered by the Landlord's insurance, the Landlord shall likewise be obligated to rebuild the Premises, all as aforesaid, unless the Landlord, within a reasonable time after the occurrence of such event, gives written notice to the Tenant of the Landlord's election to terminate this Lease. "Net proceeds of insurance recovered or damages awarded" refers to the gross amount of such insurance or damages actually received by Landlord less the reasonable expenses of Landlord incurred in connection with the collection of the same, including without limitation, fees and expenses for legal and appraisal services. If Landlord's restoration work has not been substantially completed within twelve (12) months after the taking or damage, then Tenant shall have the right to terminate this Lease by giving Landlord written notice of its election to do so within thirty (30) days after the end of such twelve (12) month period, and if Tenant timely gives such notice, this Lease shall terminate on the date which is thirty (30) days after the date of the giving of such notice, unless Landlord's restoration work is substantially completed within such thirty (30) day period, in which event such termination notice shall be null and void and this Lease shall continue in full force and effect.

7.3 Award. Irrespective of the form in which recovery may be had by law, all rights to damages or compensation for any taking of the Premises (including, without limitation, any taking of the leasehold interest of Tenant) shall belong to Landlord in all cases. Tenant hereby grants to Landlord all of Tenant's rights to such damages and covenants to deliver such further assignments thereof as Landlord may from time to time request. The Tenant shall be entitled to receive and retain only such amounts as may be specifically awarded to it in any such condemnation proceedings, as a result of the taking of its trade fixtures or furniture and its leasehold improvements to the extent the Landlord's award is not thereby reduced and the Tenant is not otherwise reimbursed for the same by the Landlord.

ARTICLE 8
Defaults

8.1 Events of Default. If any of the following occurs:

(a) Tenant shall default in the payment when due of any Fixed Rent or Additional Rent, and such default shall continue for five (5) business days after notice thereof from Landlord; or

(b) Tenant shall have previously defaulted more than twice in any twelve (12) month period in the payment when due of any Fixed Rent or Additional Rent, Tenant subsequently defaults in the payment when due of any Fixed Rent or Additional Rent; or

(c) Tenant shall default in the timely performance or observance of any other term, covenant, or condition contained in this Lease on the Tenant's part to be performed or observed and shall fail, within thirty (30) days after notice from Landlord of such default, to cure such default; or if such default is not reasonably susceptible of cure within thirty (30) days, if Tenant shall fail to commence to cure such default within thirty (30) days after notice of such default from Landlord or shall thereafter fail diligently to prosecute such cure to completion or shall fail to cure such default by not later than one hundred twenty (120) days after receipt of such notice from Landlord; or

(d) the estate of Tenant hereby created shall be taken on execution, or by other process of law; or

(e) Tenant commences a voluntary case under Title 11 of the United States Bankruptcy Code as from time-to-time in effect, or it authorizes, by appropriate proceedings of trustees or other governing body the commencement of such a voluntary case; or

(f) Tenant files an answer or other pleading admitting or failing to deny the material allegations of a petition filed against if commencing an involuntary case under said Bankruptcy Code, or if it seeks, consents to or acquiesces in the relief therein provided, or if it fails to controvert timely the material allegations of any such petition; or

(g) there is entered an order for relief in any involuntary case commenced under said Title; or

(h) Tenant seeks relief as a debtor under any applicable law, other than said Bankruptcy Code, of any jurisdiction relating to the liquidation or reorganization of debtors or to the modification or alteration of the rights of creditors, or by Tenant's consent to or acquiescence in such relief; or

(i) there is entered an order by a court of competent jurisdiction (i) finding Tenant to be bankrupt or insolvent, (ii) ordering or approving Tenant's liquidation, reorganization or any modification or alteration of the rights of its creditors, or (iii) assuming custody of, or appointing a receiver or other custodian for, all or a substantial part of Tenant's property; or

(j) Tenant makes an assignment for the benefit of, or enters into a composition with, its creditors, or appoints or consents to the appointment of a receiver or other custodian for all or a substantial part of its property; or

(k) Tenant rejects this Lease and a court of competent jurisdiction enters an order approving the rejection of the Lease under Title 11 of the United States Code as from time to time in effect, or under any applicable law, other than said Title 11, of any jurisdiction relating to the liquidation or reorganization of debtors or to the modification or alteration of the rights of creditors, or by Tenant's consent to or acquiescence in such relief;

then and in any of said cases, in addition to all other remedies available at law or in equity, Landlord may, to the extent permitted by law, immediately or at any time thereafter and with or without demand or notice to Tenant, enter into and upon the Premises, or any part thereof in the name of the whole, and repossess the same as of Landlord's former estate, and expel Tenant and those claiming by, through or under Tenant and remove its effects without being deemed guilty of any manner of trespass, and without prejudice to any remedies which might otherwise be used for arrears of Rent and preceding breach of covenant, and/or Landlord may terminate this Lease by sending written notice thereof to Tenant and this Lease shall terminate and come to an end on the earlier to occur of (i) entry as aforesaid, or (ii) the fifth (5th) day following the sending of such notice as fully and completely as if such date were on the date herein originally fixed for the expiration of the Term of this Lease. Tenant will then quit and surrender the Premises to Landlord, but Tenant shall remain liable as herein provided. To the extent permitted by law, Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws (including M.G.L. c.186, §11), in the event of Tenant being evicted or dispossessed, or in the event of Landlord obtaining possession of the Premises, by reason of the violation by Tenant of any of the covenants and conditions of this Lease. In the event of any such termination, entry or re-entry, Landlord shall have the right to remove and store Tenant's property and that of persons claiming by, through or under Tenant at the sole risk and expense of Tenant and, if Landlord so elects, (x) to sell such property at public auction or private sale and apply the net proceeds to the payment of all sums due to Landlord from Tenant and pay the balance, if any, to Tenant, or (y) to dispose of such property in any manner in which Landlord shall elect, Tenant hereby agreeing to the fullest extent permitted by law that it shall have no right, title or interest in any property remaining in the Premises after such termination, entry or re-entry.

8.2 Remedies. (a) No termination or repossession provided for in Section 8.1 shall relieve Tenant or any guarantor of the liabilities and obligations of Tenant under this Lease, all of which shall survive any such termination or repossession. In the event of any such termination or repossession, Tenant shall pay to Landlord, at Landlord's election, either (i) in advance, on the first day of each month, for what would have been the entire balance of the Term (including any unexercised Extension Term), 1/12th (and a pro rata portion thereof for any fraction of a month) of the annual Fixed Rent, Additional Rent and all other amounts for which Tenant is obligated hereunder, minus, in each case, the actual net receipts by Landlord by reason of any re-letting of the Premises (after deducting Landlord's reasonable expenses in connection with such re-letting, including, without limitation, remodeling costs and costs of preparing the Premises, removal, storage and repair costs and reasonable brokers' and attorneys' fees), or (ii) upon demand and at the option of Landlord at any time thereafter, the present value (computed at a discount rate based upon the Prime Rate) of the amount by which the payments of Fixed Rent and Additional Rent payable for the balance of the Term would exceed the fair rental value of the Premises for the balance of the Term, determined by Landlord as of such date, less any proceeds of any re-letting of the

Premises. For purposes of this Article, if Landlord elects to require Tenant to pay damages in accordance with the immediately preceding sentence, the total amount due shall be computed by assuming that Tenant's Tax Excess and Tenant's Operating Cost Excess would be, for the balance of such unexpired Term, the amount thereof respectively for the Tax Period and calendar year, respectively, in which such termination, entry or re-entry shall occur.

(b) Notwithstanding the foregoing, Landlord will use reasonable efforts to re-let the Premises after Tenant vacates the Premises; however, the marketing of the Premises in a manner similar to the manner in which Landlord markets other premises within Landlord's control in the Building shall be deemed to have satisfied Landlord's obligation to use "reasonable efforts." In no event shall Landlord be required to (i) solicit or entertain negotiations with any other prospective tenants for the Premises unless and until Landlord obtains full and complete possession of the Premises, including the final and unappealable legal right to re-let the Premises free of any claim of Tenant, (ii) lease the Premises to a tenant whose proposed use, in Landlord's reasonable judgment, will be unacceptable, (iii) re-let the Premises prior to leasing any other vacant space in the Building, suitable for the use of the prospective tenant, (iv) lease the Premises for a rental rate less than the current fair market rent then prevailing for similar space in the Building, or (v) enter into a lease with any proposed tenant that does not have, in Landlord's reasonable opinion, sufficient financial wherewithal and resources to satisfy its financial obligations under the prospective lease. Landlord may elect: (i) to re-let the Premises or any part or parts thereof, for a term or terms which may at Landlord's option be equal to or less than or exceed the period which would otherwise have constituted the balance of the Term and may grant such inducements, allowances, concessions and free rent as Landlord in its sole discretion considers advisable or necessary to re-let the same, and/or (ii) to make such alterations, repairs and decorations to the Premises as Landlord in its sole discretion considers advisable or necessary to re-let the same, and no action of Landlord in accordance with the foregoing or failure to re-let or to collect rent under re-letting shall operate or be construed to release or reduce Tenant's liability as aforesaid. In connection with any such re-letting, Landlord may take into account all relevant factors which would be considered by a sophisticated Landlord in re-letting the Premises, and Tenant hereby waives, to the extent permitted by applicable law, any obligation Landlord may have to mitigate the Tenant's damages; provided, however, the foregoing provisions shall not detract from Landlord's obligations to exercise reasonable efforts to re-let the Premises as set forth in this Section 8.2(b).

(c) Nothing contained in this Lease shall limit or prejudice the right of Landlord to prove for and obtain in proceedings for bankruptcy, insolvency or like proceedings by reason of the termination of this Lease, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceedings in which, the damages are to be proved, whether or not the amount be greater, equal to, or less than the amount of the loss or damages referred to above.

8.3 Remedies Cumulative. Any and all rights and remedies which Landlord may have under this Lease, and at law and equity, shall be cumulative and shall not be deemed inconsistent with each other, and any two or more of all such rights and remedies may be exercised at the same time insofar as permitted by law.

8.4 Landlord's Right to Cure Defaults. After the expiration of any applicable notice and cure periods and upon reasonable prior notice (except in emergencies), Landlord may, but shall not be obligated to, cure any default by Tenant under this Lease; and whenever Landlord so elects, all costs and expenses incurred by Landlord, including reasonable attorneys' fees, in curing such default shall be paid, as Additional Rent, by Tenant to Landlord on demand, together with interest thereon at the Default Rate from the date of payment by Landlord to the date of payment by Tenant.

8.5 Effect of Waivers of Default. Any consent or permission by Landlord to any act or omission which otherwise would be a breach of any covenant or condition herein, or any waiver by Landlord Of the breach of any covenant or condition, shall not in any way be held or construed to operate so as to impair the continuing obligation of any covenant or condition herein, or otherwise, except as to the specific instance, operate to permit similar acts or omissions.

8.6 No Waiver, etc. The failure of Landlord to complain of any action or omission or to seek redress for violation of, or to insist upon the strict performance of, any covenant or condition of this Lease shall not be deemed a waiver of such violation nor prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by Landlord of any payments on account of Rent with knowledge of the breach of any covenant of this Lease shall not be deemed to have been a waiver of such breach by Landlord. No consent or waiver, express or implied, by Landlord or by Tenant to or of any breach of any agreement or duty to the other shall be construed as a waiver or consent to or of any other breach of the same by the other or any other agreement or duty of the other.

8.7 No Accord and Satisfaction. No acceptance by Landlord of a lesser sum than the Fixed Rent, Additional Rent or any other charge then due shall be deemed to be other than on account of the earliest installment of such Rent or charge due, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent or other charge be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such installment or pursue any other remedy in this Lease provided.

ARTICLE 9
Rights of Mortgagees

9.1 Rights of Mortgagees. (a) The rights and interests of Tenant under this Lease shall be subject and subordinate to any mortgages that are now or may hereafter

be placed upon the Property and/or the Building, and to any and all advances to be made thereunder, together with all renewals, modifications, replacements and extensions thereof. Without limitation, any mortgagee shall have the right, at its option, to subordinate its mortgage to this Lease, in whole or in part, by recording with the Registry of Deeds a unilateral written declaration to such effect. Upon entry and taking possession of the property by a mortgagee, for the purpose of foreclosure or otherwise, such Mortgagee shall have all the rights of Landlord, and shall be liable to perform all the obligations of Landlord arising during the period of such possession, provided, however, that such Mortgagee shall have no liability for any obligations which arise prior to the date on which it makes such entry or takes possession. No act or failure to act on the part of Landlord which would entitle Tenant under the terms of this Lease, or by law, to be relieved of Tenant's obligations hereunder or to terminate this Lease, shall result in a release or termination of such obligations or a termination of this Lease unless (i) Tenant shall have first given written notice of Landlord's act or failure to act to first mortgagees of record, if any, and to any other mortgagees of whom Tenant has been given written notice, specifying the act or failure to act on the part of Landlord which could or would give basis to Tenant's rights; and (ii) such mortgagees, after receipt of such notice, have failed or refused to correct or cure the condition complained of within a reasonable time thereafter; but nothing contained in this paragraph (c) shall be deemed to impose any obligation on any such mortgagees to correct or cure any such condition. "Reasonable time" as used above means and includes a reasonable time to obtain possession of the Property if any such mortgagee elects to do so and a reasonable time to correct or cure the condition if such condition is determined to exist. This Section shall be self-operative and no further instrument of subordination shall be required. In confirmation of such subordination, Tenant shall promptly execute, acknowledge and deliver any instrument that Landlord, any mortgagee or any of their respective successors in interest may reasonably require to evidence such subordination, which instrument shall also include commercially reasonable provisions for the recognition and non-disturbance of Tenant's estate and rights under this Lease, consistent with the terms and conditions of the form of subordination, non-disturbance and attornment agreement attached hereto as Exhibit H.

Concurrently with the delivery of this Lease, Landlord will deliver a subordination, non-disturbance and attornment agreement from FMR, LLC, the current holder of a mortgage on the Property, substantially in the form attached hereto as Exhibit H. In connection with any mortgages or ground leases entered into during the Term, Landlord shall use commercially reasonable efforts to cause such mortgagee or ground lessor to execute and deliver to Tenant a subordination, non-disturbance and attornment agreement in the form attached hereto as Exhibit H, or such form which provides Tenant with similar benefits.

(b) If any mortgagee or the nominee or designee of any mortgagee shall succeed to the rights of Landlord under this Lease, whether through possession or foreclosure action or delivery of a new lease or deed, or otherwise, then at the

request of such party so succeeding to Landlord's rights (herein called "Successor Landlord") and upon such Successor Landlord's written agreement to recognize and not disturb Tenant's estate and rights under this Lease and accept Tenant's attornment, Tenant shall attorn to and recognize such Successor Landlord as Tenant's landlord under this Lease and shall promptly execute and deliver any instrument that such Successor Landlord may reasonably request to evidence such attornment. Upon such attornment, this Lease shall continue in full force and effect as a direct lease between the Successor Landlord and Tenant upon all of the terms, conditions and covenants as are set forth in this Lease, except that the Successor Landlord shall not be (a) liable in any way to Tenant for any act or omission, neglect or default on the part of Landlord under this Lease, (b) responsible for any monies owing by or on deposit with Landlord to the credit of Tenant, (c) subject to any counterclaim or setoff which theretofore accrued to Tenant against Landlord, (d) bound by any modification of this Lease not previously approved by such Successor Landlord (or its predecessors in interest), or by any previous prepayment of Annual Fixed Rent or Additional Rent for more than 1 month, (e) liable to the Tenant beyond the Successor Landlord's interest in the Property and the rents, income, receipts, revenues, issues and profits issuing from the Property, (f) responsible for the performance of any work to be done by the Landlord under this Lease to render the Premises ready for occupancy by the Tenant, or (g) required to remove any person occupying the Premises or any part thereof, except if such person claims by, through or under the Successor Landlord.

9.2 Modifications. If any mortgagee shall require any modification(s) of this Lease, Tenant shall, at Landlord's request, promptly execute and deliver to Landlord such instruments effecting such modifications) as Landlord shall require, provided that such modification(s) do not adversely affect in any material respect any of Tenant's rights under this Lease.

ARTICLE 10
Appraisal of Fair Rental Value

10.1 Dispute as to Fair Rental Value. In the event that Tenant disputes the amount claimed by Landlord as Fair Rental Value of the Premises pursuant to Section 2.3 and such dispute cannot be resolved by mutual agreement, then Tenant shall have the right to submit the dispute to the appraisal process hereinafter set forth. The amount of Fair Rental Value determined pursuant to such appraisal process shall be final and binding between the parties. The appraisal process shall be conducted as follows:

10.1.1 Appointment of Appraisers. Tenant shall make demand for appraisal in writing within twenty (20) business days after service of Landlord's determination of Fair Rental Value given under Section 2.3 specifying therein the name and address of the person to act as the appraiser on its behalf. The appraiser shall be a real estate appraiser with at least ten (10) years' experience in the field and a qualified member of the American Institute of Real Estate Appraisers, or any successor of such Institute (or if such organization or successor shall not longer be in

existence, a recognized national association or institute of land appraisers) familiar with the fair market rent of first-class commercial office space in Boston, Massachusetts. If Tenant fails to specify the name of its appraiser in its demand for appraisal, then Landlord shall give notice (a "Reminder Notice") to Tenant indicating such failure and requesting that Tenant appoint an appraiser. If Tenant fails to notify Landlord of the appointment of its appraiser within five (5) business days after the delivery of the Reminder Notice by Landlord, then such failure shall constitute a waiver of the right of Tenant to appoint an appraiser, and the appraiser appointed by Landlord shall be the sole appraiser to determine the Fair Rental Value. Within ten (10) business days after receipt of the name of, or the deemed waiver of, the appointment of Tenant's appraiser, Landlord shall give notice to Tenant, specifying the name and address of the person designated by Landlord to act as an appraiser on its behalf who shall be similarly qualified. If Landlord fails to notify Tenant of the appointment of its appraiser within said ten (10) business days, then Tenant shall send a second notice (a "Reminder Notice") to Landlord indicating such failure and requesting Landlord to appoint an appraiser. If Landlord fails to notify Tenant of the appointment of its appraiser within five (5) business days after the delivery of the Reminder Notice by Tenant, then such failure shall constitute a waiver of the right of Landlord to appoint an appraiser, and the appraiser appointed by Tenant shall be the sole appraiser to determine the Fair Rental Value.

10.1.2 Decision by Two Appraisers. In the event that two (2) appraisers are chosen pursuant to paragraph (a) above, the appraisers so chosen shall meet within ten (10) business days after the second appraiser is appointed and, if within ten (10) business days after such first meeting the two appraisers shall be unable to agree upon a determination of Fair Rental Value, they shall appoint a third appraiser, who shall be a competent and impartial person with the same minimum qualifications and experience as is required of the first two appraisers. In the event they are unable to agree upon such appointment within five (5) business days after expiration of such ten (10) day period, the third appraiser shall be selected by the parties themselves, if they can agree thereon, within a further period often (10) business days. If the parties do not so agree, then either party, on behalf of both, may request appointment of such a qualified and independent person by an officer of the American Arbitration Association in Boston, Massachusetts. The three (3) appraisers shall decide the Fair Rental Value, if it has not previously been resolved, by following the procedure set forth below.

10.1.3 Decision by Three Appraisers. Where the Fair Rental Value cannot be determined by agreement between the two appraisers selected by Landlord and Tenant, or by agreement between the parties during the course of the appraisal process, then the Fair Rental Value shall be determined by the three appraisers in accordance with the following procedure: Within twenty (20) days after the third appraiser has been selected, each appraiser shall state in writing his determination of the Fair Rental Value, supported by the reasons therefor, with counterpart copies to each party. The appraisers shall arrange for a simultaneous exchange of such proposed determinations. The Fair Rental Value shall be the mean of the three appraisals;

provided, however, if an appraisal deviates from the mean by more than 10%, such deviant appraisal shall be discarded and the Fair Rental Value shall be, if there is one deviant appraisal, the mean of the two appraisals remaining, or, if there are two deviant appraisals, the one appraisal remaining.

10.2 Binding Effect; Costs. All such determinations of Fair Rental Value shall be final and binding upon the parties. The provision for determination by appraisal shall be specifically enforceable to the extent such remedies are available under the applicable law, and any determination hereunder shall be final and binding upon the parties hereto, and either party shall have the right to enter judgment thereon, unless otherwise provided by applicable law. If a determination of Fair Rental Value is to be made pursuant to this Article 10, Landlord and Tenant shall each pay for the fees and disbursements of any appraiser appointed by it and shall share equally in the fees and expenses of any third appraiser.

ARTICLE 11
Miscellaneous Provisions

11.1 Notices from One Party to the Other. All notices required or permitted hereunder shall be in writing and addressed as follows: (i) if to the Tenant and sent prior to the Commencement Date, at the Original Notice Address of Tenant; and if sent on or after the Commencement Date, at the Premises, or such other address as Tenant shall have last designated by notice in writing to Landlord, in either case with a copy to Guarantor at Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, MA 02109, Attn: Managing Partner, and; (ii) if to Landlord, at the Original Notice Address of Landlord or such other address as Landlord shall have last designated by notice in writing to Tenant. Any notice shall be sent to such address by registered or certified mail, return receipt requested, postage prepaid, or by nationally recognized courier, charges prepaid, or by hand and shall be effective when received or when tendered delivery is refused.

11.2 Quiet Enjoyment. Landlord agrees that upon Tenant's paying the Rent and performing and observing the agreements, conditions and other provisions on its part to be performed and observed, Tenant shall and may peaceably and quietly have, hold and enjoy the Premises during the Term hereof without any manner of hindrance or molestation from Landlord or anyone claiming under Landlord, subject, however, to the terms of this Lease. The foregoing covenant of quiet enjoyment is in lieu of any other covenant, express or implied.

11.3 Lease Not to be Recorded. The Tenant agrees not to record this Lease, but each party hereto agrees, on request of the other, to execute a Notice of Lease in recordable form and complying with applicable laws, and in form and content reasonably satisfactory to both parties. In no event shall such document set forth the rental or other charges payable by the Tenant under this Lease; and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease, and is not intended to vary the terms and conditions of this Lease.

11.4 Limitation of Landlord's Liability. The term "Landlord" as used in this Lease, so far as covenants or obligations to be performed by Landlord are concerned, shall be limited to mean and include only the owner or owners at the time in question of the Property, and in the event of any transfer or transfers of title to the Property, the Landlord (and in case of any subsequent transfers or conveyances, the then grantor) shall be concurrently freed and relieved from and after the date of such transfer or conveyance, without any further instrument or agreement, of all liability and obligation with respect to the performance of any covenants or obligations on the part of the Landlord contained in this Lease thereafter to be performed, it being intended hereby that the covenants and obligations contained in this Lease on the part of Landlord, shall, subject as aforesaid, be binding on the Landlord, its successors and assigns, only during and with respect to their respective successive periods of ownership of such leasehold interest or fee, as the case may be. Tenant, its successors and assigns, shall not assert nor seek to enforce any claim for breach of this Lease against any of Landlord's assets other than Landlord's interest in the Property and in the rents, issues and profits thereof, and Tenant agrees to look solely to such interests for the satisfaction of any liability or claim against Landlord under this Lease. In no event shall Landlord or any Landlord Affiliates, including, without limitation, any general or limited partner, trustees, beneficiaries, employees, agents, officers, directors, stockholders, managers, or members of Landlord ever be personally liable for any liability or obligation of, Landlord whether under this Lease, or at law or in equity.

11.5 Acts of God. In any case where either party hereto is required to perform any work or take any action, delays caused by or resulting from Acts of God, war, civil commotion, fire, flood or other casualty, labor difficulties, shortages of labor, materials or equipment, government regulations, unusually severe weather, or other causes beyond such party's reasonable control (but financial inability shall never be deemed to be an event beyond either party's reasonable control) (each a "Force Majeure Event") shall not be counted in determining the time during which work shall be completed or such action shall be taken, whether such time be designated by a fixed date, a fixed time or a "reasonable time," and such time shall be deemed to be extended by the period of such delay. Nothing contained in this Section 11.5 shall be applicable to, or in any way affect, reduce or abate the obligations of Tenant under this Lease to pay all Rent and other charges in a timely fashion pursuant to the terms hereof.

11.6 Landlord's Default. Landlord shall not be deemed to be in default in the performance of any of its obligations hereunder unless it shall fail to perform such obligations and such failure shall continue for a period of thirty (30) days or, if such obligation is incapable of being performed within thirty (30) days, such additional time as is reasonably required to correct any such default after written notice has been given by Tenant to Landlord specifying the nature of Landlord's alleged default. Notwithstanding any provision contained herein, in no event shall Landlord ever be liable to Tenant, or any person claiming by, through or under Tenant, for any special, indirect, incidental or consequential damages, or

for any lost profits. Tenant shall have no right to terminate this Lease as a result of any breach or default by Landlord hereunder, except in the case of a wrongful eviction (constructive or actual) of the Tenant from the Premises by Landlord. In addition, Tenant shall have no right, as a result of any such breach or default, to offset or counterclaim against any Rent due hereunder.

11.7 Brokerage. Tenant warrants and represents that it has dealt with no broker in connection with the consummation of this Lease, other than the Broker, and in the event of any claims for a brokerage commission or finder's fee, of any kind, against Landlord predicated upon prior dealings with Tenant, Tenant agrees to defend the same and indemnify and hold Landlord harmless against any such claim. Landlord warrants and represents that it has dealt with no broker in connection with the consummation of this Lease, other than the Brokers, and in the event of any claims for a brokerage commission or finder's fee, of any kind, against Tenant predicated upon prior dealings with Landlord, Landlord agrees to defend the same and indemnify and hold Tenant harmless against any such claim. Landlord shall be responsible for paying the commission due to Brokers in connection with this Lease in accordance with a separate agreement or understanding between them.

11.8 Applicable Law and Construction. This Lease shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. If any provisions of this Lease shall to any extent be invalid, the remainder of this Lease shall not be affected thereby. There are no oral or written agreements between Landlord and Tenant affecting this Lease. This Lease may be amended, and the provisions hereof may be waived or modified, only by instruments in writing executed by Landlord and Tenant. The captions and titles of the several Articles and Sections contained herein are for convenience only and shall not be considered in construing this Lease. Unless repugnant to the context, the words "Landlord" and "Tenant" appearing in this Lease shall be construed to mean those named above and their respective heirs, executors, administrators, successors and assigns, and those claiming by, through or under them, respectively. If there be more than one tenant, the obligations imposed by this Lease upon Tenant shall be joint and several.

11.9 Delivery. This submission of this document for examination and negotiation does not constitute an offer to lease, or a reservation of or option for, the Premises, and this Lease shall not be binding upon Landlord or Tenant unless and until Landlord shall have executed and delivered a fully executed copy of this Lease to Tenant.

11.10 Rent. Notwithstanding anything to the contrary contained in this Lease, all charges and amounts payable by Tenant to or on behalf of Landlord under this Lease, whether or not expressly denominated Fixed Rent, Tax Excess, Operating Cost Expense, Additional Rent or Rent, shall constitute rent for the purposes of Section 502(b)(6) of the United States Bankruptcy Code. In addition, notwithstanding anything to the contrary contained in this Lease, all charges and amounts payable by Tenant to or on behalf of Landlord under this Lease

(excepting only Fixed Rent), whether or not expressly denominated Additional Rent, including, without limitation, Tax Excess, Operating Costs Excess, electricity charges, utility charges, and other fees and charges, shall be considered to be "Additional Rent" and in the event of non-payment thereof by Tenant Landlord shall have all of the rights and remedies as would accrue for nonpayment of Fixed Rent.

11.11 Certain Interpretational Rules. For purposes of this Lease, whenever the words "include", "includes", or "including" are used, they shall be deemed to be followed by the words "without limitation" and, whenever the circumstances or the context requires, the singular shall be construed as the plural, the masculine shall be construed as the feminine and/or the neuter and vice versa. This Lease shall be interpreted and enforced without the aid of any canon, custom or rule of law requiring or suggesting construction against the party drafting or causing the drafting of the provision in question. The captions in this Lease are inserted only as a matter of convenience and for reference and in no way define, limit or describe the scope of this Lease or the intent of any provision hereof.

11.12 Parties Bound. The terms, covenants, conditions and agreements contained in this Lease shall bind and inure to the benefit of Landlord and Tenant and, except as otherwise provided in this Lease, to their respective legal representatives, successors, and assigns. Each term and each provision of this Lease to be performed by the Tenant shall be construed to be both a covenant and a condition.

11.13 Prevailing Party. In any action or proceeding brought by either party against the other under this Lease, if one party obtains a judgment on the merits in such action or proceeding, then prevailing party shall be entitled to recover from the other party its reasonable professional fees for attorneys, appraisers and accountants, its reasonable investigation costs, and any other reasonable legal expenses and actual court costs incurred by the prevailing party in such action or proceeding,

11.14 Back-Up Generator. As an appurtenance to the Premises, Tenant shall have the right, upon Tenant's request, to use up to 20KW of capacity of the emergency back-up electrical generator (the "Back-Up Generator") currently located in the Building. If Tenant so requests, then Tenant may, at its sole cost and expense, tie-into the Back-Up Generator, subject to the reasonable rules and guidelines adopted from time to time by Landlord with respect thereto, and to all applicable laws, codes, regulations and guidelines. Any and all work and improvements to be performed by Tenant to effectuate Tenant's tie-in to the Back-Up Generator (such as installing conduits, and connections from the Back-Up Generator to the Premises) shall be considered to be an Alteration, shall be performed in accordance with the provisions of Section 6.2.5 of this Lease, and, unless approved by Landlord in connection with approval of the Construction Documents for Tenant's Work pursuant to Section 3.3, shall be subject to Landlord's review and prior written approval in all respects. In the event Tenant elects to tie-into the Back-Up Generator, Tenant shall pay, as Additional Rent,

within thirty (30) days after receipt of invoices therefor from Landlord, a pro rata share of the annual fuel and maintenance charges for the Back-Up Generator, which pro rata share shall be based on a ratio, the numerator of which is Tenant's total usage of Back-Up Generator capacity and the denominator of which is the aggregate usage of Back-Up Generator capacity at the applicable period of time; provided, however, Tenant's pro rata share of such annual fuel and maintenance charges for the Back-Up Generator payable hereunder shall not exceed $1,500.00 per year (the "Annual Generator Cost Cap"); provided, however, if either (a) in the event that the public utility provider has a power outage that results in a power outage at the Building for more than six (6) hours, or (b) Tenant otherwise elects - to run the Back-Up Generator for more than six (6) consecutive hours, in which event, then the cost of fuel used for the Back-Up Generator during such outage or in excess of six (6) consecutive hours shall be excluded from the Annual Generator Cost Cap and Tenant shall pay its pro rata share for such fuel used for the Back-Up Generator during such outage based on the ratio above.

ARTICLE 12
Patriot Act

12.1 Patriot Act. As an inducement to Landlord to enter into this lease, Tenant hereby represents and warrants that: (i) Tenant is not, nor is it owned or controlled directly or indirectly by, any person, group, entity or nation named on any list issued by the Office of Foreign Assets Control of the United States Department of the Treasury ("OFAC") pursuant to Executive Order 13224 or any similar list or any law, order, rule or regulation or any Executive Order of the President of the United States as a terrorist, "Specially Designated National and Blocked Person" or other banned or blocked person (any such person, group, entity or nation being hereinafter referred to as a "Prohibited Person"); (ii) Tenant is not (nor is it owned, controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) neither Tenant (nor any person, group, entity or nation which owns or controls Tenant, directly or indirectly) has conducted or will conduct business or has engaged or will engage in any transaction or dealing with any Prohibited Person, including any assignment of this Lease or any subletting or all or any portion of the Premises or the making or receiving of any contribution or funds, goods or services to or for the benefit of a Prohibited Person. In connection with the foregoing, it is expressly understood and agreed that (x) any breach by Tenant of the foregoing representations and warranties shall be an Event of Default by Tenant under Article 8 above, and (y) the representations and warranties contained in this Article 12 shall be continuing in nature and shall survive the expiration or earlier termination of this Lease.

ARTICLE 13
Termination Option

13.1 Termination Option. Subject to the full and complete satisfaction of the Termination Conditions Precedent (as hereinafter defined), in accordance with the provisions of this Article 13, Tenant shall have the one-time irrevocable option to terminate this Lease (a "Termination"). The conditions precedent (the "Termination Conditions Precedent") to the effectiveness of any such Termination shall be as follows: (i) the effective date of any such Termination shall be July 1, 2015 (the "Termination Date"); (ii) Tenant shall deliver written notice (a "Termination Notice") of such Termination to Landlord by not later than July 1, 2014; (iii) concurrent with the delivery of the Termination Notice, Tenant shall pay to Landlord, without deduction or offset, a non-refundable cash Termination Fee (as hereinafter defined); and (iv) on the Surrender Date (as hereinafter defined) no Event of Default of Tenant shall have occurred under this Lease. Said Termination Fee shall be Additional Rent and shall be in addition to, and not in lieu of, any other payments due under this Lease (including payments of Annual Fixed Rent and Additional Rent). The "Termination Fee" shall be an amount equal to the Unamortized Portion (as hereinafter defined) as of the Termination Date of all costs and expenses incurred by Landlord in connection with this Lease, including the cost of all tenant improvements paid for by Landlord (including any improvements paid for with the Allowance), and all brokerage commissions paid by Landlord in connection with this Lease. The "Unamortized Portion" shall mean the foregoing amounts, amortized on a straight line basis over the Term, together with interest thereon at the rate of 8% per annum. Upon request made by Tenant at any time after February 1, 2014, Landlord shall provide Tenant, within ten (10) business days of Tenant's request therefor, with a determination of the foregoing costs, along with Landlord's calculation of the Unamortized Portion of the costs as of the Termination Date.

13.2 Termination. Provided that all of the Termination Conditions Precedent have been fully and completely satisfied, then effective as of the Termination Date, this Lease, and the rights of the Tenant with respect to the Premises, shall terminate and expire with the same force and effect as if such Termination Date had originally been specified as the expiration date of the Term of this Lease. Prior to the later of (such later date, the "Surrender Date") (i) the Termination Date, and (ii) the date on which Tenant actually surrenders and yields-up the Premises, Tenant shall comply with all of the terms and provisions of the Lease and shall perform all of its obligations hereunder, including, without limitation, the obligation to pay when due all Fixed Rent and other Additional Rent. By not later than the Termination Date, Tenant shall remove all of its trade fixtures and personal property from the Premises, remove all Tenant's Telecommunications Equipment and wires and cables installed by or on behalf of Tenant, remove such Specialty Alterations as Landlord may request and all Tenant's signs wherever located, repair all damage caused by such removal and surrender and yield-up the Premises in good and broom-clean order, repair and condition, free of all tenants and occupants, and otherwise in the condition in which the Premises are required to be surrendered pursuant to Section 6.1.9 of this Lease at the expiration of the Term. All property and Alterations of any kind, nature or description remaining in the Premises after the Surrender Date shall be and become the property of

Landlord and may be disposed of by Landlord, without payment from Landlord and without the necessity to account therefor to Tenant. Removal or disposal by Landlord of property required to be removed by Tenant pursuant to this Lease shall be at the cost and expense of Tenant.

13.3 Release of Liabilities. Effective as of the Termination Date, Landlord shall be released from any and all obligations and liabilities thereafter accruing under this Lease. Nothing contained herein shall constitute a waiver, limitation, amendment, or modification of any of the liabilities and obligations of Landlord under this Lease which accrue or arise prior to the Termination Date. Effective as of the Surrender Date, Tenant shall be released from any and all liabilities and obligations thereafter accruing under this Lease. Nothing contained herein shall constitute a waiver, limitation, amendment, or modification of any of the liabilities and obligations of Tenant or Landlord under this Lease which accrue or arise prior to the Termination Date.

13.4 Holdover. Without limiting the foregoing, if Tenant fails to yield up and surrender the Premises by the Termination Date, then for and with respect each day between the Termination Date and the Surrender Date, Tenant shall pay a holdover charge at the rate set forth in Section 6.1.9 (b) of this Lease. Nothing herein contained shall constitute a release, waiver, limitation, or restriction of any rights or remedies of Landlord on account of Tenant's failure to surrender the Premises by the Termination Date, including any rights or remedies afforded to Landlord in Section 6.1.9 of this Lease.

13.5 Amendment. The foregoing provisions shall be self-operative; provided, however, on the request of either party Landlord and Tenant will enter into a mutually satisfactory amendment to this Lease evidencing such Termination of this Lease.

13.6 Time of Essence. Time is of the essence of this Article 13.

WITNESS the execution hereof on the day and year first above written.

Landlord:

255 STATE STREET, LLC, a Delaware limited liability company

By: Pembroke Real Estate, Inc., its manager

By: /s/ Edward C. Johnson IV
Name: Edward C. Johnson IV
Title: Senior Vice President

Tenant:

SILVER BRIDGE ADVISORS, LLC, a Delaware limited liability company

By: /s/ Stephen Prostano
Name: Stephen Prostano
Title: President

EXHIBIT A

255 STATE STREET
BOSTON, MASSACHUSETTS

LEGAL DESCRIPTION

Parcel One

That certain parcel of land situate in Boston in the County of Suffolk and Commonwealth of Massachusetts, bounded and described as follows:

NORTHERLY	by the southerly line of State Street, one hundred sixty and 8/100 (160.08) feet;
EASTERLY	by the westerly line of Atlantic Avenue for a distance of seventy-five and 12/100 (75.12) feet south from said State Street, and by said Avenue fifty-six and 86/100 (56.86) feet for the rest of the distance to Central Street;
SOUTHERLY	by the northerly line of Central Street, one hundred thirty-six and 27/100 (136.27) feet;
WESTERLY	forty-five and 45/100 (45.45) feet;
NORTHERLY	sixty-seven hundredths (0.67) of a foot;
WESTERLY	thirty-eight and 85/100 (38.85) feet;
SOUTHERLY	sixty-seven hundredths (0.67) of a foot; and
WESTERLY	forty-five and 70/100 (45.70) feet, all by land now or formerly of Robert M. Burnett.

All of said boundaries are determined by the Court to be located as shown on a plan drawn by Aspinwall & Lincoln, Civil Engineers, dated March 20, 1915, as approved by the Court, filed in the Land Registration Office as Plan No. 5360-A, a copy of a portion of which is filed with Certificate of Title No. 7462.

Parcel Two

That certain parcel of land situate in Boston in the County of Suffolk and Commonwealth of Massachusetts, bounded and described as follows: Beginning at the intersection of the northerly property line of the New England Telephone & Telegraph Building and southerly street line of State St., thence running by property line of New England Telephone & Telegraph Building and former street line of relocated Atlantic Avenue in a southerly direction a distance of thirteen and fifty-seven hundredths (13.57') feet to the point of beginning of land to be conveyed; thence continuing along former street line of relocated

Atlantic Avenue in a southerly direction a distance of sixty and ninety-nine hundredths (60.99') feet to the angle point of new street line of relocated Atlantic Avenue and former street line of relocated Atlantic Avenue;

thence continuing by street line of relocated Atlantic Avenue (back of sidewalk) S11°-51'-40"E a distance of fifty-five and fifty hundredths (55.50') feet;

thence turning in a westerly direction by southerly property line and building line of New England Telephone & Telegraph a distance of one and sixty-hundredths (1.60') feet;

thence turning and running N12°-38'46"W a distance of forty-five and forty-five hundredths (45.45') feet by the property line to a jogpoint;

thence turning on a ninety degree angle in a westerly direction by said property line, sixty-seven hundredths (0.67') feet;

thence turning and running N12°-38'-46"W a distance of thirty-eight and eighty-five hundredths (38.85') feet by said property line;

thence turning on a ninety degree angle by said property line in an easterly direction a distance of sixty-seven hundredths (0.67') feet;

thence turning and running by said property line N12°-38'-46"W a distance of thirty-two and twenty-hundredths (32.20') feet to a point of beginning of land to be conveyed to New England Telephone and Telegraph Co.

Said parcel of land containing an area of one hundred nineteen and one-tenth (119.1 s.f.) square feet, more or less.

Said Second parcel is shown on a plan entitled "Boston Redevelopment Authority Downtown Waterfront Faneuil Hall Project Mass R-77, Delivery Parcel Plan - Land To Be Conveyed to New England Telephone and Telegraph Company" dated September 30, 1980 and recorded in Book 9846, Page 257.

EXHIBIT B

PLAN SHOWING THE PREMISES

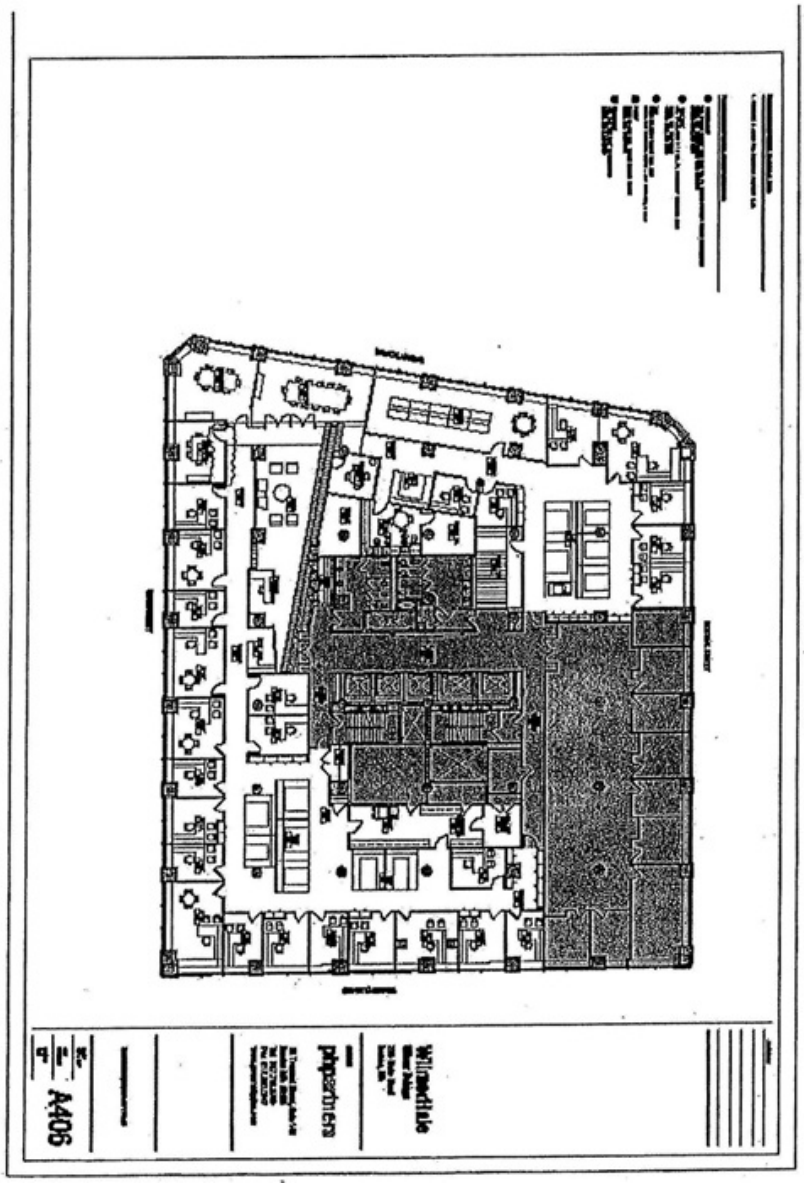


EXHIBIT C

COMMENCEMENT DATE AGREEMENT

("Landlord") and ("Tenant") are parties to a lease ("Lease") dated of premises in a building known as 255 State Street, Boston, Massachusetts. Landlord and Tenant hereby acknowledge and agree that the term of the Lease commenced on and will end on unless extended or earlier terminated pursuant to provisions set forth in the Lease, and the Rent Commencement Date occurred on .

Executed under seal this day of , 2010.

LANDLORD:

By: _____
Its:

TENANT:

By: _____
Its:

EXHIBIT D

CLEANING SPECIFICATIONS

I. Interior Tenant Areas

Nightly Monday through Friday, excluding holidays

1. Dust mop all stone, ceramic tile, terrazzo and other type of un-waxed flooring.

2. Dust mop all vinyl, asphalt, rubber and similar types of flooring. Remove gum and other substances, spot mop if necessary.

3. Vacuum all carpeted areas.

4. Dust mop all private and public stairways and vacuum if carpeted.

5. Hand dust and wipe clean all horizontal surfaces including furniture, file cabinets, fixtures, and windowsills, using chemically treated dust cloth,

6. Remove fingerprints from all painted surfaces near light switches, entrance doors, drinking fountains, etc.

7. Remove all gum and foreign matter on sight.

8. Empty and clean all waste receptacles and remove waste materials to compactors. Replace liners as necessary.

9. Damp wash interiors of all waste disposal receptacles and wash as necessary.

10. Clean and sanitize all water fountains, and water coolers with a disinfectant solution. Wash all sinks and the floors adjacent to them on a nightly basis.

11. Spot mop floors for spills, etc.

12. Clean all low ledges, shelves, bookcases, chair rails, trim, pictures, charts etc. within reach.

13. Clean mirrors, metal work, glass tabletops.

14. Upon completion of work, all slop sinks are to be thoroughly cleaned and all cleaning equipment and supplies stored neatly in locations designated by the Management of the building.

15. All cleaning operations shall be scheduled so that a minimum of lights are to be left on at any time. Upon completion of cleaning all lights are to be turned off. All entrance doors are to be kept locked during the cleaning operation.

16. Spot clean both sides of tenant entry glass doors.

17. Spot clean desk tops and counter tops.

18. Pick up all recyclable material and take to appropriate place.

Weekly

1. Hand dust all door louvers and other ventilating louvers within reach.

2. Dust all baseboards.

3. In high traffic areas, damp mop if necessary and apply spray-buffing solution fine mist and buff with a synthetic pad.

4. Damp mop all non-carpeted and public stairways.

5. Wipe clean all bright work.

6. Dust all chair rails.

7. Dust walls up to normal reach.

Monthly

1. Hose vacuum underneath all furniture.

2. Dust all vertical surfaces such as walls, furniture, partitions and surfaces not reached in nightly cleaning.

3. Dust exterior of lighting fixtures.

Quarterly

1. Dust all exterior window blinds

2. Dust and/or clean all diffusers

Other

1. Cleaning of computer rooms will be responsibility of individual tenants.

2. Coffee stations and dishware are responsibility of the tenant.

II. Public Corridors, Stairwells (Emergency Egress), Service Areas

Nightly

1. Vacuum and spot clean carpeting.

2. Sweep and mop public concrete floors.

3. Sweep and mop public stairwells and landings.

4. Clean baseboards of scuffs and marks.

5. Clean all directories, signage kiosks, wall signage and electric kiosks.

6. Clean corridor glass and metal work.

7. Spot clean walls, ceilings, lights, etc.

8. Clean telephones and telephone booth areas.

9. Dust all handrails.

10. Dust to hand height all horizontal surfaces of equipment ledge, sill, shelves, radiators, frames, partitions, handrails, etc.

11. Clean exterior surfaces of all trash containers and planters.

12. Keep slop sinks, closets, supply rooms and other janitorial areas in a clean orderly condition.

13. Keep electrical and telephone closets clean and free of storage.

Weekly

1. Clean all door vents.

2. Dust all vertical surfaces within reach.

3. Sweep emergency egress stairs and landings.

Monthly

1. Wash all corridor glass and metal completely including atriums.

2. Shampoo heavily traveled carpeted areas.

Quarterly

1. Clean handrails, wall mounted equipment casings, landings, walls, kick plates in emergency egresses.

2. Shampoo and extract all carpeting.

3. Damp clean inside reflectors of high hat lighting fixtures.

III. Restrooms

Building Operating Hours

Day porters and matrons will be assigned to perform the following:

1. Empty trash containers and insert new liners.

2. Sweep and spot wash floors as necessary.

3. Spot clean sinks and mirrors. Clean and spot polish shelves and metal dispensers. Check for Graffiti and spot clean if necessary.

4. Ensure cleanliness of urinals and toilets.

5. Refill all dispenser units as needed.

Non-Operating Hours

1. Damp wash, sanitize (using disinfectant solution) and polish all fixtures including toilet bowls, urinals and wash basins.

2. Sweep and wash floors with approved germicidal solution.

3. Wash and polish mirrors, powder shelves, dispensers, hand dryers, bright work including flushometers, piping and toilet seat hinges.

4. Clean and sanitize both sides of toilet seats.

5. Empty all containers and disposal units and insert new liners.

6. Wash and sanitize interiors and exteriors of all containers prior to inserting new liners.

7. Empty, clean and sanitize all sanitary napkin disposal units.

8. Dust and spot wash where necessary partitions, tile walls, dispensers, ceiling lights, switches and receptacles.

9. Refill all dispensers to normal limits including sanitary supplies, soap, tissue, towels, etc.

10. Remove all rubbish and transport to compactor.

11. Dust ceiling door vents and doorframes.

Periodic

Monthly

1. Machine scrub all tile floors, hand brush corners and hand brush toilet edges with approved germicidal detergent solution.

2. Wash completely all partitions, tile walls and enamel surfaces.

IV. Window Cleaning

Periodic

Windows will be washed and cleaned a minimum of two times per year.

EXHIBIT E

RULES AND REGULATIONS

1. The sidewalks, entrances, passages, corridors, vestibules, halls, elevators, or stairways in or about the Building shall not be obstructed by Tenant.

2. Tenant shall not place objects against glass partitions, doors or windows which would be unsightly from the Building corridor or from the exterior of the Building. All doors opening to public corridors shall be kept closed at all times except for normal ingress and egress to the premises, unless electrical holdbacks have been installed.

3. Tenant shall not waste electricity or water in the Building premises and shall cooperate fully with Landlord to assure the most effective operation of the Building heating and air conditioning systems. All regulating and adjusting of heating and air-conditioning apparatus shall be done by the Landlord's agents or employees. Tenant shall not use or keep in or on the Premises or the Building any kerosene, gasoline or other inflammable or combustible fluid or materials other than as permitted under the Lease.

4. Tenant shall not use the Premises so as to cause any increase above normal insurance premiums on the Building.

5. No bicycles, vehicles, or animals (except guide dogs for the disabled) of any kind shall be brought into or kept in or about the Premises. Any bicycles brought into the Building shall enter through the loading dock area and stored in the basement of the Building. No space in the Building shall be used for manufacturing or for the sale of merchandise of any kind at auction or for storage thereof preliminary to such sale.

6. Tenant shall cooperate with Landlord in minimizing loss and risk thereof from fire and associated perils.

7. The water and wash closets and other plumbing fixtures shall not be used for any purposes other than those for which they were designed and constructed and no sweepings, rubbish, rags, acid or like substance shall be deposited therein. All damages resulting from any misuse of the fixtures shall be borne by the Tenant.

8. Landlord may from time to time adopt appropriate systems and procedures for the security or safety of the Building, any persons occupying, using, or entering the Building, or any equipment, finishings, or contents of the Building, and Tenant will comply with Landlord's reasonable requirements relative to such systems and procedures.

9. No cooking will be done or permitted by Tenant within the Premises, except in areas of the Premises which are specifically constructed for cooking and except that use by the tenant of microwave ovens and Underwriters' Laboratory approved equipment for brewing coffee, tea, hot chocolate, and similar beverages will be permitted, provided that

such use is in accordance with all applicable federal, state, and city laws, codes, ordinances, rules, and regulations.

10. The elevator designated for freight by Landlord will be available for use by all tenants in the Building during the hours and pursuant to such procedures as Landlord may determine from time to time. The persons employed to move Tenant's equipment, material, furniture, or other property in or out of the Building must be acceptable to Landlord. All moving operations will be conducted at such times and in such a manner as Landlord will direct, and all moving will take place during non-Business Hours unless Landlord agrees in writing otherwise.

11. All deliveries to, and removals from the building of furniture, equipment and supplies, shall be by way of the loading dock, located on Central Street. Delivery trucks larger than 25 feet, or those that have tailgates are prohibited to use the loading dock. It is recommended that these box trucks park along Central Street and utilize the scissor lift located in the east loading dock bay.

12. All incoming and outgoing shipments must be moved directly, by the delivery or pick-up agent from the delivery entrance; such shipments will not be held at the delivery entrance. Building operating personnel are not authorized to sign receipt for shipments to or from the Building.

13. No hand truck, pallet truck or other type of wheeled transport shall be used in the lobbies, corridors or elevators of the Building.

14. Any damage to the Building or any part thereof caused by the moving.in or out of the Building of furniture, equipment, supplies, or other items, shall be repaired by the Landlord at the expense of the responsible Tenant.

15. The property management office reserves the right to control and operate the public portions of the Building and the public facilities, as well as the facilities furnished for the common use for the Tenant, in such manner, as they deem best of the tenants.

16. No additional locks or bolts of any kind shall be placed upon any of the doors in any Tenant's premises, and no lock on any door therein shall be changed or altered in any respect without property management approval.

17. Building security will provide access to building electric closets only. Tenant will be required to notify the Property Management Office should a vendor require access to the 255 State Street electric closets.

18. Tenant acknowledges that the Building has been designated a non-smoking building. At no time shall Tenant permit its agents, employees, contractors, guests or invitees to smoke in the Building. Landlord has specified smoking areas to be 25' from the south lobby entrance, located on the Central Street side of the Building.

19. Landlord reserves the right at any time and from time-to-time to rescind, alter or waive any rule or regulation at any time prescribed for the Building, and to impose

additional reasonable rules and regulations when in its judgment deems it necessary, desirable or proper for its best interest and for the best interest of the tenants. Landlord shall give Tenant notice of any such additional rules and regulations at the time adopted or imposed by Landlord. No alteration or waiver of any rule or regulation in favor of one tenant shall operate as an alteration or waiver in favor of any other tenant. Landlord shall not be responsible to any tenant for the nonobservance or violation by any other tenant of any rules or regulations at any time prescribed for the Building or any part thereof. In the event of any conflict of inconsistency between the foregoing Lease and such rules and regulations, the Lease shall govern and control.

EXHIBIT F

STANDARD TENANT FIT-OUT SPECIFICATIONS FOR 255 STATE STREET

Introduction

This Standard Tenant Fit-out Specification has been prepared for the purpose of communicating expectations and minimum requirements for the design and construction of Tenant Fit-Outs. Landlord may impose additional requirements in connection with particular fit-out by tenant.

The Landlord will provide the Tenant with available architectural and MEP drawings for use in planning. The Tenant's consultants are responsible for field verifying existing conditions which may impact their fitout. The Tenant's consultants shall provide architectural/engineering services and documentation necessary for the design, permitting and construction of a Building Standard space. Tenant's architectural and engineering designs shall conform to all applicable regulations including but not limited to ADA and local building codes.

The build-out shall conform to the building standards established from time-to-time by the Landlord.

Reuse/Second Generation Space: Where minor cosmetic improvements are planned to modify an existing space formerly fit-out and occupied by a tenant, the existing conditions may prevail as the standard. An inspection will occur between Landlord and Tenant to confirm the scope of improvements and determine the usefulness of existing fit-out components.

Landlord Review

The Tenant's design documents are to be reviewed and approved by the Landlord/Landlord's Agents before permitting and commencing of such work in accordance with the Lease. Landlord's review is to confirm compliance with building standards and expectations and does not imply approval for any code or regulatory issues.

Prior to enclosing any work affecting the building systems (MEP, structural, etc), the Landlord and its consultants will review the work and produce punch list items where necessary. The Tenant will provide the Landlord with reasonable advance notice for review. Landlord will also have the opportunity to review work affecting common spaces and produce punch list items where required.

Upon completion, the Tenant's Contractor shall provide the Landlord with a complete set of electronic CAD as-built plans in AutoCad (.dwg) format including: architectural floor and ceiling plans, electrical, mechanical, fire-sprinkler and plumbing plans, and a certified air balance report. Additionally, copies of operational manuals for MEP equipment, related warranties, etc. should be provided.

In accordance with the Lease, retainage will be held on payment of the Tenant Improvement allowance by the Landlord until receipt of the as-built documentation and completion of Punch list items.

Substitutions: The information given here and any manufacturers listed are intended to provide minimum quality levels for construction standards. Substitutions will be considered but must be approved in writing by the Landlord or Landlord's Agent.

Coordination with Landlord

Logistics Plan and Schedule

A preconstruction meeting will be required that includes the Tenant's representatives and contractor as well as the Landlord/Landlord's agents to review logistics and schedule. The logistics plan should address any potential issues that have an effect on the common spaces, building operations or other tenants. These include but are not limited to deliveries, staging, protection, dust/odor control, hours of operation, noise, cleaning, security/access, service shut-downs/tie-ins, etc).

The Tenant's Contractor shall provide timely, regular updates to the Landlord/Landlord's agent on the progress of the construction, issues affecting the schedule/logistics plan or any other issues that affect the job as it progresses. Landlord's agent will have the opportunity to attend regular construction meetings regarding the Tenant fit-out work.

Protection/ Cleaning

Tenant's Contractor is to perform routine job site cleaning to maintain a safe and clean working environment and to not interfere with any other Tenant's space or building common areas (i.e. corridors, lobby, elevators, etc). No materials or debris shall be stored at any time in any common areas.

The Tenant's Contractor shall prevent damage as well as the spread of dust, fumes, noise, etc. by properly protecting the common areas or other Tenants spaces. Contractor shall prepare and execute an Indoor Air Quality Management Plan that complies with the recommended Design Approaches of the Sheet Metal and Air Conditioning National Contractors Association (SMACNA) IAQ Guideline for Occupied Buildings Under Construction, 1995, Chapter 3.

Any damage that may occur as a result of the fit-out shall be cured by the Tenant at no cost to Landlord and returned to existing conditions in accordance with Landlord's approval.

Shutdowns

In the event that any interruptions are required to building services or operations (e.g. shutdowns for tie-ins, testing, etc.) the Tenant's Contractor shall provide a minimum advance notice of 5 business days to the Landlord's Agent in order to facilitate coordination. Shutdowns will be outside of regular business hours.

Permits/fees

AH local building permit and inspection fees connected to the fit-out project shall be secured and paid by the Tenant's Contractor. It is also the responsibility of the Tenant's Contractor to coordinate all necessary inspections by the particular governmental authorities in order to obtain a final Certificate of Occupancy. All necessary permits must be prominently posted at the site.

Guarantee

Tenant's Contractor agrees that performance of work under this Contract shall be guaranteed free of defective materials and poor workmanship for a minimum period of (1) one year from final Certificate of Occupancy date. Contractor shall also provide Landlord with copies of any applicable manufacturer's warranties and operations manuals at the completion of the project.

Insurance Certificates

Prior to any execution of work on site, the Tenant's general contractor and subcontractors shall supply current insurance certificates to the Landlord. Confirm the following as per 255 State Street standard contracts:

Amount and type of required coverage's.

Correct project name and address.

255 State Street LLC, FMR Corp, Pembroke Real Estate, Inc., CB Richard Ellis-New England Partners LP named as additional insured.

Expiration date covers project duration.

Demolition, Waste Management

All existing conditions as indicated on the Construction Documents (i.e. partitions, ceiling, doors, carpet, HVAC, wiring, etc.) to be removed shall be disposed of by the Contractor in a lawful manner. "Remove" shall mean completely and entirely from the building and property unless otherwise noted by Landlord.

Contractor shall be responsible for terminating all electrical, data, telephone and plumbing where items are removed in order to leave the space in a safe and code compliant manner. Contractor shall note terminated utilities on the as built-drawings.

Each project shall have a plan to recycle construction waste to the maximum extent possible. Contractor shall develop and implement a construction waste management plan, quantifying material diversion goal of at minimum 50% by weight of construction, demolition and packaging debris by recycling and/or salvaging.

Materials and Specifications – Architectural

Tenant Entry Doors and Hardware

Multi-floor tenant entries shall consist of 3' x 8' solid core door (1-3/4 inch thick) with anegre veneer (stained **to** match approved sample) with tempered glass sidelight 2'6" x 8'. Door frames to be painted metal to match building standard color. Where required, closers shall be surface mounted painted to match the door frame.

Hardware shall consist of Schlage L-Series mortise lock (Lever Model: 12 605 with small rose), two pair butt hinges, closer, silencer, floor stop, all in brushed stainless steel finish. All hardware shall have interchangeable cores manufactured by Sergeant HB Series sequence 48D order #1-07087 through Pasek Lock Company. Any security requirements of the Tenant must be reviewed by Landlord.

Single floor tenant entrances may vary from the Building Standard, subject to, Landlord's prior review and approval.

Card Access System and Suite Keys

All Security Cards must be "Proximity" type #1690207 to be compatible with the base building system.

Tenant's Contractor to supply (5) five keys, unless specified otherwise, to Landlord to be keyed on Landlord's master using Landlord's approved keying vendor.

Partitions at Windows

Partitions should align with center lines of vertical window mullions and avoid offsets that are exposed to the exterior. Exceptions to be reviewed and approved by Landlord.

Perimeter Ceiling Soffits

Dropped ceilings lower than the exterior window head height shall have painted drywall soffits and shall be installed no closer to the window frame than 24". Soffits must be constructed of drywall, all other materials including ACT is not acceptable.

Ceiling Tile

24" x 24" Ultima by Armstrong with a Beveled Tegular edge to coordinate with the standard suspension system. Color-White.

Window Blinds

Exterior Window blinds are Riviera Classic 1" wide horizontal aluminum slats by Levolor Corporation, Color: white. No window film is permitted on exterior glass.

Wood Blocking

Contractor shall provide proper blocking/plywood for all wall openings for mechanical, electrical and architectural features (i.e. shelving, doors, stops, toilet partitions, restroom

accessories, and kitchen accessories to be installed in or on walls. Blocking/Plywood shall be fire rated where required, All composite and substrate wood such as plywood or MDF shall not contain added urea-formaldehyde resins.

VOC Limitations (Paints, Adhesives, Sealants and Sealant Primers)

For all interior applications, incorporate VOC material limits as outlined in South Coast Air Quality Management District (SCAQMD) Rule #1168. (See APAC Adhesives example below).

Paint

Paint shall be certified low odor, low VOC as manufactured by Benjamin Moore, ICI or approved equal.

Signage

All signage visible from common areas (including single tenant floor entrances) must be approved by the Landlord. No signage shall be visible from the exterior of the building.

Signage locations in common areas:

- Main Lobby: Main lobby directory provided by Landlord.
- Multi Tenant Elevator Lobby Signage: Elevator lobby directory provided by Landlord.
- Tenant Entry Signage at Multi-Tenant Lobby Floors: Signage review and approval required by Landlord.
- Full Floor Tenant Entry Signage: Signage review and approval required by Landlord.

Appliances.

All appliances are the responsibility of the tenant and are to be EnergyStar rated.

Materials and Specifications - Heating, Ventilation & Air Conditioning

General

Heat and air-conditioning is supplied to the floor by means of perimeter Titus DFCL series fan powered boxes and interior Titus DFCL series fan powered boxes. The fan powered boxes all work in conjunction with the ring duct that supplies primary air to the floor's core area. The ring duct is considered to be a base building item and is provided by the owner. All branch lines off of the ring duct, fan powered boxes, and exhaust fans

(if not existing) are tenant related expenses. Base Building Wall-mounted thermostats are TAC Model #ACI/10K-TAC. Any alteration to this configuration is a tenant expense.

The Building Management System "BMS" is a BMS Network by TAC Inc., the base building controls contractor.

All spaces shall be balanced for heating and cooling efficiency and maximum comfort. Contractor to provide Landlord with Certified Balancing report prepared by N.E.B.B. certified contractor.

The selection of HVAC equipment (fan powered boxes, heat pumps, etc) is to be approved by Landlord. It will be the responsibility of the Tenant's Contractor to coordinate with the Landlord during bid process.

HVAC subcontractor to provide mechanical schematic and design with bid for review and approval by Landlord. Tenant's Contractor to provide CAD as-built diagrams of new space serviced by HVAC and (1) one copy of all warranty and maintenance manuals upon completion of job, the closeout package.

Zoning

Provide appropriate zoning according to the following guidelines:

Interior Zones – interior zones must be separate from perimeter zones. The particular zones will be determined by the design team and will be based on the space layout.

Private Offices – must have active controls to modulate the system when the space is unoccupied.

Kitchens, Conference Rooms, etc. – must have active controls to modulate the system when the space is unoccupied.

Demand controlled ventilation (DCV) should be considered in large, variable occupancies to avoid conditioning outdoor air when the space is partially or completely unoccupied. DCV is typically achieved by using wall mounted Carbon Dioxide (C02) Sensors.

Ductwork Distribution

All medium pressure, high pressure, flex, changes and additions must be approved by Landlord.

All ductwork from trunk line shall have volume dampers installed.

Fire dampers must be installed through any demising wall that may be affected.

Runs of flex duct are not to exceed ten (10) feet, and shall comply with all code and industry requirements. Stove pipe aluminum extension from hard duct is allowed so long as it is insulated. All flex duct to be insulated.

All enclosed rooms to have at least one supply air diffuser and one return (excluding closets). All square diffusers must be louvered faced. Undercut doors may be considered a return depending on the carpet weight. All transfer grills to have two 90 degree angles between openings and must be insulated.

Duct Construction

Gage, pressure, material, class hanging methods, sealing, etc. changes and additions must be approved by Landlord.

All sealants to meet VOC material limits as outlined in South Coast Air Quality Management District (SCAQMD) Rule #1168.

Coordinate all work with Indoor Air Quality Management Plan as per Division One “Protection” including capping ductwork.

All hard ductwork shall be galvanized sheet metal per SMACNA standards. Hard duct (excluding returns) must be insulated with external duct wrap (1/2” or better). Any interior acoustical duct shall be lined with sheet metal. AH un-insulated existing metal ductwork shall be insulated with external duct wrap.

Duct Insulation

Size, material, R-value, lining, etc changes and additions must be approved by Landlord.

Fan Powered Boxes

Manufacturer and type: Titus DFCL Series. All office spaces shall have variable air volume, multi-zoned HVAC systems unless otherwise approved by Landlord. All boxes shall be Titus or equivalent quality and all perimeter VAV boxes shall be fan powered with electric heat as required.

Diffusers

Manufacturer and type: Titus.

Linear Diffusers

Manufacturer and type: Titus.

Return Diffusers

Manufacturer and type: Titus, concealed type.

Thermostats

Manufacturer and type: TAC Model #ACI/10K-TAC.

Controls/Energy Management System

All thermostats shall be manufactured by TAC and all final connections will be scheduled with Property Management for work to be performed by the base building controls contractor, TAC, Inc.

Duct Hanging Methods

Must comply with all SMACNA standards.

Data/TOF Room Cooling

All split system units shall be Trane or equivalent quality and designed for each space and specific use as required.

Materials and Specifications - Electrical

Switches, Outlets & Devices

All switches, plates and devices shall be white. Office switching device shall be occupancy sensor type manufactured by Leviton or equivalent.

Smoke Detectors

Smoke Detectors shall be installed where required by code or at the direction of the building department and/or fire department. Final tie-in of all devices to the base building fire alarm system will be coordinated with Property Management and performed by the base building fire alarm contractor. All devices must be compatible with the Notifier AM2020/AFP1010 base building fire alarm system.

Fire Alarm Annunciator/Strobe

Fire Alarm Speaker/Strobes shall be installed where required by code or at the direction of the building department and/or fire department and shall be compatible with the Notifier AM2020/AFP1010 base building fire alarm system. Final tie-in of all devices to the base building fire alarm system will be coordinated with Property Management and performed by the base building fire alarm contractor.

Power Panels: Power Receptacles

The base building power panels are GE Spectra Series / “A” Series. All electrical equipment shall be installed as per local or national code. Tenant’s electrical equipment and wiring/conduits shall be clearly labeled.

Power Disconnects/Distribution System

The base building electric disconnects are GE Spectra RMS Bus Plug / Hi-Break type.

Meters

Office space and office floors not metered by NStar, the local utility will require a tenant check meter. Tenant check meters will be manufactured by E-mon Demon or equal.

Lighting Fixtures

General office lighting shall be high-performance, energy efficient fluorescent light fixture 2 x 2 Direct/Indirect fluorescent fixtures (T8 lamps). Recessed downlights to be compact fluorescent light fixtures.

Re-lamp Second Generation Space

If existing lighting is T-12 then Contractor shall inform Landlord for approval of re-lamping with F32 T-8 electronic ballast light lens with #841 tubes or other more energy efficient lighting fixture. Landlord shall approve all re-lamping bulbs, ballasts and fixtures so as to obtain a standard throughout the building.

Exit Signs

Lithonia Precise Edge-Lit Green LED exit lights. Locate exit lighting in tenant areas as directed by architect.

Telephone/ Data Rooms

The Tenant is required to provide all individual tel/data equipment in an area other than the building Tel/Data Closet. The Tenant must provide plywood backboards for mounting of required equipment. Tenant tel/data wiring and equipment shall be clearly labeled.

Communications Rough-ins

Tel/Data Communications equipment and installation shall remain the responsibility of the Tenant. Rough-ins can be coordinated with the tenant buildout, but is the responsibility of the Tenant. All communications wiring that is installed by the tenant above the ceiling shall be plenum rated and shall be suspended from the slab above. All wiring shall conform to applicable codes. Demolition of obsolete wiring is the responsibility of the Tenant. Pipes and conduits shall avoid adjacent tenant spaces and those that pass through common core building areas must be labeled with Tenant's name and use.

Telephone Outlets

Contractor to provide outlets with conduit to above ceiling along with pull cord. Tenant will make arrangements with and pay for telephone and data cabling installation within the demised premises and will cause phone installation work to be performed at a time compatible with Landlord's work. Telephone and data cabling installation shall be in compliance with all local, state and federal code requirements. Telephone and data cabling contractor must be licensed. Telephone and/or data cabling contractor shall

provide copies of installer's license, electrical exemption certificate, permits and municipal approvals to Contractor and Landlord.

(A.) All old or unusable above ceiling and in-wall communication lines must be removed and disposed of prior to installation of new lines.

(B.) All wiring shall be plenum fire rated wire.

Materials and Specifications - Fire Protection and Plumbing

Fire Protection

Provide all alarms, horn strobes and bells (including replacement of existing product) to comply with all NFPA ADA, local Fire Marshall and other applicable codes and regulations. Landlord's authorized contractor to be used for the above work. Landlord requires (48) forty-eight hours notice to put the building on test for installation purposes.

Sprinkler

Relocate or add sprinkler heads to meet all applicable codes and regulations. Review with Landlord any insurance requirements that may affect the sprinkler system. All heads are concealed type and locations shall meet low and high hazard areas as required. For installation/relocation purposes, Landlord requires (48) forty-eight hours notice to put the building on test.

Fire Extinguishers

Fire extinguishers shall be installed where required by the local fire department. Where space allows flush, recessed extinguisher cabinets shall be provided. If space is not available, surface-mounted fire extinguishers shall be installed.

Hot water tank

Hot water point of use and under the counter instant hot tanks must be accessible from all sides for repair and maintenance. All new point of use and instant hot water tanks shall be monitored by Leak Detection and have drip pans mounted below with drainage.

General Base Building Information

Number of Floors

12 Floors

Corridor & Typical Tenant Suite Standard Finishes

Each floor is an open floor environment with approximately 10' 4" foot clearance from top of slab to underside of the deck above. Building standard ceiling height is approximately 8'-2". Core walls and exterior columns are drywall finished and are in paint-ready condition. Window soffits and perimeter induction covers are in place and

are in paint-ready condition. The concrete floor slab is skimmed as required and made ready to receive carpet or other flooring.

Individual floor lobbies are built to tenant specifications with Landlord review and approval. Multi-tenant floors are built to building standards and are compliant with the most recent fire code for multi-tenant floors.

Structural

Office Floor Loading is designed for:

Live load	80psf
Partition Load	20psf
TOTAL	100psf

No coring of the floor is permitted without prior approval by the Landlord/ Landlord's agent. X-ray verification shall be performed to verify the location of any obstructions/reinforcements.

The Landlord will provide a F(F) factor of 15-20 in accordance with the F-number system provided by the American Concrete Institute for the Specification and measurement of concrete floor flatness and levelness.

Elevators

The building has five (5) passenger elevators and two freight elevators Freight Elevator #6 can accommodate up to 2,500 pounds, and materials up to 16' in length. Freight/Passenger Elevator #4 can accommodate up to 3,000 pounds, and materials up to 16' in length with hatch access only (requires two elevator mechanics, cost incurred by tenant).

Loading Dock & Parking

The building loading dock is located on Central Street side of the building. The loading dock is staffed by security 5:00 AM to 6:00 PM Monday – Friday and Saturdays between 7:00 AM to 1:00 PM. The dock can accommodate one truck up to 24' in length with an overhead clearance of up to 10' 6". Tailgate deliveries allowed with street parking only and must be coordinated with Property Management.

Emergency Generator/Back-up Power

The building has (1) one emergency diesel powered generator to power the base building's life safety systems, elevators and emergency lighting and is located on the roof of the building.

Base Building Engineer

R.G. Vanderweil Engineering.

HVAC System

The HVAC system consists of Trane; floor mounted, water cooled, self contained units.

Cooling Tower

700 Tons, multi-celled.

Economizer Mode

Delivers chilled water at 45 degrees Fahrenheit when outdoor conditions permit.

Heat Pumps

All supplemental heat pumps that do not have economizer coils must be extended range type.

Fresh Air

Outdoor air is delivered at a rate of 20/CFM per person based on one person per 150 usable square feet, as per BOCA National Mechanical Code.

HVAC Equipment (each floor)

Each office floor will be served by a 55 ton water-cooled package air conditioning unit, with one set of (2) two compressors and a water side economizer coil.

Floor Distribution

Air distribution is provided by variable air volume (VAV) boxes. The VAV boxes are equipped with electric heating coils and built-in transformer controls.

Plumbing

Two wet stacks are available, (1) one is off the woman's toilet room plumbing chase and (2) two is at the elevator core on each floor for waste tie-ins. Domestic water connections are off the woman's room plumbing chase.

Glazing

Thermally efficient insulated glazing system.

Main Telephone Room

Located in the basement. Fiber optic service is available.

EXHIBIT G

FORM OF GUARANTY

FOR VALUE RECEIVED, and in consideration for, and as an inducement to 255 STATE STREET, LLC (the "**Landlord**") to make that certain lease (the "**Lease**") dated as of October , 2010 with SILVER BRIDGE ADVISORS LLC ("**Tenant**"), the undersigned, WILMER CUTLER PICKERING HALE AND DORR LLP ("**Guarantor**"), a Delaware limited liability partnership with an address of 60 State Street, Boston, Massachusetts, unconditionally guarantees the full performance and observance of all the covenants, conditions and agreements therein provided to be performed and observed by Tenant under the Lease(collectively, the "**Guaranteed Obligations**"). Guarantor expressly agrees that the validity of this agreement and the obligations of Guarantor hereunder shall in no wise be terminated, affected or impaired by reason of the granting by Landlord of any indulgences to Tenant or by reason of the assertion by Landlord against Tenant of any of the rights or remedies reserved to Landlord pursuant to the provisions of the Lease or by the relief of Tenant from any of Tenant's obligations under the Lease by operation of law or otherwise (including, but without limitation, the rejection of the Lease in connection with proceedings under the bankruptcy laws now Or hereafter enacted); Guarantor hereby waiving all suretyship defenses. The obligations of Guarantor include the payment to Landlord of any monies payable by Tenant under any provisions of the Lease, at law, or in equity, including, without limitation, any monies payable by virtue of the breach of any warranty, the grant of any indemnity or by virtue of any other covenant of Tenant under the Lease.

Guarantor further covenants and agrees that this Guaranty shall remain and continue in full force and effect as to any renewal, modification or extension of the Lease, whether or not Guarantor shall have received any notice of or consented to such renewal, modification or extension; provided, however, Guarantor will not be obligated with respect to any additional liabilities or obligations imposed by any amendment of the Lease which is entered into without its consent, to the extent such amendment increases the Rent payable under the Lease or materially increases the obligations or liabilities of Tenant under the Lease (excepting amendments confirming or effectuating the exercise by Tenant of the extension option pursuant to Section 2.3 of the Lease, and/or the exercise of the rights of first offer pursuant to Section 2.4 of the Lease). Guarantor further agrees that its liability under this Guaranty shall be primary (and that the heading of this instrument and the use of the word "Guaranty(s)" shall not be interpreted to limit the aforesaid primary obligations of Guarantor), and that in any right of action which shall accrue to Landlord under the Lease, Landlord may, at its option, proceed against Guarantor, any other guarantor, and Tenant, jointly or severally, and may proceed against Guarantor without having commenced any action against or having obtained any judgment against Tenant or any other guarantor; provided, however, Landlord shall provide Guarantor with notice of the breach or default by Tenant and Guarantor shall have the opportunity to cure such breach or default within the applicable period of grace, if any, offered to Tenant under the Lease. Guarantor agrees that, while this Guaranty remains in effect and while any guaranteed obligations remain outstanding and unpaid, Guarantor shall refrain from exercising any and all rights Guarantor may have (whether arising directly or indirectly, by operation of law or by contract or otherwise) to assert any claim against Tenant on account of payments made under this Guaranty, including, without limitation, any and all rights of or claim for subrogation,

contribution, reimbursement, exoneration and indemnity, and provided that any such claims by Guarantor against Tenant shall be subordinate to any and all claims of Landlord against Tenant, and further waives any benefit of and any right to participate in any security deposit or other collateral which may be held by Landlord; and Guarantor will not claim any set-off or counterclaim against Tenant in respect of any liability Guarantor may have to Tenant. Guarantor further represents to Landlord as an inducement for it to make the Lease, that as of the date of this Guaranty, Guarantor owns all of the entire outstanding membership interests of Tenant.

It is agreed that the failure of Landlord to insist in any one or more instances upon a strict performance or observance of any of the terms, provisions or covenants of the Lease or to exercise any right therein contained shall not be construed or deemed to be a waiver or relinquishment for the future of such term, provision, covenant or right, but the same shall continue and remain in full force and effect. Receipt by Landlord of rent with knowledge of the breach of any provision of the Lease shall not be deemed a waiver of such breach.

No subletting, assignment or other transfer of the Lease, or any interest therein, shall operate to extinguish or diminish the liability of Guarantor under this Guaranty; and wherever reference is made to the liability of Tenant named in the Lease, such reference shall be deemed likewise to refer to Guarantor.

All payments becoming due under this Guaranty and not paid within ten (10) days after written notice from Landlord that the same is due shall bear interest from the applicable due date until received by Landlord at the Interest Rate as defined in the Lease.

This Guaranty shall terminate upon the first day that both of the following conditions are satisfied: (a) the Lease shall have terminated, and (b) no Guaranteed Obligations shall be outstanding and/or unpaid; provided, however, that if and to the extent that duties, liabilities and/or obligations of the Tenant under the Lease survive the expiration or earlier termination of the Lease, then this Guaranty shall remain in full force and effect unless and until such duties, liabilities, and/or obligations expire by their terms or are satisfied in full.

It is further agreed that all of the terms and provisions hereof shall inure to the benefit of the heirs, executors, administrators and assigns of Landlord, and shall be binding upon the heirs, successors and assigns of Guarantor.

IN WITNESS WHEREOF, Guarantor has caused this Guaranty to be executed under seal as of this day of October, 2010.

WILMER CUTLER PICKERING HALE & DORR LLP, a Delaware limited liability partnership

WITNESS:

EXHIBIT H

FORM OF
SUBORDINATION, NONDISTURBANCE AND ATTORNMENT AGREEMENT

THIS AGREEMENT, made this day of , 2010, by and among SILVER BRIDGE ADVISORS LLC, a Delaware limited liability company having an address at 60 State Street, Boston, Massachusetts 02109 (hereinafter called "Tenant"), 255 STATE STREET, LLC, a Delaware limited liability company having an address at 255 State Street, Boston, Massachusetts 02109 (hereinafter called "Landlord") and FMR LLC, a Delaware limited liability company, having an address at 82 Devonshire Street, #F7B, Boston, Massachusetts 02109 (hereinafter called "Mortgagee").

W I T N E S S E T H:

WHEREAS, the Tenant has entered into a certain lease (the "Lease") dated , 2010 with Landlord covering a portion of certain premises located in Boston, Suffolk County, Massachusetts (the "Premises") and more particularly described in Exhibit "A" attached hereto and incorporated herein; and

WHEREAS, the Mortgagee has agreed to make a mortgage loan (the "Loan") to Landlord secured by, among other security, a mortgage (the "Mortgage") on the Premises from Landlord; and

WHEREAS, Mortgagee has been requested by Tenant and Landlord to enter into a nondisturbance agreement with Tenant.

NOW, THEREFORE, in consideration of the premises and mutual covenants hereinafter contained, the parties hereto covenant and agree as follows:

1. The Lease and any extensions, renewals, replacements or modifications thereof, and all of the right, title and interest of the Tenant in and to said Premises are and shall be subject and subordinate to the Mortgage and to all of the terms and conditions contained therein (including, without limitation, the casualty and condemnation provisions thereof), and to any renewals, modifications, replacements, consolidations and extensions thereof.

2. In the event of foreclosure of said Mortgage, or in the event Mortgagee comes into possession, makes entry upon or acquires title to the Premises as a result of the enforcement or foreclosure of the Mortgage or the promissory note, or as a result of any other means, Mortgagee agrees that the Lease shall not thereby be terminated and further agrees that Tenant shall not be disturbed in its possession of the premises demised under the Lease for any reason other than one which would entitle the Landlord to terminate the Lease under its terms or would cause, without any further action by such Landlord, the termination of the Lease or would entitle such Landlord to dispossess the Tenant from such demised premises.

3. Tenant agrees with Mortgagee that if the interests of Landlord in the Premises shall be transferred to and owned by Mortgagee by reason of foreclosure or other proceedings brought by it, or by any other manner, or if Mortgagee takes possession of or makes entry upon the Premises pursuant to the Mortgage or any other document evidencing or securing the Loan, Tenant shall be directly bound to Mortgagee under all of the terms, covenants and conditions of the Lease for the balance of the term thereof remaining and any extensions or renewals thereof which may be effected in accordance with any option therefor in the Lease, with the same force and effect as if Mortgagee were the Landlord under the Lease, and Tenant does hereby attorn to Mortgagee as its Landlord, said attornment to be effective and self-operative without the execution of any further instruments on the part of any of the parties hereto immediately upon Mortgagee succeeding to the interest of the Landlord in the Premises. Tenant agrees, however, upon the election of and written demand by Mortgagee within twenty (20) days after Mortgagee receives title to the Premises to execute an instrument in confirmation of the foregoing provisions, satisfactory to Mortgagee, in which Tenant shall acknowledge such attornment and shall set forth the terms and conditions of its tenancy.

4. Tenant agrees with Mortgagee that if Mortgagee shall succeed to the interest of Landlord under the Lease, Mortgagee shall not be (a) liable for any action or omission of any prior landlord under the Lease, or (b) subject to any offsets or defenses which Tenant might have against any prior landlord, or (c) bound by any rent, percentage rent or additional rent or charges which Tenant might have paid for more than the current month to any prior landlord, or (d) bound by any security deposit which Tenant may have paid to any prior landlord, unless such deposit is in an escrow fund available to Mortgagee, (e) bound by any amendment or modification of the Lease (other than amendment to confirm or effectuate the exercise of the extension option pursuant to Section 2.3 of the Lease, and/or the exercise of the rights of first offer pursuant to Section 2.4 of the Lease) or any consent by any prior landlord under the Lease to any assignment or sublease of the lessee's interest in the Lease made without Mortgagee's prior written consent, (f) bound by any provision in the Lease which obligates the Landlord to erect or complete any building or to perform any construction work or to make any improvements to the Premises or any parts thereof (g) bound with respect to breaches other than those occurring during Mortgagee's possession of the Premises or ownership of the landlord's interest under the Lease. In addition, Tenant agrees to look solely to the landlord's interest in the Premises for recovery of any judgment from Mortgagee, it being specifically agreed that neither Mortgagee nor anyone claiming under the Mortgagee shall ever be personally liable for any such judgment, Tenant further agrees with Mortgagee that Tenant will not voluntarily subordinate the Lease to any lien or encumbrance without Mortgagee's consent.

5. Tenant hereby acknowledges that all of Landlord's right, title and interest as lessor under the Lease is being duly assigned to the Mortgagee pursuant to the terms of the Mortgage and that pursuant to the terms thereof all rental payments under the Lease shall continue to be paid to Landlord in accordance with the terms of the Lease unless and until Tenant is otherwise notified in writing by the Mortgagee. Upon receipt of any such written notice from the Mortgagee, Tenant covenants and agrees to make payment of all rental payments then due or to become due under the Lease directly to the Mortgagee or to the Mortgagee's agent designated in such notice, whether or not the Mortgagee has made entry or become mortgagee in possession pursuant to the Mortgage, and to continue to do so until otherwise notified in writing by the

Mortgagee. Landlord hereby irrevocably directs and authorizes Tenant to make rental payments directly to the Mortgagee following receipt of such notice, and covenants and agrees that Tenant shall have the right to rely on such notice without any obligation to inquire as to whether any default exists under the Mortgage or the indebtedness secured thereby, and notwithstanding any notice or claim of Landlord to the contrary, and that Landlord shall have no right or claim against Tenant for or by reason of any rental payments made by Tenant to the Mortgagee following receipt of such notice. Tenant further acknowledges and agrees: (a) that under the provisions of the Mortgage, the Lease (and any guarantees thereof) cannot be terminated (nor can Landlord accept any surrender of the Lease) or modified in any of its terms, or consent be given to the waiver or release of Tenant from the performance or observance of any obligation under the Lease or to any assignments or subleases thereof, without the prior written consent of the Mortgagee, arid without such consent no rent may be collected or accepted by Landlord more than one month in advance; and (b) that the interest of Landlord as lessor under the Lease has been assigned to the Mortgagee for the purposes specified in Mortgage and the Mortgagee assumes no duty, liability or obligation under the Lease, except only under the circumstances, terms and conditions specifically set forth in the Mortgage, copies of which are being recorded concurrently herewith.

6. Tenant, as lessee under the Lease, hereby covenants and agrees to give the Mortgagee written notice properly specifying wherein the lessor under the Lease has failed to perform any of the covenants or obligations of the lessor under the Lease, simultaneously with the giving of any notice of such default to the lessor under the provisions of the Lease. Tenant agrees that the Mortgagee shall have the right, but not the obligation, within thirty (30) days after receipt by the Mortgagee of such notice (or within such additional time as is reasonably required to correct any such default) to correct or remedy, or cause to be corrected or remedied, each such default before the lessee under the Lease may take any action under the Lease by reason of such default. Such notices to the Mortgagee shall be delivered in duplicate to:

FMR LLC
82 Devonshire Street, #F7B,
Boston, Massachusetts 02109

or to such other address as the Mortgagee shall have designated to Tenant by giving written notice to at:

Silver Bridge Advisors, LLC
60 State Street
Boston, MA 02109

With a copy to Guarantor:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Managing Partner

or to such other address as may be designated by written notice from Tenant to the Mortgagee.

7. This Agreement shall bind and inure to the benefit of the parties hereto, their successors and assigns. As used herein, the term "Tenant" shall include the Tenant, its successors and assigns, and the term "Landlord" shall include the Landlord and its successors and assigns. The foregoing references to successors and assigns of Tenant and Landlord is not intended to and does not constitute a consent by Landlord or Mortgagee to any assignment by Tenant of its interests under the Lease or any consent by Mortgagee to any assignment by Landlord of its interests under the Lease. The words "foreclosure" and "foreclosure sale" as used herein shall be deemed to include the acquisition of Landlord's estate in the Premises by voluntary deed (or assignment) in lieu of foreclosure, and the word "Mortgagee" shall include the Mortgagee herein specifically named and any of its successors and assigns, including anyone who shall have succeeded to Landlord's interest in the Premises by, through or under foreclosure of the Mortgage.

8. This Agreement shall not be modified or amended except in writing signed by all parties hereto.

9. The use of the neuter gender in this Agreement shall be deemed to include any other gender, and words in the singular number shall be held to include the plural, when the sense requires.

[Signatures on the Following Page]

IN WITNESS WHEREOF, the parties hereto have placed their hands and seals, the day and year first above written.

MORTGAGEE:

WITNESS:

FMR LLC, a Delaware limited liability company

_____

By: _____
Name:
Title:

TENANT:

WITNESS:

SILVER BRIDGE ADVISORS, LLC, a Delaware limited liability company

_____

By: _____
Name:
Title:

LANDLORD:

WITNESS:

255 STATE STREET, LLC, a Delaware limited liability company

By: Pembroke Real Estate, Inc., its manager

_____

By: _____
Name:
Title:

COMMONWEALTH OF MASSACHUSETTS)
) ss
COUNTY OF SUFFOLK)

On this day of , 2010, before me, the undersigned notary public, personally appeared , proved to me through satisfactory evidence of identification which was to be the person whose name is signed on the preceding or attached document and acknowledged to me that he/she signed it voluntarily for its stated purpose as of FMR LLC.

Notary Public
My Commission Expires:

COMMONWEALTH OF MASSACHUSETTS)
) ss
COUNTY OF SUFFOLK)

On this day of , 2010, before me, the undersigned notary public, personally appeared , proved to me through satisfactory evidence of identification which was to be the person whose name is signed on the preceding or attached document and acknowledged to me that he/she signed it voluntarily for its stated purpose as of FMR LLC.

Notary Public
My Commission Expires:

COMMONWEALTH OF MASSACHUSETTS)
) ss
COUNTY OF SUFFOLK)

On this day of , 2010, before me, the undersigned notary public, personally appeared , proved to me through satisfactory evidence of identification which was to be the person whose name is signed on the preceding or attached document and acknowledged to me that he/she signed it voluntarily for its stated purpose as of FMR LLC.

Notary Public
My Commission Expires:

EXHIBIT A

Legal Description

(to be attached)

EXHIBIT I
SCHEDULE OF CONSTRUCTION DOCUMENTS - TENANT'S WORK

September 21, 2010
Construction Documents for 255 State Street
6th Floor Dated: September 1, 2010

Silver Bridge:

Architectural:

A001	Drafting Conventions and Symbols, Genera Notes and List of Drawings
D106	Demolition Plan
A106	Construction Plan
A206	Reflected Ceiling Plan
A306	Elec/Tel/Data Plan
A406	Furniture/Equipment Plan
A506	Finish Plan
A600	Elevations
A601	Elevations
A800	Door and Frame Schedule, Door and Frame Types, Partition Types
A801	Door and Frame Details
A900	Interior Details
A901	Interior Details

Plumbing:

P0.00	Detail, Legend, Schedules and General Notes
P2.00	Sixth Floor Plan
P7.00	Specifications

Fire Protection:

FP0.00	Details, Legend and Specifications
FP2.00	Fire Protection Plan, Sixth Floor

HVAC:

H0.00	Legend, Symbols and Abbreviations
H2.00	Sixth Floor
H6.00	Control Diagrams
H7.00	Details Sheet No. 1
H7.01	Details Sheet No. 2
H8.00	Schedules
H9.00	Specifications and Notes

Electrical:

E0.00	Legend, Notes and Abbreviations
E2.00	Lighting Plan Sixth Floor
E3.00	Power Plan Sixth Floor
E4.00	Fire Alarm Plan Sixth Floor
E8.00	Detail Sheet No. 1
E8.01	Detail Sheet No. 2
E9.00	Schedules and Power Riser Diagram
E10.00	Specifications and Demolition Notes

Addendum #1 September 9, 2010
SKA-01 Relocated Door, Conference Room 611
SKA-02 Finish Schedule Revisions

EXHIBIT J
SCHEDULE OF CONSTRUCTION DOCUMENTS –
STAIRWAY/COMMON AREA WORK

Elevator Lobby /Common Corridors and Stair Removal Drawings

Dated: September 1, 2010

Architectural:
IA-001 Legends, Abbreviations & Key Plan Floor 6
ID-106 Demolition Plan Floor 6
ID-107 Demolition Plan Floors 7, 8 & 9 Stairwell
ID-206 Demolition Reflected Ceiling Plan Floor 6
ID-207 Demolition RCP Floors 7, 8 & 9 Stairwell
IA-106 Partition & Power Signal Plan Floor 6
IA-107 New Partition & Finish Plans Floors 7, 8 & 9 Stairwell
IA-181 Door Types, Door & HDWR Sched., Glazing Dtls
IA-182 Door and Hardware Schedule
IA-206 Reflected Ceiling Plan Floor 6
IA-207 New Reflected Ceiling Plan Floors 7, 8 & 9 Stairwell
IA-406 Finish Plan Floor 6
IA-731 Elevations and Details Floor 6 Elev. Lobby
IA-732 Interior Details Floor 6

Structural:
S-100 Slab Infill Part Plans & Details

Fire Protection:
FP-001 Fire Protection Legend, Notes, Detail and Specifications
FP-206 Fire Protection 6th Floor Sprinkler Part Plan

Mechanical:
H0.01 HVAC Specifications
H0.02 HVAC Schedules Details
H1.01 HVAC Demolition Plan
HI.02 HVAC New Work Plan

Electrical:
E-001 Electrical Legend and Schedules
E-002 Electrical Specifications
E-106 Electrical Lobby Demolition Plan
E-206 Electrical Lobby Lighting & Power Plan
E-306 Electrical Lobby Fire Alarm Plan

Addendum #1 Additional Scope
Dated September 14, 2010

E-206 Electrical Lighting & Power Plan (New Check Meter for Electrical Service)
E-789 Electrical Stairway Demo. And New Work Plans
FP-789 Fire Protection 7th – 9th Floor Sprinkler Part Plans

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

Exhibit 10.20

EXCLUSIVE LICENSE AGREEMENT

THIS **LICENSE AGREEMENT** (the **"Agreement")** is entered into by and between **THE JOHNS HOPKINS UNIVERSITY,** a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, Maryland 21218-2695 **("JHU")** and **TOKAI PHARMACEUTICALS, INC.,** a Delaware corporation having an address at One Broadway, 14th Floor, Cambridge, Massachusetts 02142 **("LICENSEE").**

RECITALS

WHEREAS, a valuable invention or inventions listed and described in Exhibit A **("INVENTION")** was/were developed during the course of research conducted by the inventors listed on Exhibit A (all hereinafter, **"INVENTORS")**. **JHU** has acquired through assignment all rights, title and interest of said **INVENTORS** in said valuable **INVENTION** and the related patent rights. **JHU** desires that the invention be perfected and marketed as soon as possible so that resulting products may be available for public use and benefit.

WHEREAS, **LICENSEE** desires to obtain certain rights in such **INVENTIONS** and related patent rights and know-how as herein provided, and to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions and/or know-how, and **JHU** desires to grant such rights to **LICENSEE** on the terms set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledge, the parties to this Agreement hereby agree as follows:

1. DEFINITIONS

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. Any reference herein to any defined term shall include both the singular and the plural, whether or not both forms are included in the reference. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 **"AFFILIATED COMPANY"** means any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with **LICENSEE**. For purposes of this Paragraph control shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting stock or other ownership interest of such entity.

1.2 **"EFFECTIVE DATE"** means the date that the last party hereto has executed this Agreement.

1.3 **"EXCLUSIVE LICENSE"** means that, subject to specific limitations in this Agreement, and subject to rights retained by the United States Government, if any, **JHU** grants to **LICENSEE** all of **JHU's** rights under the **LICENSED PATENT(S)** in the **FIELD OF USE** in the **LICENSED TERRITORY**. Exclusive refers to **LICENSED PATENTS** only. **KNOW HOW,** data and other materials licensed are provided on a non-exclusive basis only.

1.4 **"FIELD OF USE"** has the meaning given it in Exhibit A.

1.5 **"FIRST COMMERCIAL SALE"** means the first transfer by a **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** of a **LICENSED PRODUCT or LICENSED SERVICE** for value, but shall not include

a transfer of materials for the purpose of use in a clinical trial, where the consideration received is intended to cover the manufacturing costs of the materials.

1.6 **"IMPROVEMENT"** means an invention(a) that is first conceived or reduced to practice on or after the **EFFECTIVE DATE,** (b) where an **INVENTOR** is an inventor as determined under U.S. patent law, and (c) the use or practice of which in the **FIELD OF USE** would be dominated by one or more claims of the **LICENSED PATENTS.**

1.7 **"JHU REF. NUMBER"** means the **JHU** Technology Transfer Office case number or numbers, shown on Exhibit A, to which the **TECHNOLOGY** licensed pertains. It is used for **JHU** reference only. The **TECHNOLOGY** licensed herein is described in this Agreement, and may not include all the technology that may be a part of the **JHU** reference number.

1.8 **"JHU INDEMNITEES"** means **JHU,** The Johns Hopkins Hospital, The Johns Hopkins Health System Corporation, and their affiliated entities, their present and former trustees, officers, **INVENTORS,** agents, faculty, employees and students.

1.9 **"KNOW HOW"** means non-public information, including but not limited to data, test results, research methodology or manufacturing techniques created by **INVENTORS** that is necessary or useful for the effective practice of the **LICENSED PATENTS.**

1.10 **"LICENSED PATENT"** means (a) [**] and the inventions disclosed and claimed therein, (b) any patent or patent application that claims priority to and is a divisional, continuation, reissue, renewal, reexamination, substitution or extension of any patent application identified in (a); (c) any patents issuing on any patent application identified in (a) or (b), including any reissues, renewals, reexaminations, substitutions or extensions thereof; (d) any claim of a continuation-in-part application or patent (including any reissues, renewals, reexaminations, substitutions or extensions thereof) that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications identified in (a), (b), (c); (e) any foreign counterpart (including PCTs) of any patent or patent application identified in (a), (b), or (c) or of the claims identified in (d); and (f) any supplementary protection certificates, pediatric exclusivity periods, any other patent term extensions and exclusivity periods and the like of any patents and patent applications identified in (a) through (e).

1.11 **"LICENSED PRODUCT"** shall mean any process or method, material, compositions, drug, or other product, created or developed using **TECHNOLOGY,** or for which the development, manufacture, use or sale, if done by a third party without rights under the **LICENSED PATENT(S),** would constitute an infringement of a **VALID CLAIM of LICENSED PATENTS.**

1.12 **"LICENSED SERVICE"** includes any service or services, including the manufacture of any product or the use of any product or composition, performed by **LICENSEE** for any third party using or incorporating the **TECHNOLOGY,** or which, if done by a third party without rights under the **LICENSED PATENT(S),** would constitute an infringement of a claim of **LICENSED PATENTS.**

1.13 **"LICENSED TERRITORY"** means all of the countries in the world.

1.14 **"NET REVENUES"** whether they be **NET SALES REVENUES OR NET SERVICE REVENUES** shall include everything of value actually received by **LICENSEE, AFFILIATED COMPANIES** and

SUBLICENSEE(S) for the sale, license, lease or other transfer of **LICENSED PRODUCTS,** or the performance of **LICENSED SERVICES**. Consideration includes but is not limited to currency, equity of the purchaser, lessee or other transferee, intangible rights, services and other things of value provided or received as part of the transaction for **LICENSED PRODUCTS or LICENSED SERVICES,** the fair value of which must be included to determine **NET REVENUES**. **NET REVENUES** may be calculated using the accrual or cash method, but such calculation must be consistent from month to month and year to year, and must be the same method used by **LICENSEE** for all similar transactions, or if none, the same method used generally by **LICENSEE** in reporting its business activity for United States federal tax purposes.

NET REVENUES may exclude the following items, but only to the extent that they are included in gross revenue, and are separately billed to purchaser, and paid or remitted by **LICENSEE** to third parties:

(i) import, export, excise and sales taxes, custom duties, and shipping charges;

(ii) costs of packing, insurance covering damage during shipping, and transportation from the place of manufacture to the customer's premises or point of installation; and

(iii) amounts repaid or credited by reason of rejections, defects, errors, overbilling, recalls or returns.

In the event that a **LICENSED PRODUCT or LICENSED SERVICE** is sold in a country or other jurisdiction in the Territory in the form of a combination product/service, **NET REVENUES** shall be calculated by multiplying **NET REVENUES** for the combination product/service by the fraction A/(A+B), where A is the invoice price of the **LICENSED PRODUCT or LICENSED SERVICE** and B is the invoice price of the other service(s) in the combination product/service if both the **LICENSED PRODUCT or LICENSED SERVICE** (as applicable) and the other product(s) or service(s) are sold separately. If either the **LICENSED PRODUCT or LICENSED SERVICE** (as applicable) or the other product(s) or service(s) in the combination product/service are not sold separately, **NET REVENUES** shall be calculated by multiplying **NET REVENUES** for the combination product/service by the fraction C/(C+D), where C is the value of the **LICENSED PRODUCT or LICENSED SERVICE** (as applicable) and D is the reasonably estimated value (using accepted industry standards) of the other product(s) or service(s) in the combination product/service, based at least in part on the value of the other active component or components used in the combination product/service.

1.15 **"NET SALES REVENUES"** shall mean **NET REVENUES** derived from the sale of **LICENSED PRODUCTS,** where a sale includes any license of use, lease, sale or other transfer of rights to the **LICENSED PRODUCT.**

1.16 **"NET SERVICE REVENUES"** SHALL mean **NET REVENUES** derived from the sale or performance of **LICENSED SERVICES**.

1.17 **"PATENT COSTS"** means all unreimbursed costs of prosecuting and maintaining any **LICENSED PATENT,** including reasonable attorneys' fees or costs paid or incurred, and expenses paid or incurred for filing, maintenance, annuities, translation, or other costs directly related to the PATENT prosecution and maintenance.

1.18 **"SUBLICENSEE"** means any person or entity other than an **AFFILIATED COMPANY** to which **LICENSEE** has granted a sublicense of the **TECHNOLOGY** under this Agreement, but shall not include any service provider of **LICENSEE, an AFFILIATED COMPANY or SUBLICENSEE** obtaining an implied

license under the **TECHNOLOGY** to perform the contracted services on behalf of **LICENSEE, an AFFILIATED COMPANY or SUBLICENSEE.**

1.19 **"SUBLICENSING INCOME"** means everything of value received by **LICENSEE** in consideration for any sublicense which includes rights to the **TECHNOLOGY** licensed herein. For clarity, and subject in all cases to clause (v) below, **SUBLICENSING INCOME** is the total amount received, regardless of whether or not the **SUBLICENSE** includes intellectual property in addition to the licensed **TECHNOLOGY,** and includes the sublicense fee, milestone payments, stock or other forms of equity, and the fair value of any services or other compensation received. The following may be excluded from the gross amount received for the sublicense when calculating **SUBLICENSING INCOME:**

(i) The reasonable cost of services to be performed thereafter by **LICENSEE** or an **AFFILIATED COMPANY** for or on behalf of the **SUBLICENSEE** if, but only if, those services are specifically described and the cost itemized and stated separately in the sublicense. Payments on the achievement of results shall be deemed to be milestone payments and are included in **SUBLICENSING INCOME.**

(ii) Reimbursement of the amount paid for fees incurred by **LICENSEE,** such as patent costs, or fees paid to governmental agencies, which are incurred after the date of the sublicense and are actually paid to third parties by **LICENSEE.**

(iii) Royalty payments on **SUBLICENSEE'S NET REVENUES,** which will be paid to **JHU** on pursuant to and on the terms of this Agreement.

(iv) The amount of any milestone payment made to **JHU** under this Agreement as a result of activity of **LICENSEE or SUBLICENSEE,** which results in a milestone payment by the sublicense to **LICENSEE** under the **SUBLICENSE**. The difference between the milestone payment to be paid to **JHU** and the milestone payment paid to **LICENSEE** by the sublicensee shall be considered **SUBLICENSING INCOME**. For clarification, if **SUBLICENSEE** makes a payment to **LICENSEE** as a milestone, and **LICENSEE** is obligated to make a milestone payment to **JHU** under this Agreement for that same milestone, that milestone payment amount paid to **JHU** shall be deducted from the milestone amount paid under the **SUBLICENSE,** and the remainder shall be the **SUBLICENSING INCOME.**

(v) The amount received for technology independently developed by **LICENSEE** or its **AFFILIATED COMPANIES,** or technology of third parties licensed or acquired by **LICENSEE** or its **AFFILIATED COMPANIES** and included in the **SUBLICENSE,** including **LICENSEE'S** patent rights claiming the composition of galeterone and related methods and formulations, if said amount is separately stated in the sublicense.

If the **SUBLICENSE** includes the right or obligation of the **SUBLICENSEE** to purchase equity in **LICENSEE** at a cost greater than the then current fair market value of the equity, the difference between the fair market value and the amount paid shall be **SUBLICENSING INCOME.**

1.20 **"TECHNOLOGY"** means the **LICENSED PATENT(S)** and **KNOW HOW**.

1.21 **"VALID CLAIM"** means those claims of an issued patent in any country that (i) has not expired; (ii) has not been disclaimed; (iii) has not been revoked, held invalid, or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such

claim in such country from which no further appeal has or may be taken; and (iv) in the case of a pending application, was filed and is being prosecuted in good faith towards allowance.

2. GRANT

2.1 **Grant**. Subject to the terms and conditions of this Agreement, **JHU** grants **LICENSEE** and its **AFFILIATED COMPANIES an EXCLUSIVE LICENSE** under the **LICENSED PATENTS** and a non-exclusive license under the **KNOW-HOW** in the **FIELD of USE** to make, have made, use, sell, offer to sell and import **LICENSED PRODUCTS** and perform **LICENSED SERVICES** in the **LICENSED TERRITORY**. If any **AFFILIATED COMPANY** exercises rights under this Agreement, such **AFFILIATED COMPANY** shall be bound by all terms and conditions of this Agreement, including but not limited to indemnity and insurance provisions and royalty payments. In addition, **LICENSEE** shall remain fully liable to **JHU** for all acts and obligations of **AFFILIATED COMPANY** such that acts of the **AFFILIATED COMPANY** shall be considered acts of the **LICENSEE.**

2.2 **Retained Rights**.

2.2.1 **JHU Rights**. JHU retains the right, on behalf of itself, the **INVENTORS** and all other non-profit academic or research institutions to whom **JHU** extends rights, to practice and use **TECHNOLOGY** in the **FIELD OF USE** for any research or non-profit purpose, including, but not limited to sponsored research and collaborations with commercial entities (including for clinical trials), and assessment of patients at JHHS/JHU institutions (such as via the JHU CUA laboratory). **JHU** also has the right to publish any information included in the **TECHNOLOGY.**

2.2.2 **Government Rights**. This Agreement is subject to Title 35 Sections 200-204 of the United States Code as implemented in 37 CFR Part 401, as may be amended from time to time. Among other things, these provisions provide the United States Government with certain nonexclusive rights in a **LICENSED PATENT** if federal funds were used to develop the **TECHNOLOGY**. They also impose the obligation that **LICENSED PRODUCTS** sold or produced in the United States be "manufactured substantially in the United States. **LICENSEE** will ensure all required obligations of these provisions are met.

2.2.3 **No Implied licenses**. The practice of the foregoing retained rights by **JHU** shall under no circumstances be construed as a license or ownership interest in, or other right to, any patent rights, know-how or other intellectual property rights of **LICENSEE** or its **AFFILIATED COMPANIES** and **SUBLICENSEES,** including without limitation any intellectual property rights covering or claiming galeterone or methods of manufacture or use thereof.

2.3 **Option Grant**. **JHU** will inform **LICENSEE** in writing of **IMPROVEMENTS**. **JHU** grants to **LICENSEE** an option to negotiate for an exclusive license in the **FIELD OF USE** to any and all of **JHU's** interests in the **IMPROVEMENTS**. The parties agree to negotiate in good faith the commercially reasonable terms and conditions of such an exclusive license, that may arise out of this Agreement. **LICENSEE** shall exercise its option by notifying **JHU** in writing of **IMPROVEMENTS** which **LICENSEE** intends to license within [**] days of **LICENSEE's** notification by **JHU** of such **IMPROVEMENTS**. **LICENSEE** shall also provide **JHU** with a diligence plan providing reasonable assurance to **JHU of LICENSEE'S** plans and capabilities to develop **IMPROVEMENTS** into a **LICENSED PRODUCT or LICENSED SERVICE** in the **FIELD OF USE** for public use or benefit. The option will be subject to **LICENSEE** reimbursing **JHU** for all unreimbursed costs of preparation, filing, prosecution and maintenance of patent rights incurred during the option and negotiation periods with respect to any **IMPROVEMENTS**. **JHU** and **LICENSEE** will have [**] months to come to terms after **JHU** receives notice of **LICENSEE's** intent to license any

IMPROVEMENTS, after which, **JHU** will be free to license such **IMPROVEMENTS** to third parties without restriction. Such option will be subject to (i) Section 2.2 above, and (ii) any third party rights.

2.4 **Specific Exclusions**. **JHU** does not:

2.4.1 commit to **LICENSEE** to bring suit against third parties for infringement, except as described in Article 9;

2.4.2 agree to furnish to **LICENSEE** any technology or technological information other than the **TECHNOLOGY;** or

2.4.3 agree to provide **LICENSEE** with any know how, invention, data, results or other assistance in the future unless specifically and clearly identified in this Agreement.

2.5 **Transfer of Know-How**. Promptly following the **EFFECTIVE DATE, JHU,** through the **INVENTORS,** shall provide **LICENSEE** with tangible manifestations of the **KNOW-HOW** in existence as of the **EFFECTIVE DATE** that may be reasonably requested by **LICENSEE,** and shall ensure that the **INVENTORS** will be reasonably available to **LICENSEE** during the [**] month period following the **EFFECTIVE DATE** to respond to questions that **LICENSEE** may have regarding the use or practice of the **KNOW-HOW** in the **FIELD OF USE.**

3. SUBLICENSING

3.1 **Permitted Sublicensing**. **LICENSEE** may grant sublicenses in the **FIELD OF USE** in the **LICENSED TERRITORY**. For clarity, **LICENSEE** shall be responsible to pay **JHU** royalties due **JHU** on sales of **LICENSED PRODUCTS** and **LICENSED SERVICES** by a **SUBLICENSEE**, to the same extent as if **LICENSEE** made those sales directly, and whether or not **SUBLICENSEE** remits required royalty payments to **LICENSEE**.

3.2 **Sublicense Requirements**. Any sublicense agreement executed pursuant to Section 3.1:

(i) is subject to this Agreement;

(ii) will not permit a **SUBLICENSEE** to further sublicense without **JHU's** consent;

(iii) will, as a condition of validity, expressly include the provisions of Articles 7, 8, 10.3 and 12.2 for the benefit of **JHU;**

(iv) will, if this Agreement is terminated, require the transfer to **JHU** of all obligations, including the payment of royalties specified in the **SUBLICENSE,** without setoff for debts or obligations of **LICENSEE to SUBLICENSEE;** and

(v) will not be valid against **JHU** as to terms, conditions, obligations or limitations that are inconsistent with this Agreement and these sublicensing requirements.

3.3 **Notice and Copy of Sublicense**. **LICENSEE** will notify **JHU** and within [**] days of execution will submit to **JHU** an unredacted copy of each sublicense, the terms of which will not be considered confidential as to **JHU,** but which terms **JHU** will treat as **LICENSEE's** confidential information.

3.4 **Sublicensing Income**. **LICENSEE** will share with and pay to **JHU** that portion of **SUBLICENSING INCOME** as stated in Exhibit A.

4. DILIGENCE REPORTING AND DEVELOPMENT

4.1 **Federal Funding**. It is the requirement of federal law, and the obligation of **JHU** and **LICENSEE,** that inventions created with federal funding be diligently developed into useful products and services.

4.2 **Milestones**. **LICENSEE** will diligently develop markets for and develop, manufacture, and sell **LICENSED PRODUCTS** and **LICENSED SERVICES**. In addition, **LICENSEE** will use commercially reasonable efforts to meet the milestones and target dates, if any, shown in Exhibit A, and notify **JHU** in writing within [**] days after each milestone is met.

4.3 **Diligence Report**.

4.3.1 By [**] of each year, **LICENSEE** will submit a written annual report to **JHU** covering the preceding calendar year. The report will follow the Diligence Report Guidelines stated on Exhibit C and shall include information reasonably sufficient to enable **JHU** to satisfy reporting requirements of the U.S. Government and for **JHU** to ascertain progress by **LICENSEE** toward meeting this Agreement's diligence requirements. Each report will describe, where relevant:

(i) progress by **LICENSEE**, **AFFILIATED COMPANIES** or **SUBLICENSEE(S)** toward commercialization of **LICENSED PRODUCTS** or **LICENSED SERVICES**;

(ii) any FDA or other governmental filings and/or approvals regarding any **LICENSED PRODUCTS or LICENSED SERVICE** made or obtained by **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE,** the patents or patent applications licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service;

(iii) a certificate of insurance or other evidence of insurance, as required by this Agreement, or a statement of why such insurance is not currently required;

(iv) identification of all **AFFILIATED COMPANIES** and **SUBLICENSEE(S)** which have exercised rights to the **TECHNOLOGY,** or a statement that no **AFFILIATED COMPANY** or **SUBLICENSEE** has exercised such rights;

(v) description of any diligence milestones achieved during the prior, and identification of any milestones expected to be achieved in the next year;

(vi) description of any sublicenses under the **TECHNOLOGY** that were entered during the year, with a copy of the sublicense agreement if not previously provided.

(vii) notification of any change of control, name change or other significant change related to this Agreement or **LICENSEE.**

4.3.2 Reports may be submitted electronically to an email address provided on request by **JHU**. Such reports shall be the Confidential Information of **LICENSEE.**

5. FEES, ROYALTIES AND OTHER PAYMENTS

5.1 **License Fee**. **LICENSEE** shall pay to **JHU** the noncreditable, nonrefundable license fee as described in Exhibit A within [**] days of the **EFFECTIVE DATE.**

5.2 **Patent Costs**. Exhibit A includes a summary of unreimbursed **PATENT COSTS,** and **LICENSEE** will reimburse **JHU** the amount stated in Exhibit A at such time or in such manner as stated in Exhibit A.

5.3 **Minimum Annual Royalty**.

5.3.1 **LICENSEE** will pay **JHU** a yearly Minimum Annual Royalty **("MAR")** as described in Exhibit A, which will be paid in advance on or before [**] of each calendar year and which will apply to that calendar year.

5.3.2 MAR payments are nonrefundable. Earned royalty payments due on **NET REVENUES** occurring in the year to which the MAR pertains may be offset against the Minimum Annual Royalty paid for that year, but only for that year, without carry forward or back.

5.4 **Milestone Payments**. **LICENSEE** will pay **JHU** milestone payments as stated on Exhibit A. Within [**] days of achieving a milestone set forth on Exhibit A. **LICENSEE** will report the achievement to **JHU,** and pay to **JHU** the milestone payment required. Milestones achieved should be included in the diligence report described in Section 4.3, even if previously reported.

5.5 **Earned Royalty**. **LICENSEE** will pay **JHU** earned royalties, as described in Exhibit A, which shall be paid quarterly unless a different payment schedule is specifically stated. **LICENSEE** may deduct from the earned royalty the amount of any MAR paid for the year in which the quarter occurs, until all of the MAR has been deducted from payments due for that year, after which any earned royalty in excess of the MAR shall be paid to **JHU.**

5.6 **Duration of Royalty Payments**. Royalties shall be paid as described in Exhibit A for each **LICENSED PRODUCT** manufactured or produced or each **LICENSED SERVICE** performed, on a country-by- country basis, until the later to occur of: (a) ten (10) years from date of **FIRST COMMERCIAL SALE** of that particular **LICENSED PRODUCT or LICENSED SERVICE** in that country and (b) the last to expire patent included within the **LICENSED PATENTS** in such country.

5.7 **Payment for All Activities Performed under this Agreement**. **If LICENSED PRODUCTS** are made, used, imported, or offered for sale before the date this Agreement terminates, and those **LICENSED PRODUCTS** are sold after the effective date of termination, **LICENSEE** will pay **JHU** the earned royalty based on the **NET REVENUE** of those **LICENSED PRODUCTS**. In addition, use of the **TECHNOLOGY** by **LICENSEE** shall be deemed to be use which is licensed under this Agreement, regardless of where performed, whether or not specific **LICENSED PATENTS** exist in the location of the activity for which activity a royalty or other payment is due under this Agreement.

5.8 **Obligation to Pay Royalties and Other Payments**. Payments required herein must be paid on the dates or upon the conditions stated, notwithstanding any claims by either **LICENSEE** or third party challenging the validity of the **LICENSED PATENTS**. Payments once made are not refundable even if the **LICENSED PATENTS** are later determined to be invalid or not applicable to the particular product or service.

5.9 **Currency**. For **NET REVENUES** in currencies other than U.S. Dollars, **LICENSEE** will calculated the royalty in U.S. Dollars quarterly, using the appropriate foreign exchange rate for the currency as quoted by the United States Federal Reserve Bank, for the last business day of each calendar quarter, to apply to payments earned by activities during that quarter.

5.10 **Non-U.S. Taxes**. If non-U.S. taxes are due on royalty or other payments, such taxes shall be deemed to be in addition to the payment, and **LICENSEE** will pay all non-U.S. taxes related to royalty and any other payments under this Agreement. These tax payments are not deductible from any payments due to **JHU**. **JHU** will cooperate with **LICENSEE** to receive a refund of such taxes to the extent available, and such refund shall be retained by **LICENSEE.**

5.11 **No requirement of invoice**. All payments are due on the due date without invoice or demand for payment by or from JHU.

5.12 **Interest**. Payments are considered due on the dates and at the times described in this agreement, and if not so stated, within [**] days of the date of the event requiring the payment. Payment is made when received by **JHU**. Payments not received within [**] days of the due date shall, beginning on the due date, bear interest at the rate of [**]% per annum, whether or not **JHU** has made a demand for such payment or interest. Acceptance of late payments without interest will not act as a waiver of this provision.

5.13 **Payments and Obligations**. All payments and obligations which come due shall be and remain due, and the existence of a dispute shall not suspend any duties under this License Agreement.

5.14 **Invoicing by JHU**. **JHU** may submit all invoices for any payments due in electronic form via e-mail sent to the e-mail address supplied by **LICENSEE** from time to time. An invoice directed to the last email address provided by **LICENSEE to JHU** shall be deemed received by **LICENSEE** when sent by **JHU.**

5.15 **Method of Payment**. All payments under this Agreement shall be made in U.S. Dollars by either check or wire transfer.

5.16 **Payment Information**. Payments shall be made as follows, or as further notified from time to time by **JHU:**

All check payments from **LICENSEE to JHU** shall be sent to:

Attention: Executive Director
Johns Hopkins Technology Transfer
The Johns Hopkins University
100 N. Charles Street
5th Floor
Baltimore, MD 21201
Attn: A26360

or such other addresses which JHU may designate in writing from time to time. Checks are to be made payable to the “Johns Hopkins University”. Wire transfers may be made through:

ACH Info: [**]

FED WIRE: [**]

FED WIRE: [**]

Company shall be responsible for any and all costs associated with wire transfers.

6. ROYALTY REPORTS AND ACCOUNTING

6.1 **Quarterly Earned Royalty Payment and Report**. Beginning with the **FIRST COMMERCIAL SALE** of a **LICENSED PRODUCT or LICENSED SERVICE, LICENSEE** will thereafter submit to **JHU** a written report [**] days after the end of each calendar quarter (even if there are no **NET REVENUES** during that quarter), along with payment of any earned royalty due. This report will be in the form of Exhibit B and will state the number, description, and aggregate **NET REVENUES of LICENSED PRODUCTS** and **LICENSED SERVICES** for the completed calendar quarter. Such reports must be filed and payments made during any claim against or challenge to the scope or validity of the **LICENSED PATENTS.**

6.2 **No Refund**. In the event that a validity or non-infringement challenge of a **LICENSED PATENT** is successful, **LICENSEE** will have no right to recoup any royalties paid before or during the challenge period.

6.3 **Termination or Expiration Report**. **LICENSEE** will pay to **JHU** all applicable royalties and submit to **JHU** a written report within [**] days after the license expires or terminates. **LICENSEE** will continue to submit required earned royalty payments and reports to **JHU** after the license terminates, until all **LICENSED PRODUCTS** made or imported under the license have been sold, and thereafter until the time for paying earned royalties has expired.

6.4 **Accounting**. **LICENSEE** will maintain records showing manufacture, importation, sale, and use of **LICENSED PRODUCTS** or performance of **LICENSED SERVICES** and the revenue received for [**] years from the date of sale of that **LICENSED PRODUCT or LICENSED SERVICE**. Records will include general ledger records showing cash receipts and expenses, and records that include production records, customers, invoices, serial numbers and related information in sufficient detail to enable **JHU** to determine the royalties payable under this Agreement.

6.5 **Audit by JHU**. **LICENSEE** will allow an independent accounting firm designated by **JHU** to examine **LICENSEE's** records during regular business hours upon [**] days' prior written notice to LICENSEE for the sole purpose of verifying payments made by **LICENSEE** under this Agreement. Such inspection may not be made more than [**]. The costs of such inspection shall be paid by JHU; provided, however, that if the audit reveals an underreporting of earned royalties due **JHU** of more than [**] percent ([**]%) for the period being audited, **LICENSEE** will pay the additional royalties due, and reimburse **JHU** the reasonable audit costs incurred.

7. WARRANTIES, EXCLUSIONS AND NEGATION

7.1 **JHU Warranty**. **JHU** warrants and represents that the Inventors listed have provided an invention disclosure to the JHU Office of Technology Transfer **("JHTT"),** that the Inventors have assigned such rights as they have in the Inventions to **JHU,** and that **JHU,** as assignee of the Inventions, has filed the patent applications referred to in this Agreement. **JHU** further warrants and represents that it has the complete right and authority to grant the licenses to **LICENSEE** hereunder, and that this Agreement and the exercise by **LICENSEE** of its rights hereunder does not violate or conflict with an contractual or other right that **JHU** or its affiliated entities has with a third party. To the best of **JHU's** knowledge, information and belief, the **LICENSED PATENT(S)** accurately list the inventors of that Patent and **JHU** has received no claims of a third party to rights in the **LICENSED PATENTS** other than as may be specifically stated in this Agreement. **JHU** does not warrant against presently unknown claims of third parties that may arise after this Agreement.

7.2 **Negation of Warranties**. Except as set forth in Section 7.1, **JHU** provides **LICENSEE** the rights granted in this Agreement AS IS and WITH ALL FAULTS. **JHU** makes no other representations and extends no warranties of any kind, either express or implied. Among other things, **JHU** disclaims any express or implied warranties of merchantability or fitness for a particular purpose.

7.3 **No Representation of LICENSED PATENT**. **LICENSEE** also acknowledges that **JHU** does not represent or warrant:

(i) the validity or scope of any **LICENSED PATENT,** or

(ii) that the exploitation of **LICENSED PATENT or TECHNOLOGY** will be successful, or

(iii) except as set forth in Section 7.1,that there are no third party claims or prior filed patents that would affect ownership of the **TECHNOLOGY** or freedom to operate.

7.4 **No other Promises or Warranties**. Other than the obligations specifically stated in this Agreement, **JHU** makes no promises, express or implied, regarding the **TECHNOLOGY**. **LICENSEE** agrees that no representation or statement by any **JHU** employee shall be deemed to be a statement or representation by **JHU,** and that **LICENSEE** was not induced to enter this Agreement based upon any statement or representation of **JHU,** or any employee of **JHU**. **JHU** is not responsible for any publications, experiments or results reported by any **JHU** employee, now or in the future, including any of the **INVENTORS** and it is the sole responsibility of **LICENSEE** to evaluate the **TECHNOLOGY** and the accuracy of any data or results.

8. INDEMNITY AND INSURANCE

8.1 **Application**. **LICENSEE** shall have exclusive control over the **LICENSED PRODUCTS** and **LICENSED SERVICES** provided by **LICENSEE,** and the risks and costs associated therewith. Therefore, LICENSEE will protect JHU INDEMNITEES from exposure to damages which arise from the actions of LICENSEE.

8.2 **Indemnification**. **LICENSEE, AFFILIATED COMPANY** and/or **SUBLICENSEE** agree that each shall be responsible for injuries or losses to third parties arising from or related to their own acts or omissions, or caused by or arising from **LICENSED PRODUCTS or LICENSED SERVICES,** or allegedly arising as a consequence of the exercise by **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** of any rights granted in this Agreement. To that end, **LICENSEE, AFFILIATED COMPANY** and **SUBLICENSEE** shall protect **JHU INDEMNITEES** from any third party claims arising therefrom, including defending any action brought against **JHU INDEMNITEES,** with counsel reasonably acceptable to **JHU,** and indemnifying **JHU INDEMNITEES** as against any judgments, fees, expenses, or other costs arising from or incidental to any such lawsuit, claim, demand or other action, whether or not any **JHU INDEMNITEE,** is named as a party defendant in any such lawsuit and whether or not the **JHU INDEMNITEES** are alleged to be negligent or otherwise responsible for any injuries to persons or property. Exercise of the rights granted in this Agreement, by an **AFFILIATED COMPANY** or an agent or a **SUBLICENSEE** or a third party on behalf of or for the account of **LICENSEE,** shall be considered **LICENSEE's** practice of said inventions for purposes of this Paragraph.

8.3 **Exclusions**.

8.3.1 No indemnification will be provided for claims arising from the practice by a **JHU INDEMNITEE** of the **LICENSED PATENTS,** or exercise of rights retained by **JHU** under this Agreement, or the practice of the **LICENSED PATENTS** outside the FIELD OF USE by a third party licensee of **JHU.**

8.3.2 No indemnification will be provided for a claim against a **JHU INDEMNITEE** for injuries allegedly caused solely and directly by negligent use or administration by a **JHU INDEMNITEE** of a **LICENSED PRODUCT or LICENSED SERVICE,** but any products liability or similar claim based upon a **LICENSED PRODUCT or LICENSED SERVICE,** made by or provided by **LICENSEE** or any **AFFILIATED COMPANY or SUBLICENSEE** will be covered by this indemnification requirement.

8.4 **Survival after Termination**. The obligation of **LICENSEE** to defend and indemnify as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an **AFFILIATED COMPANY or SUBLICENSEE,** and shall not be limited by any other limitation of liability elsewhere in this Agreement.

8.5 **Rights and Obligations of JHU**. **JHU** shall provide **LICENSEE** with prompt notice of any claims covered by **LICENSEE's** obligation to indemnify, and will provide reasonable cooperation to **LICENSEE in LICENSEE's** investigation and defense of such claims. **JHU** shall have the right to participate in such defense with counsel of its choice and at **JHU's** own expense. **JHU** shall have the right to approve the settlement of any claim hereunder that imposes any liability or obligation on **JHU,** or affects the **LICENSED PATENTS,** other than the payment of money damages paid by the **LICENSEE.**

8.6 **Insurance**. Prior to initial human testing or **FIRST COMMERCIAL SALE** of any **LICENSED PRODUCT or LICENSED SERVICE, LICENSEE** will establish and maintain Comprehensive General Liability Insurance, including Product Liability Insurance, with a reputable and financially secure insurance carrier acceptable to **JHU** to cover any liability of **LICENSEE** and **JHU** to third parties related to any **LICENSED PRODUCT or LICENSED SERVICE,** or otherwise arising from the activities of **LICENSEE,** any **AFFILIATED COMPANY or SUBLICENSEE**. The **LICENSEE** or the acquired insurance will provide minimum limits of liability of $[**] per claim and $[**] in aggregate and will include all **JHU INDEMNITEES** as additional insureds. **LICENSEE** will furnish a Certificate of Insurance or other evidence of compliance upon reasonable request. All insurance of **LICENSEE** will be primary coverage; other insurance of **JHU** and **JHU INDEMNITEES** will be excess and noncontributory.

9. PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

9.1 **Prosecution & Maintenance**.

9.1.1 **Filing and Prosecution**. **JHU, at LICENSEE's** expense, shall file, prosecute and maintain all patents and patent applications specified under **LICENSED PATENTS**. Title to all such patents and patent applications shall reside in **JHU**. **JHU** shall have final decision authority over all patent matter. **JHU** shall (a) request its patent counsel to timely copy **LICENSEE** on all official actions and written correspondence with any patent office, and (b) allow **LICENSEE** an opportunity to comment and advise **JHU** on all matters relating to the prosecution and maintenance of the **LICENSED PATENTS**. **JHU** will consider any of **LICENSEE's** comments and advice in good faith.

9.1.2 **Responsibility of Licensee**. **LICENSEE** shall be responsible for assuring that **LICENSED PATENTS** desired by **LICENSEE** are protected to the extent and in the areas desired by **LICENSEE,** including assuring timely review of patents drafted or filed, timely filing as necessary and payment of required costs.

9.1.3 **Election Not to File in Certain Jurisdictions**. By concurrent written notification to **JHU** and its patent counsel at least [**] days in advance (or later at **JHU's** discretion) of any filing or response deadline, or fee due date, **LICENSEE** may elect not to have a patent application filed in any particular country or not to pay expenses associated with prosecuting or maintaining any patent application or patent, provided that **LICENSEE** pays for all costs incurred up to **JHU's** receipt of such notification. Failure to provide such notification will be considered by **JHU** to be **LICENSEE's** authorization to proceed at **LICENSEE's** expense. Upon such notification, **JHU** may file, prosecute, and/or maintain such patent applications or patent at its own expense and for its own benefit, and any rights or license granted hereunder held by **LICENSEE, AFFILIATED COMPANIES or SUBLICENSEE(S)** relating to the **LICENSED PATENTS** which comprise the subject of such patent applications or patent and/or apply to the particular country, shall terminate, and thereafter reside solely in **JHU.**

9.2 **Notification of Infringement by Third Party**. Each party will notify the other promptly in writing when any infringement by another is uncovered or suspected.

9.3 **Suit for Infringement**.

9.3.1 **LICENSEE** shall have the first right to enforce the **LICENSED PATENTS** in the **FIELD OF USE** against any infringement or alleged infringement thereof, and shall at all times keep **JHU** informed as to the status thereof. This right to sue for infringement shall not be used in an arbitrary or capricious manner. Before **LICENSEE** commences an action with respect to any infringement of such patents, **LICENSEE** shall give careful consideration to the views of **JHU** and to potential effects on the public interest in making its decision whether or not to sue. Thereafter, **LICENSEE** may, at its own expense, institute suit against any such infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof.

9.3.2 No settlement, consent judgment or other voluntary final disposition of the suit may be concluded without the prior written consent of **JHU**, which consent shall not be unreasonably withheld or delayed. **JHU** shall reasonably cooperate in any such litigation at **LICENSEE's** expense, including being named as a party plaintiff in such action to the extent required.

9.3.3 If **LICENSEE** elects not to enforce any patent within the **LICENSED PATENTS**, it shall so notify **JHU** promptly in writing and **JHU** may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom.

9.4 **Patent Invalidity Suit**. **LICENSEE** shall defend at **LICENSEE's** expense a declaratory judgment or other action brought by a third party naming **LICENSEE or JHU** as a defendant and alleging invalidity of any of the **LICENSED PATENTS**. **JHU** in its discretion may elect to take over the sole defense of the action at its own expense, in which case **LICENSEE** shall cooperate fully with **JHU** in connection with any such action.

9.5 **Recovery. LICENSEE** shall pay to **JHU** [**] percent ([**]%) of any monetary award, settlement or recovery, net of all reasonable attorneys' fees and out-of-pocket costs and expenses incurred by **LICENSEE** in connection with each suit or settlement. If the cost and expenses exceed the recovery no additional amount shall be paid to **JHU.**

10. HANDLING AND RESOLUTION OF DISPUTES.

10.1 **Governing Law**. This Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of Maryland applicable to contracts executed and wholly to be performed within the State of Maryland without giving effect to the principles of conflicts of laws. Any disputes between the parties to the Agreement including the applicability or validity of any **LICENSED PATENTS** may be brought in the state or federal courts located in Baltimore, Maryland. Both parties agree to waive their right to a jury trial and to consent to jurisdiction in such courts.

10.2 **Resolution**. The parties shall attempt to resolve all disputes through informal means. This may include mediation, arbitration, or any other procedures upon which the parties agree. Each

party agrees that, prior to resorting to litigation, it will confer with other party to determine whether other procedures that are less expensive or less time consuming can be adopted to resolve the dispute.

10.3 **Challenges to LICENSED PATENTS, Scope and Applicability – Requirements During and After Challenge of LICENSED PATENTS by LICENSEE**. The provisions of this Paragraph 10.3 shall be included in any **SUBLICENSE** and pertain also to actions by a **SUBLICENSEE**. If **LICENSEE**, Affiliate or **SUBLICENSEE** brings an action against **JHU** challenging the validity or scope of the **LICENSED PATENTS,** or applicability of the **LICENSED PATENTS** to a **LICENSED PRODUCT** or **LICENSED SERVICE** the following shall apply.

10.3.1 Actions by a **SUBLICENSEE** shall be attributed to **LICENSEE** unless **LICENSEE** demonstrates that the action was taken independent of any influence by **LICENSEE**, and **LICENSEE** fully cooperates in defending the action, including affirming the validity of the **LICENSED PATENTS** challenged.

10.3.2 If such action determines that at least one claim of a patent challenged by **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** is valid and, if applicable, but for this Agreement, infringed by a **LICENSED PRODUCT or LICENSED SERVICE,** the party challenging will thereafter, except as to **PATENT COSTS,** [**]. For clarity, this shall apply to [**], except incurred **PATENT COSTS** which will be paid as otherwise agreed.

10.3.3 If such action determines that at least one claim of a patent challenged by **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** is valid and, if applicable, but for this Agreement, infringed by a **LICENSED PRODUCT or LICENSED SERVICE,** the **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** challenging will [**].

10.3.4 During the course of such challenge, all payments otherwise required by this Agreement shall be paid as and when due, to the same extent as if there were no challenge to the **LICENSED PATENTS,** and **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** will have no right to recoup any payments, including royalties, which become due before or during the challenge.

10.3.5 **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE** shall not pay royalties into any escrow or other similar account, but shall make all payments to **JHU** as due and when due, unless **LICENSEE or SUBLICENSEE** has prior to the payment becoming due, voluntarily and completely terminated this Agreement. Timely and complete payment and full compliance by **LICENSEE,** Affiliate and **SUBLICENSEE** with all terms of this Agreement shall be a condition precedent to bringing and maintaining the legal action challenging the **LICENSED PATENTS.**

10.3.6 No less than [**] months prior to bringing an action seeking to invalidate or limit a LICENSED PATENT, LICENSEE or AFFILIATED COMPANY will provide written notice of the expected challenge to JHU which shall include a clear statement of the factual and legal basis for the challenge, and an identification of all prior art and other matter believed to invalidate any claim on the LICENSED PATENTS or which supports the claim that the LICENSED PATENT does not apply to the LICENSED PRODUCT or LICENSED SERVICE.

11. TERM AND TERMINATION

11.1 **Term.** The term of this Agreement shall commence on the **EFFECTIVE DATE** and shall continue, in each country, until the date of expiration of the last to expire patent included within **LICENSED PATENTS** in that country or if no patents issue then for a term of ten (10) years from the **FIRST COMMERCIAL SALE** in such country.

11.2 **Termination by Licensee**. LICENSEE may terminate this Agreement by giving **JHU** written notice at least 90 days in advance of the proposed effective date of termination selected by **LICENSEE**. **LICENSEE** shall pay all sums due under this Agreement, including MARs, earned royalties, milestone payments or **PATENT COSTS** which are incurred or are or become due prior to the effective date of termination. In addition, **LICENSEE** shall also be obligated to pay any **PATENT COSTS** which are required to be incurred to preserve the patent prior to the effective date of termination. Termination will not preclude JHU from enforcing its right to collect from LICENSEE amounts accrued and payable prior to the effective date of termination.

11.3 **Termination by JHU**.

11.3.1 **JHU** may terminate this Agreement if **LICENSEE** fails to perform or otherwise materially breaches any of its material obligations hereunder, or of any related agreement including a sponsored research agreement if, following the giving of notice by JHU of its intent to terminate and stating the grounds therefor, LICENSEE has not cured the failure or breach within [**] days. If **LICENSEE** is diligently and in good faith attempting to cure the default, **LICENSEE** may request, and **JHU** shall grant an additional [**] days to cure the default. JHU may also terminate this Agreement if LICENSEE voluntarily or involuntarily enters bankruptcy or receivership proceedings.

11.3.2 **Failure to Meet a Required Diligence Milestone**. If this Agreement provides for diligence milestones which must be accomplished by specified dates or within specified periods of time, **LICENSEE** may cure any default for failure to meet a required diligence milestone in accordance with this subsection.

(i) **LICENSEE** must be diligently pursuing the milestone and provides **JHU** a reasonable explanation of the reasons for such failure and (b) a reasonable, detailed, written plan for promptly achieving a reasonable extended and/or amended milestone. If **LICENSEE** so notifies **JHU** and provides **JHU** with the foregoing explanation and plan, both of which are acceptable to **JHU** in its reasonable discretion, then the applicable diligence milestone will be amended in writing to incorporate the extended and/or amended milestone set forth in the plan presented by **LICENSEE.**

(ii) **JHU** may not withhold its approval to any extended and/or amended milestone if the explanation provided by **LICENSEE** demonstrates to JHU's reasonable satisfaction that (A) the existence of technical difficulties or delays in preclinical or clinical studies *(e.g.,* negative toxicological or pharmacological test results or an adverse clinical event) or regulatory processes that **LICENSEE,** its **AFFILIATED COMPANIES** and/or **SUBLICENSEES** could not have reasonably avoided; (B) the issuance of an injunction or the grant of other equitable relief by a court of competent jurisdiction preventing **LICENSEE,** its **AFFILIATED COMPANIES** and/or SUBLICENSEES from practicing an invention under the **LICENSED PATENTS;** or (C) a failure to achieve, or a material delay in achieving, marketing approval for galeterone, a **LICENSED PRODUCT or LICENSED SERVICE.**

(iii) If the explanation and plan provided by LICENSEE are not reasonably acceptable to **JHU,** then **LICENSEE** may extend the milestone for up to an additional [**] months by paying [**] of the milestone payment associated with the milestone.

11.4 **Survival of Sublicenses.** Upon termination of this Agreement for any reason, any **SUBLICENSEE** shall become a direct licensee of **JHU** under the terms of this Agreement, provided that **JHU's** obligations to **SUBLICENSEE(S)** are no greater than **JHU's** obligations to **LICENSEE** hereunder.

12. MISCELLANEOUS PROVISIONS.

12.1 **Confidentiality**.

12.1.1 As used in this Agreement, the term **"Confidential Information"** means any technical or business information furnished by **LICENSEE** to JHTI in connection with this Agreement which is (a) disclosed in writing or other tangible form and is labeled or identified as "CONFIDENTIAL" at the time of disclosure or, by written notice to **JHU,** within [**] days following disclosure; (b) disclosed verbally and reduced to writing or other tangible form and similarly labeled, within [**] days of verbal disclosure. It is understood and agreed that reports provided to **JHU** pursuant to paragraphs 4.3 and 6.1are Confidential Information hereunder.

12.1.2 **JHU** shall and shall cause its employees, faculty, staff, students, trustees and advisors engaged in the performance of this Agreement to: (a) employ all reasonable and diligent efforts to maintain all Confidential Information in strict confidence, except that **JHU** may disclose or permit the disclosure of any Confidential Information to its employees who are obligated to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information to perform this Agreement; (b) use all Confidential Information solely for purposes of performing this Agreement; and (c) reproduce the Confidential Information only to the extent necessary to perform this Agreement, with all such reproductions being considered Confidential Information.

12.1.3 The obligations of **JHU** under Paragraph 12.1.2 shall not apply to Confidential Information to the extent that **JHU** can demonstrate that such applicable Confidential Information: (a) was in the public domain prior to the time of its disclosure under this Agreement; (b) entered the public domain after the time of its disclosure under this Agreement through means other than an unauthorized disclosure resulting from an act or omission by **JHU;** (c) is or was disclosed to **JHU** at any time, whether prior to or after the time of its disclosure under this Agreement, by a third party having no fiduciary obligation of confidentiality with respect to such Confidential Information; (d) is or was developed by or for **JHU** without reference to information provided by **LICENSEE** or (e) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that **LICENSEE** receives prior written notice of such disclosure and the opportunity to assess the need to disclose and/or limit the scope of disclosure, and that **JHU** takes all reasonable and lawful actions at **LICENSEE's** request and expense to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure.

12.2 **Patent Marking. LICENSEE** agrees that all **LICENSED PRODUCT(S)** sold by **LICENSEE, AFFILIATED COMPANIES** and **SUBLICENSEE(S)** will be marked with the number of the applicable patent(s) licensed hereunder in accordance with, and to the extent required by, each country's patent laws.

12.3 **Use of Name**. **LICENSEE, AFFILIATED COMPANIES** and **SUBLICENSEE(S)** shall not use the name of The Johns Hopkins University or The Johns Hopkins Health System or any of its constituent parts, such as the Johns Hopkins Hospital, Johns Hopkins Medicine or any contraction thereof or the name of

Inventors in any advertising, promotional literature, web sites, electronic media applications, sales literature, fundraising documents, or press releases and other print or electronic communications without prior written consent from an authorized representative of **JHU**. **LICENSEE, AFFILIATED COMPANIES** and **SUBLICENSEE(S)** shall allow at least [**] business days' notice of any proposed public disclosure for **JHU's** review and comment or to provide written consent, unless a shorter period is required in order for **LICENSEE** to comply with its disclosure obligations under federal and state securities laws. Such request shall be made through JHTI.

12.4 **No Partnership**. Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the parties other than that of a licensor/licensee. Neither party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

12.5 **Notice of Claim**. Each party shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the inventions licensed hereunder.

12.6 **Assignment.**

12.6.1 **Permitted Assignment by Licensee**. **LICENSEE** may assign this Agreement as part of a sale or merger, regardless of whether such a sale occurs through an asset sale, stock sale, merger or other combination, if the sale or merger is of **LICENSEE's** entire business.

12.6.2 **Any Other Assignment by Licensee**. Any other attempt to assign this Agreement by **LICENSEE** is null and void in the absence of **JHU's** written permission.

12.6.3 **Conditions of Assignment**. For any assignment, the following conditions must be met:

(i) **LICENSEE** must give **JHU** written notice of the assignment once complete, including the new assignee's contact information; and

(ii) the new assignee must agree in writing to **JHU** to be bound by this Agreement.

12.6.4 **Assignment Payment to JHU**. Where the assignment is the result of complete sale or merger of LICENSEE, then **LICENSEE** (or its assignee) shall pay to **JHU** an assignment fee set forth in Exhibit A. For all other assignments, the assignment shall be treated in the same manner as a sublicense, such that assignment income shall be treated as **SUBLICENSING INCOME.**

12.6.5 **After the Assignment**. Upon a permitted complete assignment of this Agreement, **LICENSEE** will be released from further obligations under this Agreement, except for those sections that survive termination, and the term **"LICENSEE"** in this Agreement will thereafter mean the assignee.

12.7 **Notice**. Except for those communications which specifically under this Agreement may be sent via e-mail or other electronic communication (such as notification of **PATENT COSTS** incurred and due, and other routine communications), all notices, requests or communication required or permitted to be given by either party hereunder shall be given by registered mail or certified mail, return receipt

requested, or sent by overnight courier, such as Federal Express, to the other party at its respective address set forth below or to such other address as one party shall give notice of to the other from time to time hereunder. Notices shall be deemed effective when received.

If to **LICENSEE:** One Broadway, 14th Floor
Cambridge, MA 02142
Attn: Chief Operating Officer
jmcbride@tokaipharma.com

If to **JHU:** Executive Director
Johns Hopkins Technology Transfer
100 N. Charles Street, 5th Floor
Baltimore, MD 21201
RE: Agreement No. A26360

Communications requiring a prompt response should also be sent via email to [**]

12.8 **Compliance with All Laws**. In all activities undertaken pursuant to this Agreement, both **JHU** and **LICENSEE** covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

12.9 **Successors and Assigns**. Other than as specifically stated herein, neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned by either party, in whole or in part, without the prior written consent of the other party. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties hereto.

12.10 **No Waivers; Severability**. No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing and signed by the party waiving. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the parties hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the parties.

12.11 **Entire Agreement; Amendment**. **LICENSEE** and **JHU** acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the parties hereto and supersedes any and all prior or contemporaneous oral or written communications with respect to the subject matter hereof, all of which communications are merged herein. It is expressly understood and agreed that: (i) there being no expectations to the contrary between the parties hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the parties hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the parties hereto.

12.12 **Binding Agreement**. Exchange of this Agreement in draft or final form between the parties shall not be considered a binding offer, and this Agreement shall not be deemed final or binding on either party until the final Agreement has been signed by both parties.

12.13 **Delays or Omissions**. Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party hereto, shall impair any such right, power or remedy to such party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

12.14 **Survival**. All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed or continue to apply after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. In addition, the following shall explicitly and specifically survive any termination or expiration:

(i) **LICENSEE's** obligation to make payments to **JHU,** accrued or accruable during the License, including earned royalties, sublicensing payments, reimbursement of **PATENT COSTS,** late payments and interest;

(ii) any claim of **LICENSEE or JHU,** accrued or to accrue, because of any breach or default by the other party; and

(iii) the provisions of Articles 7, 8 and Paragraphs 11.4, 12.1 and 12.13.

12.15 **No Third Party Beneficiaries**. Nothing in this Agreement shall be construed as giving any person, firm, corporation or other entity, other than the parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

12.16 **Headings**. Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

12.17 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument.

[signature page follows]

IN WITNESS WHEREOF, this Agreement shall take effect as of the **EFFECTIVE DATE** when it has been executed below by the duly authorized representatives of the parties.

THE JOHNS HOPKINS UNIVERSITY

/s/ Jill E. Uhl
Name: Jill E. Uhl
Title: Interim Executive Director
Date: 9 Jan 2015

TOKAI PHARMACEUTICALS, INC.

/s/ John McBride
Name: John McBride
Title: COO
Date: December 23, 2014

EXHIBIT A

LICENSE DEAL SHEET

PATENTS, FEES, ROYALTIES, SUBLICENSING PAYMENTS AND OTHER TERMS SPECIFIC TO THE LICENSE

1. **INVENTIONS and INVENTORS**:

   [**].

2. **Unreimbursed Patent Costs:** Estimated to be $[**]. Exact amount will be calculated and billed after execution of this Agreement.

   LICENSEE will reimburse half of the unreimbursed **PATENT COSTS** within [**] days of the **EFFECTIVE DATE**. The remainder of unreimbursed **PATENT COSTS** shall be paid in [**] equal quarterly installments until fully paid.

   If **JHU** grants additional commercial licenses under the **LICENSED PATENTS** outside the **FIELD OF USE** for consideration after the **EFFECTIVE DATE, JHU** shall notify **LICENSEE** thereof in writing and, from and after the effective date of any such license, **LICENSEE's** obligation to reimburse **JHU** for any **PATENT COSTS** shall be reduced on a *pro rata* basis based on the number of additional commercial licensees of **JHU**. Any **PATENT COSTS** paid to **JHU** prior to the effective date of any such commercial license will be credited against future payments to **JHU,** if any such future payments to **JHU** are pending, on a pro rata basis.

3. **Field of Use:** companion diagnostic for Galeterone (excluding commercial sale as research reagent).

4. **Major Market:** U.S., France, Germany, Italy, Spain, U.K., Japan, Canada

5. **License Fee:** The license fee due under Paragraph 5.1 is seventy-five thousand dollars ($75,000).

6. **Minimum Annual Royalties:** The MARs described under Paragraph 5.3 are:

   - [**]
   - [**]
     - [**]
     - [**]
     - $30,000 [**]

7. **Royalties:** The earned royalty rate payable under Paragraph 5.5 is [**] percent ([**]%) of **NET REVENUE.**

Should **LICENSEE**, any **AFFILIATED COMPANY or SUBLICENSEE** be required to pay running royalties to a third party in order to make, have made, use, sell, offer for sale or import a particular **LICENSED PRODUCT or LICENSED SERVICE** (an **"Other Royalty"**), then **LICENSEE** shall be entitled to credit [**] percent ([**]%) of such Other Royalties against the running royalty due to **JHU,** provided that the running royalties shall not be reduced below [**] percent ([**]%) of those that would otherwise be due **JHU** for that **LICENSED PRODUCT or LICENSED SERVICE.**

Notwithstanding the foregoing, the earned royalty rate under Paragraph 5.5 shall be [**] percent ([**]%) of **NET REVENUE** in any country for any **LICENSED PRODUCT and LICENSED SERVICE** not covered by an issued patent within **LICENSED PATENTS** in the country of sale.

8. **Milestone Payments**. The milestone payments under Paragraph 5.4 are as follows:

[**]

9. **Diligence Milestones**. The following milestones shall be achieved no later than the date shown.

[**]

10. Sublicensing Income. LICENSEE shall pay to JHU twenty percent (20%) of all SUBLICENSING INCOME.

Where multiple technologies or licenses are included on one **SUBLICENSE,** where the amount attributed to each is not specifically stated in the **SUBLICENSE,** the amount attributable to each shall be deemed to apply equally to each technology or license that is included in the **SUBLICENSE**. Where reasonable to do so, **LICENSEE** may request another application of the **SUBLICENSING INCOME,** by providing a written request and analysis to JHTI of the basis for **LICENSEE's** request, but in no circumstance shall less than [**]% of the **SUBLICENSING INCOME** be applied to the **TECHNOLOGY** licensed by this Agreement.

11. **Assignment Payment to JHU**. If an assignment of this Agreement under Section 12.6.4 is the result of complete sale or merger of **LICENSEE,** then **LICENSEE** (or its assignee) shall pay to JHU an assignment fee equal to the greater of:

[**].

EXHIBIT B

QUARTERLY SALES & ROYALTY REPORT

FOR LICENSE AGREEMENT BETWEEN

_____

AND

THE JOHNS HOPKINS UNIVERSITY

DATED

JHU Reference Number(s) _____ _____

PERIOD: From _____ To _____

TOTAL ROYALTIES DUE FOR THIS PERIOD $

PRODUCT ID	PRODUCT NAME	*JHU REFERENCE	1st COMMERCIAL SALE DATE	TOTAL NET SALES/ SERVICES	ROYALTY RATE	AMOUNT DUE

* Please provide the JHU Reference Number or Patent Reference

This report format is to be used to report quarterly royalty statements to **JHU**. It should be placed on **LICENSEE** letterhead and accompany any royalty payments due for the reporting period. After the first sale on which royalties accrue, this report shall be submitted even if no sales are reported.

EXHIBIT C

DILIGENCE AND ANNUAL

REPORT GUIDELINES

FOR LICENSE AGREEMENT BETWEEN

_____

AND

THE JOHNS HOPKINS UNIVERSITY

DATED

JHU Reference Number(s) _____ _____

PERIOD: From _____ To _____

A. Progress by **LICENSEE, AFFILIATED COMPANIES** or **SUBLICENSEE(S)** toward commercialization of **LICENSED PRODUCTS** or **LICENSED SERVICES**:

B. Notice of all FDA or other governmental filings and/or approvals regarding any **LICENSED PRODUCT** or **LICENSED SERVICE** made or obtained by **LICENSEE, AFFILIATED COMPANY or SUBLICENSEE,** the patents or patent applications licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service:

C. A Certificate of Insurance or other evidence of insurance

is required and is attached.

is not required. Reason:

D. **AFFILIATED COMPANIES** and **SUBLICENSEES** which have exercised rights to the **TECHNOLOGY**:

NONE

List attached with description of rights exercised.

E. Diligence and other milestones achieved:

F. Diligence and other milestones expected to be achieved this year:

G. Sublicense(s) entered during the year:

NONE

Identification of **SUBLICENSEE's** (copy of the **SUBLICENSE** attached, if not previously provided)

H. Change of control, name change or other significant change related to this Agreement or **LICENSEE:**

NONE

Details:

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-200413) of Tokai Pharmaceuticals, Inc. of our report dated March 26, 2015 relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, MA
March 26, 2015

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)) 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) 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

c) 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 26, 2015

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

EXHIBIT 31.2

CERTIFICATIONS

I, Lee H. Kalowski, 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)) 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) 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

c) 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 26, 2015

/s/ Lee H. Kalowski
Lee H. Kalowski
Chief Financial 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, 2014, 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 26, 2015

/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, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lee H. Kalowski, 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 26, 2015

/s/ Lee H. Kalowski
Lee H. Kalowski
Chief Financial Officer
(Principal Financial and Accounting Officer)