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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36620

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

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

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

One Broadway, 14th floor
Cambridge, MA 02142
(Former name, former address and former fiscal year, if changed since last report)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

As of April 30, 2015 there were 22,413,594 shares of Common Stock, $0.001 par value per share, outstanding.

Tokai Pharmaceuticals, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- the anticipated timing, cost and conduct of our planned pivotal Phase 3 clinical trial of galeterone 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 an *in vitro* 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 Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Tokai Pharmaceuticals, Inc.

Consolidated Balance Sheets

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

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 94,162	$ 105,256
Prepaid expenses and other current assets	2,170	2,255
Total current assets	96,332	107,511
Property and equipment, net	73	33
Restricted cash	200	200
Other assets	45	—
Total assets	$ 96,650	$ 107,744
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,434	$ 765
Accrued expenses	2,320	3,478
Total current liabilities	5,754	4,243
Total liabilities	5,754	4,243
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 173,018,331 shares authorized; 22,396,540 and 22,382,340 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	22	22
Additional paid-in capital	190,485	189,830
Accumulated deficit	(99,611)	(86,351)
Total stockholders' equity	90,896	103,501
Total liabilities and stockholders' equity	$ 96,650	$ 107,744

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)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue	$ —	$ —
Operating expenses:		
Research and development	10,559	3,556
General and administrative	2,741	1,336
Total operating expenses	13,300	4,892
Loss from operations	(13,300)	(4,892)
Interest and other income	40	45
Net loss and comprehensive loss	$ (13,260)	$ (4,847)
Net loss per share, basic and diluted	$ (0.59)	$ (9.79)
Weighted average common shares outstanding, basic and diluted	22,384,233	495,049

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

Tokai Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Three months ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (13,260)	$ (4,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	634	90
Depreciation expense	5	4
Release of reserve for loan to former advisor	(34)	(45)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	85	(344)
Accounts payable	2,669	798
Accrued expenses	(1,158)	(432)
Other assets	(45)	—
Net cash used in operating activities	(11,104)	(4,776)
Cash flows from investing activities:		
Purchases of property and equipment	(45)	(12)
Net cash used in investing activities	(45)	(12)
Cash flows from financing activities:		
Repayment of notes receivable	34	45
Proceeds from exercise of common stock options	21	4
Net cash from financing activities	55	49
Net decrease in cash and cash equivalents	(11,094)	(4,739)
Cash and cash equivalents at beginning of period	105,256	31,753
Cash and cash equivalents at end of period	$ 94,162	$ 27,014
Supplemental disclosure of non-cash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 98

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

Tokai Pharmaceuticals, Inc.

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

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the "Company") was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a 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 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. Expenses incurred by Diotima for the three months ended March 31, 2014 were $5.

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 public offering 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.

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 March 31, 2015, the Company had an accumulated deficit of $99,611. The Company believes its cash and cash equivalents balance of $94,162 as of March 31, 2015 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.

Tokai Pharmaceuticals, Inc.

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

Unaudited Interim Financial Information

The consolidated balance sheet at December 31, 2014 was derived from audited financial statements, but does not include all disclosures required by U.S. generally accepted accounting principles ("GAAP"). The accompanying unaudited consolidated financial statements as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K, filed with the SEC on March 26, 2015.

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 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.

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 $94,162 and $105,256 as of March 31, 2015 and December 31, 2014, respectively, which were invested in money market accounts, 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.

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.

Tokai Pharmaceuticals, Inc.

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

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 Company reported a net loss attributable to common stockholders for the three months ended March 31, 2015 and 2014.

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

	March 31,	
	2015	2014
Stock options to purchase common stock	2,113,423	1,327,419
Restricted common stock units	54,604	—
Redeemable convertible preferred stock (as converted to common stock)	—	14,860,185
Total options, restricted stock units and redeemable convertible preferred stock exercisable or convertible into common stock	2,168,027	16,187,604

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board 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. The Company is evaluating the effect that this guidance will have on its consolidated financial statements.

3. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2015	December 31, 2014
Accrued research and development expenses	$ 1,518	$ 1,853
Accrued payroll and related expenses	305	963
Accrued professional fees	397	497
Accrued other	100	165
	$ 2,320	$ 3,478

Tokai Pharmaceuticals, Inc.

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

4. Income Taxes

The Company did not provide for any income taxes in the three months ended March 31, 2015 or 2014. The Company had gross deferred tax assets of $33,272 at December 31, 2014 which increased by approximately $5,000 at March 31, 2015. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 2015 and December 31, 2014, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of March 31, 2015 or December 31, 2014. As of March 31, 2015 and December 31, 2014, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since December 31, 2011 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

5. Stock-Based Compensation

The Company grants stock-based awards under its 2014 Stock Incentive Plan and is authorized to issue common stock under its 2014 Employee Stock Purchase Plan. The Company also has outstanding stock options under its 2007 Stock Incentive Plan but is no longer granting awards under this plan. As of March 31, 2015, 2,090,695 shares of common stock were available for issuance under the 2014 Stock Incentive Plan. As of March 31, 2015, 225,000 shares of common stock were available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded stock-based compensation expense related to stock options and restricted common stock units in the following expense categories of its statements of operations:

	Three Months Ended March 31,	
	2015	2014
Research and development	$ 168	$ 29
General and administrative	466	61
	$ 634	$ 90

6. Commitments and Contingencies

Leases

In February 2015, the Company entered into a sublease with a Massachusetts limited liability company (the "sublandlord") for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease, dated October 5, 2010, with the prime landlord. The term of the sublease commenced 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 terminate immediately and the Company will have no recourse against the sublandlord for such termination. The Company is obligated to make monthly payments under this lease totaling $408 and $555 for the years ending December 31, 2015 and 2016, respectively, aggregating $963 in total minimum lease payments. Prior to April 2015, the Company leased office space in Cambridge, Massachusetts, and obtained certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. The Company recorded exit costs of $133 in the first quarter of 2015 in connection with the termination of the Cambridge lease.

During the three months ended March 31, 2015 and 2014, the Company recognized $306 and $106, respectively, of rental expense related to office space.

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.

Tokai Pharmaceuticals, Inc.

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

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 investigational new drug application filed for a licensed product and a $100 milestone payment upon the approval of each new drug application ("NDA") for a licensed product by the U.S. Food and Drug Administration. Because the achievement of these milestones has not occurred as of March 31, 2015, 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 March 31, 2015, 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 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, which was recognized as research and development expense during the three months ended March 31, 2015. The Company is obligated to pay Johns Hopkins an annual minimum royalty of up to $30 and to make milestone payments to Johns Hopkins upon the achievement of specified technical and commercial milestones. If all such milestones were achieved, the total milestone payments owed to Johns Hopkins would equal $700 in the aggregate. Because the achievement of these milestones has not occurred as of March 31, 2015, no liabilities for such milestone payments have been recorded in the Company's consolidated financial statements. 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. As of March 31, 2015, 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.

Tokai Pharmaceuticals, Inc.

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

Companion Diagnostic Development Agreement

In March 2015, the Company entered into a project work plan with Qiagen Manchester Limited ("Qiagen") under a Master Collaboration Agreement, dated January 12, 2015, between the Company and Qiagen (together with the project work plan, the "Agreement"). Pursuant to the Agreement, Qiagen has agreed to develop and commercialize an assay as an *in vitro* 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 *in vitro* 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 *in vitro* companion diagnostic test and to make the *in vitro* 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 *in vitro* companion diagnostic in each such country. If Qiagen elects not to commercialize the *in vitro* 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 *in vitro* companion diagnostic test to the Company in order for the Company to market galeterone in combination with the *in vitro* 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 *in vitro* companion diagnostic test for use with galeterone in Japan.

Subject to the terms of the Agreement, the Company paid Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the *in vitro* companion diagnostic test, which was recognized as research and development expense during the three months ended March 31, 2015. The Company will also pay Qiagen fees for the development of the assay and a contingent milestone payment of $1,000 upon Qiagen obtaining pre-market approval of the assay. Furthermore, the Company 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 *in vitro* companion diagnostic test.

The Agreement expires on the later to occur of (i) the fifth anniversary of regulatory approval of the *in vitro* 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.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers, which provide, among other things, that the Company will indemnify such directors and executive officers to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of the indemnification agreements described above. 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 March 31, 2015.

7. 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 records payments received as other income. As a result, the Company recorded other income of $34 and $45 for the three months ended and March 31, 2015 and 2014, respectively, representing cash collected during those periods.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in our Annual Report on Form 10-K, filed with the SEC on March 26, 2015. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the ''Risk Factors'' section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Overview

We are a 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 April 30, 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 second quarter 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 $13.3 million for the three months ended March 31, 2015 and $23.3 million for the year ended December 31, 2014. As of March 31, 2015, we had an accumulated deficit of $99.6 million. This deficit has resulted principally from costs incurred in connection with research and development activities, general and administrative costs associated with our operations and in-licensing our product candidates. 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 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 March 31, 2015, we had cash and cash equivalents of $94.2 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, include the following:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- third-party contract costs relating to development of 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. See "Results of Operations—Comparison of the Three Months Ended March 31, 2015 and 2014."

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 $10.6 million for the three months ended March 31, 2015 and $3.6 million for the three months ended March 31, 2014. 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 second quarter 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.

Interest and Other Income

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

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 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 consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies which are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 26, 2015, the following accounting policies involve the most judgment and complexity:

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2015 and 2014

The following table summarizes our results of operations for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	10,559	3,556	7,003
General and administrative	2,741	1,336	1,405
Total operating expenses	13,300	4,892	8,408
Loss from operations	(13,300)	(4,892)	(8,408)
Interest and other income	40	45	(5)
Net loss and comprehensive loss	$(13,260)	$(4,847)	$(8,413)

Research and Development Expenses

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Galeterone for prostate cancer	$ 9,272	$2,960	$6,312
Other early-stage development programs and additional indications for galeterone	103	44	59
Unallocated research and development expenses	1,184	552	632
Total research and development expenses	$10,559	$3,556	$7,003

The increase in research and development expenses for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily due to increased costs associated with our galeterone for prostate cancer program and an increase in unallocated research and development expenses. The increase in costs of our galeterone for prostate cancer program consisted primarily of increased costs of clinical trials of $4.1 million and increased manufacturing costs of $2.4 million. The increase in clinical trial costs was primarily due to costs associated with the development of the clinical trial assay to be used in our planned ARMOR3-SV trial, start-up costs for our ARMOR3-SV trial and costs associated with other clinical trials to support the submission of an NDA for galeterone. Costs associated with the development of our clinical trial assay include a fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the AR-V7 *in vitro* companion diagnostic tests as well as costs of the development of the assay. The increase in manufacturing costs was primarily due to a large purchase of raw materials during the three months ended March 31, 2015 for use in manufacturing process optimization and validation studies required to support the submission of an NDA. The increase in unallocated research and development costs was primarily 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

	Three Months Ended March 31,		
	2015	2014	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 1,243	$ 559	$ 684
Professional and consultant fees	974	615	359
Facility related and other	524	162	362
Total general and administrative expenses	$ 2,741	$ 1,336	$1,405

The increase in general and administrative expenses for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily due to an increase in personnel related costs, professional and consultant fees and facility related and other costs. The increase in personnel related costs was primarily due to an increase in stock-based compensation expense of $0.5 million related to additional employee stock options granted and a higher value of our common stock. The increase in professional and consultant fees was primarily due to an increase in legal and patent fees associated with ongoing business activities and additional costs associated with operating as a public company. Facility related and other costs increased primarily due to increased insurance costs, facility costs and other taxes related to our growth and operating as a public company.

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.

Cash Flows

As of March 31, 2015, we had cash and cash equivalents of $94.2 million. We invest our cash equivalents in money market accounts in order to preserve principal.

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

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Cash used in operating activities	$(11,104)	$(4,776)
Cash used in investing activities	(45)	(12)
Cash provided by financing activities	55	49
Net decrease in cash and cash equivalents	$(11,094)	$(4,739)

Operating activities. During the three months ended March 31, 2015, cash used in operating activities consisted of our net loss of $13.3 million, partially offset by net non-cash charges of $0.6 million and by net cash provided by changes in our operating assets and liabilities of $1.6 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense of $0.6 million. Cash provided by changes in our operating assets and liabilities consisted primarily of a net increase in accounts payable and accrued expenses of $1.5 million.

During the three months ended March 31, 2014, cash used in operating activities was $4.8 million, resulting from our net loss of $4.8 million. A nominal amount of cash was provided by changes in our operating assets and liabilities due to a net increase in accounts payable and accrued expenses of $0.4 million, partially offset by an increase in prepaid expenses and other current assets of $0.3 million.

Our net losses for the three months ended March 31, 2015 and 2014 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 three months ended March 31, 2015 and 2014 related to purchases of property and equipment.

Financing activities. During the three months ended March 31, 2015 and 2014, net cash provided by financing activities was due to the repayment of notes receivable and proceeds from the exercise of stock options.

Funding Requirements

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

- conduct our planned pivotal 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 an 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 March 31, 2015, we had cash and cash equivalents of $94.2 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

During the three months ended March 31, 2015, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 26, 2015.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board 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 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of March 31, 2015 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 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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this quarterly report on Form 10-Q. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to 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 $13.3 million for the three months ended March 31, 2015, $23.3 million for the year ended December 31, 2014 and $15.7 million for the year ended December 31, 2013. As of March 31, 2015, we had an accumulated deficit of $99.6 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 March 31, 2015, we had cash and cash equivalents of $94.2 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 second quarter 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 second quarter 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 an *in vitro* 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 *in vitro* 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 April 30, 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 April 30, 2015, we had completed enrollment in the trial and had 17 of the 121 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 second quarter of 2015. We believe that patients' prostate tumor cells may not be responsive to treatment with Zytiga (abiraterone acetate) and Xtandi (enzalutamide) 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 or Xtandi 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 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 an *in vitro* 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 an *in vitro* 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 Valeant Pharmaceuticals International Inc.; and Xofigo® (radium-223), marketed by Bayer HealthCare Pharmaceuticals, Inc. It is uncertain whether we could compete with such products, and our failure to compete or decision to reduce the price of galeterone or other future products we may develop in order to compete could severely impact our business.

In addition, there are numerous prostate cancer products in clinical development by many public and private biotechnology and pharmaceutical companies targeting numerous different cancer types. 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 April 30, 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 six issued U.S. patents and 66 issued foreign patents as well as three U.S. patent applications and ten 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 2036, 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 no patent protection specifically covering the chemical structure of galeterone. As a result, a third party that obtains regulatory approval of a product with the same active ingredient as galeterone may be able to market such product so long as the third

party does not infringe any other patents owned or licensed by us with respect to galeterone. A U.S. patent we have exclusively licensed from UMB covering galeterone-related compounds and their use expires in 2017. We do not expect this patent to provide significant protection for galeterone given its expiration date and our anticipated timing of development and commercialization of galeterone. For this reason, we have filed for or licensed additional patents and patent applications relating to galeterone covering methods of use, pharmaceutical compositions, combination treatments, prodrugs, metabolites and analogs of galeterone and their use.

We also have an exclusive license from Johns Hopkins for 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 the *in vitro* 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 2036. 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 April 30, 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 April 30, 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 April 30, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

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 March 31, 2015, we estimate that we have used approximately $20.4 million of the net proceeds from our initial public offering to fund the clinical development of galeterone and for working capital and other general corporate purposes. We have invested the unused proceeds from the offering in 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. Exhibits.

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

SIGNATURES

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

TOKAI PHARMACEUTICALS, INC.

Date: May 12, 2015

By: /s/ Lee H. Kalowski
Lee H. Kalowski
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1†	Master Collaboration Agreement, dated January 12, 2015, between the Registrant and Qiagen Manchester Limited
10.2†	License Agreement, dated as of January 9, 2015, between the Registrant and The Johns Hopkins University (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
10.3	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Jodie P. Morrison (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
10.4	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and John S. McBride (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
10.5	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Karen J. Ferrante (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
10.6	Amendment to Employment Letter, dated as of January 15, 2015, between the Registrant and Lee H. Kalowski (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
10.7	Sublease Agreement, dated as of February 27, 2015, between the Registrant and Boston Private Wealth LLC (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K filed on March 26, 2015)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal 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 Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

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

* 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 10.1

Execution Copy

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

Companion Diagnostics

MASTER COLLABORATION AGREEMENT

Between Tokai Pharmaceuticals, Inc.
One Broadway, 14th floor
Cambridge, MA 02142 USA
hereinafter **"Tokai"**

and QIAGEN Manchester Limited
Skelton House, Lloyd Street North
Manchester, M15 6SH,
England
hereinafter **"QIAGEN"**

WHEREAS

(A) Tokai is a world-wide operating pharmaceutical company engaged in the research, development, manufacture and commercialization of pharmaceutical products and methods of treatment of patients with pharmaceutical products.

(B) QIAGEN is a global provider of sample and assay technologies including *in vitro* diagnostics and companion diagnostics in relation to the pharmaceutical industry.

(C) The Parties hereby wish to establish a legal framework for their Project-specific collaborations in the field of development and commercialization of *in vitro* diagnostics and/or companion diagnostics for Tokai Compounds.

NOW, THEREFORE, the Parties agree as follows:

1. Definitions

1.1 Many terms are defined within the provisions of this Agreement. For convenience, the following terms are defined "up-front" for use throughout the Agreement:

"Activities" shall mean the activities set out in a Schedule to be performed by either Party in connection with a particular Project.

"Affiliate" shall mean any entity which, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with a Party, as the case may be. As used in this definition, "control" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise.

"Agreement" shall mean this Master Collaboration Agreement.

"Background Intellectual Property" shall mean Intellectual Property, which is in existence and Controlled by a Party at the effective date of the respective Schedule.

"Business Day" means any day other than a Saturday, Sunday, bank holiday or public holiday in Boston, Massachusetts USA.

"Clinical Trial" shall mean a clinical investigation of a Tokai Product undertaken or supported by Tokai as part of the development of such pharmaceutical product to obtain information relating to patient outcome and/or selection for therapy with such pharmaceutical product, which clinical investigation includes the use of the QIAGEN IVD or any prototype of it developed in the respective Project.

"Commercialization" and **"Commercialize"** shall refer to all activities undertaken relating to the manufacture for commercial sale, new product planning, marketing, distribution and sale of a Tokai Product or QIAGEN IVD, and the process of Commercialization, respectively. For clarification, this excludes development and regulatory activities.

"Confidential Information" shall mean any confidential or proprietary information of a Party relating to any assay, diagnostic, biomarker, genetic sequence, compound, research project, work in process, future development, scientific, engineering, launch, manufacturing, marketing, business plan, financial or personnel matter relating to such Party, its present or future products, sales, suppliers, customers, employees, investors or business, including the results arising from this Agreement, whether in oral, written, graphic or electronic form, that is disclosed by or on behalf of a Party to another Party, or becomes known to a Party as a consequence of performing Activities under this Agreement. Notwithstanding the foregoing, Tokai shall be the disclosing Party with respect to Clinical Data, Biomarker Data, Tokai Background Intellectual Property and Tokai Foreground Intellectual Property, and QIAGEN shall be the disclosing Party with respect to Analytical Performance Data, QIAGEN Background Intellectual Property and QIAGEN Foreground Intellectual Property, in each case regardless of the Party that actually discloses such information.

"Control" or "Controlled" or "Controlling" shall mean, with respect to any item of Intellectual Property, the possession (other than by operation of this Agreement) of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or to grant the other Party access or a license or sublicense to, such Intellectual Property as provided for herein without violating the terms of any agreement or other arrangement with a third party.

"Data" shall mean any and all data, results, conclusions, reports, and other information generated by or for Tokai resulting from the activities performed under a Project.

"Deliverables" shall mean the Data and/or materials to be provided to Tokai by QIAGEN in connection with a particular Project.

"Development Project" shall mean a project performed under this Agreement, as agreed between the Parties and set out in a Schedule. Development Projects may include: (i) biomarker identification and validation, (ii) prototype assay development, (iii) companion diagnostic proof of concept, (iv) *in vitro* diagnostic development, (v) enrolment assay

development, (vi) Clinical Trial support and regulatory consultation, or (vii) support of a Regulatory Submission for a Tokai Product; which project ultimately may result in the creation and Commercialization of a QIAGEN IVD in Markets under this Agreement.

"Effective Date" shall mean the date on which this Agreement has been signed by both Parties.

"EU" shall mean the European Union.

"Foreground Intellectual Property" shall mean any and all Intellectual Property arising from work performed under a Project during the Term, whether conceived, discovered, reduced to practice or writing, generated or developed by the employees, consultants, contractors or agents of Tokai and/or its Affiliates and/or by the employees, consultants, contractors or agents of QIAGEN and/or its Affiliates, solely or jointly. For clarification, Foreground Intellectual Property shall exclude Data.

"Governmental Authority" shall mean any court, agency authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

"Indication" shall mean any disease, syndrome or condition for which a product can be used for treatment or prevention of such condition, which use is the subject of a separate Regulatory Approval.

"Intellectual Property" shall mean all intellectual property rights, including patent rights (pending or issued), know-how, materials, methods, processes, protocols, inventions or discoveries (whether or not patentable), utility models, registered designs, design rights, copyrights, copyright registrations, trade secret and other Confidential Information, and similar intellectual property rights.

"IVD" shall mean *in vitro* diagnostic medical device as defined in the European directive 98/79/EC; for the avoidance of doubt the term IVD includes companion diagnostics for a pharmaceutical product as defined in FDA's "Guidance for Industry and Food and Drug Administration Staff—In Vitro Companion Diagnostic Devices" dated August 6, 2014.

"Major Market" shall mean the United States, the EU, Japan, Canada and Australia, unless otherwise agreed in a Project Schedule.

"Market" shall mean any country of the world in which the applicable Tokai Product is Commercialized.

"Materials" shall mean the biological samples, compounds, reagents, supplies, products and other goods that Tokai delivers to QIAGEN, or QIAGEN procures from a third party, for purposes of performing the this Agreement, and all modifications and derivatives of such Materials.

"Party" shall mean Tokai or QIAGEN as the context requires and **"Parties"** shall mean both Tokai and QIAGEN.

"Project" shall mean a Development Project performed under this Agreement and/or subsequent Commercialization of the respective QIAGEN IVD.

"QIAGEN Domain Names" shall mean any Domain Name identical or similar with the QIAGEN Trademarks under any ccTLD (country code Top Level Domain) and gTLD (generic Top Level Domain) address area.

"QIAGEN IVD" shall mean an IVD developed by QIAGEN in the course of a Project including its respective development stages.

"QIAGEN IVD Platform" shall mean a diagnostic instrumentation or device, firmware base software and user interface software, which may include, for example, the RGQ or QIAsymphony instruments.

"QIAGEN Trademarks" shall mean the trademarks which QIAGEN uses for the Commercialization of the QIAGEN IVD to be used in connection with a Tokai Product.

"Regulatory Approval" shall mean with respect to a regulatory jurisdiction, any and all approvals, product and/or establishment licenses, registrations or authorizations of any Governmental Authority, necessary for the commercial manufacture, use, storage, import, export, transport, or Commercialization of a product in such regulatory jurisdiction, including, where applicable, (i) pricing and reimbursement approval in such regulatory jurisdiction, (ii) pre- and post-approval marketing authorisations (including any prerequisite manufacturing approval or authorisation related thereto), (iii) labelling approval and (iv) technical, medical and scientific licences. With regard to an IVD, Regulatory Approval would occur upon FDA approval of a Premarket Approval Application or *de novo* classification or premarket authorization for the IVD, and similar approvals of Governmental Authorities in other jurisdictions.

"Regulatory Submission" shall mean with respect to a regulatory jurisdiction, any and all submissions, which are necessary to obtain a Regulatory Approval.

"Schedule" shall mean an attachment executed by the Parties under this Agreement, as described in Section 2, which details a Project containing a list of Activities, Tokai Compounds, Deliverables, Markets and other terms applicable to a Development Project.

"Tokai Compound" shall mean a single biological or chemical substance identified in a Schedule that Tokai is developing or Commercializing for the prevention, treatment, palliation or cure of a disease, syndrome or condition in humans or animals.

"Tokai Domain Names" shall mean any Domain Name identical or similar with the Tokai Trademarks under any ccTLD (country code Top Level Domain) and gTLD (generic Top Level Domain) address area.

"Tokai Product" shall mean any product containing a Tokai Compound.

"Tokai Trademarks" shall mean the trademarks which Tokai uses for the Commercialization of the Tokai Products with which a QIAGEN IVD will be used.

"Trademark" shall mean the Tokai Trademarks and the QIAGEN Trademarks.

"Valid Claim" shall mean a claim in a granted patent for the Tokai Product that: (a) has not lapsed, expired or been disclaimed and (b) and that has not been revoked, held invalid or otherwise declared unenforceable by a final judgment of a court, tribunal or patent authority of competent jurisdiction from which no appeal has or can be taken; or a claim in a patent application that has not been: (i) abandoned or disclaimed, or (ii) finally rejected or disallowed by an appropriate administrative agency or court of competent jurisdiction from which no appeal has or can be taken, or (iii) [**].

1.2 Other Definitional And Interpretative Provisions. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. Any capitalized term used in any Schedule but not otherwise defined therein shall have the meaning as defined in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. Except where the context otherwise requires, the word "or" is used in the inclusive sense connoted by the term "and/or". This Agreement will be fairly interpreted in accordance with its terms and without any strict construction in favor of or against either Party.

2. Projects

2.1 Schedules, Generally. This Agreement shall govern all Projects identified under a Schedule. The period during which Projects may be initiated (hereinafter **"Initiation Term")** under this Agreement is five (5) years as of the Effective Date, or until terminated in accordance with Section 10. QIAGEN shall perform the Activities and provide the Deliverables as set forth in the relevant Schedule and this Agreement in accordance with the highest prevailing standards of care and skill to be reasonably expected in the field of developing and Commercializing *in vitro* diagnostics and companion diagnostics, including adherence to all applicable laws, cGLP (with respect to Tokai Products developed for animals), cGMP, and cGCP practices, and any additional requirements set forth in a Schedule. QIAGEN shall comply with all reasonable and applicable guidelines and instructions that Tokai provides in writing regarding the use, storage or handling of patient samples or the Tokai Product. QIAGEN shall be responsible for the quality, technical accuracy and completeness of all Deliverables to be generated or provided by it under this Agreement or a Schedule. QIAGEN shall be responsible for the professional quality, training and supervision of all of its, its Affiliates' and permitted subcontractors' personnel who are engaged in the performance of any Activities for a Project under a Schedule. QIAGEN will perform its foregoing obligations in good faith, using commercially reasonable and diligent efforts to meet the milestones set forth in each Schedule.

2.2 Negotiation of Schedules. For each Project conducted under this Agreement, the Parties shall negotiate the specific details and execute a separate written Schedule. Each Schedule shall detail, *inter alia*, the scope of Activities, Tokai Compounds, Deliverables, Project time lines, Markets and compensation terms. Throughout the term of Project each Schedule may be subject to scope changes to be agreed in accordance with section 2.3. Once executed by both Parties, each Schedule and amendment to a Schedule shall be incorporated in its entirety into this Agreement. No Party shall be obliged to enter into any Schedule by virtue of this Agreement. QIAGEN shall not be obligated to perform any Activities for Tokai until the Parties have executed a Schedule for that Project.

2.3 Scope Changes. Each time that the Parties agree that the Activities or Deliverables of a Project should be amended or additional Activities or Deliverables should be added to a Project, the Parties shall prepare a written amendment of the Schedule for such Project. A Party shall not vary from the Activities and Deliverables set out in the original Schedule until the Parties have agreed to do so in writing.

2.4 Conflicting Provisions. In the event there is a specific conflict between the terms or conditions of this Agreement and the terms or conditions of any Schedule, the terms and conditions of this Agreement shall govern, unless the Schedule specifically and expressly supersedes this Agreement on a specific matter and then only with respect to the particular Schedule and the matter so specified.

3. Materials and Records

3.1 Materials Delivery. As more specifically provided in each Schedule, Tokai shall without undue delay provide the relevant Materials free of charge to QIAGEN. If QIAGEN considers that Materials provided by Tokai do not conform to their specifications, then (a) QIAGEN shall provide Tokai a written notice hereof explaining in detail why Materials do not conform and (b) in case the Parties agree on such non-conformance Tokai shall: (i) provide new or replacement Materials or (ii) if that is not possible, propose and discuss with QIAGEN in good faith an alternative, and amend the Schedule in writing to reflect such alternative. In case the Parties disagree on the question of non-conformance of Material, the Parties will discuss this matter and agree in good faith on a solution. To the extent Tokai requests that QIAGEN procure Materials directly from the relevant vendor, such procurement may be subject to a handling charge to be agreed by the Parties in advance.

3.2 Use Restrictions. QIAGEN shall handle the Materials in accordance with any applicable documentation, reasonable handling procedures for similar materials, applicable common scientific standards of care, and Tokai's written instructions. QIAGEN undertakes to use the Materials only in connection with the Activities described in the applicable Schedule and for no other purpose. QIAGEN shall use the Materials in accordance with applicable laws. None of the Materials shall be transferred or sold to third parties except to subcontractors approved by Tokai. QIAGEN shall not use the Materials for testing in or

treatment of human subjects except to the extent described in the applicable Schedule. QIAGEN understands and agrees that the Materials are experimental in nature and that Tokai shall not be liable for any loss, claim, damage or liability which may arise from the use, storage or handling of the Materials by QIAGEN.

3.3 Audits. During and following the Term, Tokai retains the right to audit or have audited QIAGEN's records and any other documentation and facilities in relation to development and regulatory activities for a Project no more than one time per twelve (12) month period during the Term unless there arises a material quality issue that impacts the Project (a "For Cause Audit by Tokai"). QIAGEN agrees to maintain accurate and detailed records of information pertaining to any particular Project and agrees to grant access to Tokai (or its nominees) or the FDA or any other Governmental Authority in a Market at QIAGEN's and any other Project related facility upon request. Such audit(s) will require reasonable prior written notice, no less than 45 days (other than in the case of a For Cause Audit by Tokai and be subject to commercially reasonable security and safety procedures. Should the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") or any other Governmental Authority in a Market conduct or give notice of intent to conduct any inspection at any investigation site, or take any other action with respect to any Project, excluding routine audits of the facility, QIAGEN will promptly give Tokai notice thereof, and supply all information and findings pertinent thereto.

If any audit performed within QIAGEN's internal program results in any critical and major findings concerning a Project, QIAGEN shall provide Tokai with a summary of such findings and proposed corrective actions following the completion of such audit. Should the FDA, EMA or any other Governmental Authority conduct or give notice of intent to conduct any inspection at QIAGEN's offices or other QIAGEN facility relating to the development or regulatory activities for a Project, excluding routine audits of the facility, QIAGEN will promptly (and no longer than 48 hours) give Tokai notice thereof, and supply all information and findings which may have an adverse impact on a Tokai Compound, Tokai Product, a QIAGEN IVD or Project(s) to Tokai, but for clarification, excluding any information relating to a third party's Project or compound. Prior to responding to the findings of any aforementioned inspection, QIAGEN shall review and discuss such response with Tokai. If the inspection relates solely to a QIAGEN IVD or Project for Tokai, and to the extent permitted by law, Tokai shall be entitled to have a representative present for such inspection and all interactions with the FDA, EMA or other Governmental Authority with respect thereto.

3.4 Financial Records. QIAGEN agrees to maintain for a period of seven (7) years after the expiration or termination of this Agreement adequate records of, and copies of all receipts for third party expenses incurred in connection with the performance of the Activities and allow access to Tokai and its authorized representatives to inspect such records and receipts upon reasonable notice during ordinary business hours and subject to QIAGEN's generally applicable security and safety procedures.

4. Interactions with Affiliates and Third Parties

4.1 Subcontractors.

4.1.1 Either Party may involve any of its' Affiliates in the performance of a Project without notice to or consent from the other Party. Any involvement of third party contractors by either Party in performance of a Development Project under a Schedule requires the prior written consent of the other Party, such consent not to be unreasonably withheld. The foregoing shall not be construed as preventing either Party from using individual consultants.

4.1.2 To the extent that a Party utilizes its' Affiliates or third party contractors to perform tasks within the scope of a Project, such Party shall ensure all such Affiliates or third party contractors are obligated to: (i) treat the other Party's Confidential Information in accordance with the provisions of **Section 6**, and (ii) assign rights to any Foreground Intellectual Property, Materials and/or Data so that such rights can be conveyed in accordance with the terms and conditions of **Section 7**, and (iii) with respect to QIAGEN, that its Affiliates or third party contractors grant audits and inspection rights similar to the right set forth in **Section 3.3 and 3.4**; whereas the foregoing shall not limit QIAGEN's audit and inspection responsibilities. Each Party shall be liable and solely responsible for the acts, performance and compensation of its respective third party contractors.

4.2 Contract Laboratories. The Parties may use third party contract laboratories for the performance of certain services such as sample testing pursuant to a Schedule (hereinafter "**Contract Laboratories**"). Tokai and QIAGEN shall cooperate reasonably on a case-by-case basis when contracting with such Contract Laboratories. In the absence of an agreement under a Schedule to the contrary, however, Tokai shall be responsible and authorized to select and contract the Contract Laboratories engaged to assess the clinical utility of a QIAGEN IVD, subject to QIAGEN's prior consent which may only be withheld in case QIAGEN has reasonable quality concerns with respect to the performance of such sample testing by such Contract Laboratory. Tokai and QIAGEN shall ensure that the Contract Laboratories are properly certified to do the clinical utility work according to the applicable Schedule for the Project and this Agreement. QIAGEN shall be solely responsible for the manufacture and supply of a QIAGEN IVD to the Contract Laboratories for clinical utility testing and for sufficient educating and training of the Contract Laboratories personnel as necessary for conducting the clinical utility testing. QIAGEN also shall be responsible for ensuring that each such Contract Laboratory has or is provided the necessary equipment (including any upgrades) needed to perform any assay developed hereunder, all of which shall be at Tokai's expense.

5. Payment

5.1 Fees and Invoices. Tokai shall pay QIAGEN in accordance with the fee/payment provisions set forth in the applicable Schedule. The Parties hereby agree that all Projects shall be performed on the basis of a milestone-based fee structure, unless agreed otherwise. Payments are made in U.S. Dollars by wire transfer to a bank account specified by QIAGEN in the Schedule. QIAGEN shall issue invoices for payments which are milestone based upon their completion in accordance with this Agreement and the relevant Schedule. In addition, QIAGEN shall issue separate invoices, at the end of each month, for all reimbursable expenses set forth in Section 5.2 which accrued in the relevant month. Invoices shall be sent to the following address:

mentioning John McBride and of the respective Project in the reference line. Tokai shall pay such invoices within 30 days of receipt of the relevant invoice.

5.2 Reimbursable Expenses. In addition to the fees payable under Section 5.1, Tokai shall reimburse any direct, out-of-pocket costs reasonably incurred by QIAGEN and labelled as "pass-through costs" in the Schedule, without any mark-up or surcharge unless otherwise agreed by the Parties in writing in advance.

5.3 Currency Conversion.

IF USD, use: Any costs to be reimbursed by Tokai in accordance with Section 5.2 which were incurred in a currency other than U.S. Dollars shall be converted into U.S. Dollars using the average of the fixing exchange rates published by Bloomberg under the function "BFIX" for the respective currency at noon New York time for the applicable calendar quarter If, on any business day, no U.S. Dollar foreign exchange fixing rate is determined by Bloomberg for the relevant currency, the last Bloomberg price of such day (data field "PX last") shall be used instead.

http://markets.ft.com/ft/markets/researchArchive. asp?report=WORL.

5.4 Delay: Any payments due under this Agreement shall be due on such date as specified in this Agreement. Any failure by Tokai to make a payment within [**] days after the date when due shall obligate Tokai to pay interest on the due payment to QIAGEN. The interest period shall commence on the due date (inclusive) and end on the payment date (exclusive). Interest shall be calculated based on the actual number of days in the interest period divided by 360. The interest rate per annum shall be equal to the [**] rate, fixed [**] prior to the due date and reset to the prevailing [**] rate in monthly intervals thereafter, plus a premium of [**] percent ([**]%). In addition, if Tokai fails to make an undisputed payment under a Schedule within sixty (60) days after the date due, QIAGEN shall be entitled, in lieu of other remedies hereunder, to suspend its performance under such Schedule until the undisputed payment is made. However, if Tokai fails to make an undisputed payment under a Schedule within [**] days after the date due, QIAGEN shall be entitled to treat such failure as a material breach by Tokai and terminate this Agreement immediately so long as advance notice pursuant to Section 10.2.1 had been provided.

5.5 Taxes.

5.5.1 All agreed remunerations/fees are considered to be net of value added tax (hereinafter "**VAT**"). VAT will be due additionally as legally owed to the applicable jurisdiction, payable after receipt of a proper invoice, which meets all legal requirements according to the applicable VAT-law.

5.5.2 To the extent that the goods or services to be provided hereunder are subject to any sales, use, rental, personal property, or any other transaction or indirect taxes under law, payment of said taxes is Tokai's responsibility, subject to any applicable exemption entitlement.

5.5.3 Any Party required to make a payment (hereinafter the "**Paying Party**") to the other Party (hereinafter the "P**ayee**") under this Agreement shall be entitled to deduct and withhold from the amount payable the withholding tax for which the Paying Party is liable under any provisions of tax law. Any withheld tax shall be treated as having been paid by Paying Party to Payee for all purposes of this Agreement. Paying Party shall timely forward the tax receipts certifying the payments of withholding tax on behalf of Payee. In case Paying Party cannot deduct the withholding tax due to fulfillment completion of payment obligation by settlement or set-off, Payee will pay the withholding tax to Paying Party separately. If Paying Party failed to deduct withholding tax but is still required by tax law to pay withholding tax on account of Payee to the tax authorities, Payee shall assist Paying Party with regard to all procedures required in order to obtain reimbursement by tax authorities or, in case tax authorities will not reimburse withholding tax to Paying Party, Payee will immediately refund the tax amount.

6. Confidentiality

6.1 Use of Confidential Information. Except for the use in connection with the Activities or the performance of this Agreement, including the permitted use in filings and processes for Regulatory Approval, or as otherwise permitted by either this Agreement or the disclosing Party, each Party shall: (i) not use any Confidential Information of the other Party, (ii) maintain the disclosing Party's Confidential Information in confidence using the same degree of care that it uses for its own Confidential Information of like importance, but in no event using less than reasonable care, and (iii) not disclose or transfer any Confidential Information of the disclosing Party (or any materials which contain such Confidential Information), to any third party; provided, however, that disclosure shall be permitted to the receiving Party's employees, consultants, agents or subcontractors (and those of its Affiliates) who reasonably require such Confidential Information for the purposes of this Agreement and who are bound by obligations of non-use and confidentiality with respect to such Confidential Information equal to those set forth in this Section 6.1. Each Party hereby consents to the disclosure of its Confidential Information by the other Party to any Affiliate of the other Party who reasonably requires such Confidential Information for the purposes of this Agreement, and any such Affiliate shall treat such Confidential Information in accordance with the terms of this Agreement. Tokai shall also be entitled to disclose QIAGEN's Confidential Information, only to the extent directly related to the development and commercialization of the Tokai Product in combination with the QIAGEN IVD and under a binder of confidentiality no less restrictive than the provisions of this Section 6, to: (a) potential or actual commercialization partners for the Tokai Product; and/or (b) potential or actual sources of financing or acquirers of Tokai. Any disclosures made pursuant to the foregoing Section 6.2(a) or (b) shall not require QIAGEN's prior written consent unless the party to which Tokai is making the disclosure is a competitor of QIAGEN as described in QIAGEN's periodic filings with the Securities Exchange Commission as required by the Securities Exchange Act of 1934.

6.2 Non-Confidential Information. The obligations set forth in Section 6.1 shall not apply to any information that the receiving Party can demonstrate by competent proof: (i) was possessed by the receiving Party or any of its Affiliates prior to disclosure or development under this Agreement, (ii) was developed by the receiving Party or any of its Affiliates independently from disclosure or development under this Agreement, in case of QIAGEN particularly also without use of the Materials, (iii) is now or becomes later publicly available other than by breach of this Agreement by receiving Party or any of its Affiliates, or (iv) is available to the receiving Party or any of its Affiliates from a third party that is not legally prohibited from disclosing such information.

6.3 Compelled Disclosure. Either Party may disclose Confidential Information of the other Party to the extent required to be disclosed by applicable judicial or governmental order, provided, however, that the receiving Party takes reasonable steps to give the disclosing Party sufficient prior notice in order to contest such order at the request and expense of the disclosing Party, such request made in the disclosing Party's reasonable discretion, and, in the event the receiving Party is ultimately required to disclose such Confidential Information, that the receiving Party discloses only such portion of the Confidential Information as is required to be disclosed and seeks, at the disclosing Party's request and expense, a protective order to protect the confidentiality of such Confidential Information.

6.4 Equitable Relief. Each Party agrees that damages may not be an adequate remedy for breach of this Article 6 and that, accordingly, either Party shall be entitled to seek injunctive or other equitable relief to prevent disclosure of its Confidential Information.

6.5 Publicity. Promptly following the Effective Date, the Parties shall issue a press release in the form agreed by the Parties. Following such initial press release, no Party hereto may issue any other press release or other public statement or announcement concerning the terms of this Agreement without the other Party's prior written consent unless such release includes only those facts that were initially released in accordance with the first sentence of this Section 6.5. In addition, no Party hereto shall use the name or any trademarks, logos or trade dress of another Party or its Affiliates in any publicity, press release or other form of public announcement or disclosure without the prior written consent of such other Party. Notwithstanding the foregoing, any Party may disclose the terms or existence of this Agreement if required by law or regulation, including without limitation applicable securities laws and regulations and rules and regulations of securities exchanges. If the terms or existence of this Agreement are required to be disclosed by law or regulation, such Party will give the other Parties' prior written notice of the disclosure requirement and a reasonable opportunity to review and comment on what is intended to be disclosed before disclosure.

6.6 Publications. Each Party shall have the right to publish, present or use Foreground Intellectual Property and/or any portion thereof that it Controls in furtherance of its publication objectives, or for non-confidential discussions with a Third Party (a "**Publication**"). Tokai will be responsible for and control the timing and scope of any Publication of [**] and Tokai Foreground Intellectual Property. QIAGEN will be responsible for and control the timing and scope of any Publication of the [**] and QIAGEN Foreground Intellectual Property. Any Publications of the Joint Foreground

Intellectual Property must be agreed and approved by all Parties. Furthermore, Tokai shall not have the right to publish, present or use the [**], QIAGEN Foreground Intellectual Property or any portion thereof for any Publication without QIAGEN's prior written consent, and QIAGEN shall not have the right to publish, present or use the [**] or Tokai Foreground Intellectual Property or any portion thereof for any Publication without Tokai's prior written consent. Such Publication shall be subject to the provisions of this Agreement relating to confidentiality and non-disclosure. At least [**] days prior to submission for publication, the publishing Party shall submit to the other Party for review any proposed Publication. The other Party shall review the proposed Publication and provide its comments to the publishing Party within [**] days of receipt. The Parties agree that the non-publishing Party may request the proposed submission date to be delayed, and the publishing Party agrees to delay, by up to an additional [**] days in order to provide its comments or address concerns regarding the Publication. In addition, upon the other Party's notice to the publishing Party that the other Party reasonably believes that one or more patent applications should be filed which relate to Foreground Intellectual Property Controlled by the other Party or Joint Foreground Intellectual Property prior to any Publication, the publishing Party shall delay the Publication until such patent application(s) have been filed, provided that the other Party will cooperate in expeditiously filing any such patent application(s), and provided further that any such delay of a Publication will not exceed [**] days from the date of such notice by the other Party to the publishing Party. If the other Party believes that any Publication contains Confidential Information or other proprietary information belonging to such Party, such Party will notify the publishing Party, which will remove all references to such Confidential Information or proprietary information prior to publication, presentation or use.

7. Intellectual Property; Licenses

7.1 Background Intellectual Property. Each Party acknowledges and agrees that the other Party Controls certain Background Intellectual Property that relates to that Party's business or operations. Each Party further acknowledges and agrees that Background Intellectual Property Controlled by the other Party shall, as between the Parties, remain the exclusive property of the other Party.

Each Party hereby grants to the other Party during the Term a non-exclusive, worldwide, sub-licensable, non-transferable and royalty-free license under its Background Intellectual Property relevant for a Project solely to the extent such license is necessary for the other Party to carry out its Activities under the respective Project, including subsequent Commercialization by QIAGEN of the QIAGEN IVD developed in the respective Project for use with the respective Tokai Product and subsequent Commercialization by Tokai of the Tokai Product with the QIAGEN IVD under this Agreement. For the avoidance of doubt, the Parties agree that the foregoing license does not provide QIAGEN any right to promote or Commercialize a Tokai Product. For the further avoidance of doubt, the Parties agree that the foregoing license does not provide Tokai with any right to promote or Commercialize a QIAGEN IVD or a laboratory developed test.

Notwithstanding the foregoing, if Intellectual Property Controlled by a third party is included in the Background Intellectual Property of a Party, such Intellectual Property shall only be included into the license grant of this Section 7.1 paragraph 2, if (i) the other Party has committed in writing to comply with the relevant terms and conditions of the agreement with the third party and (ii) if applicable, the Parties have agreed in writing on the allocation or sharing of any payment obligations towards the third party which may result from the other Party's use of the third party's Intellectual Property. In addition, if the relevant (license) agreement with such third party requires an allocation of Data and Foreground Intellectual Property or licenses deviating from Sections 7.2 and 7.3, (i) the Controlling Party shall inform the other Party hereof and (ii) upon request of the other Party to include such third party's Intellectual Property into the license grant under this section 7.1, (iii) the Parties shall negotiate in good faith provisions deviating from Sections 7.2 and 7.3 and set them forth in writing. For the avoidance of doubt, the foregoing shall also apply to third party Intellectual Property acquired pursuant to Section 7.7.

7.2 Assignment and License Back of Data. All Data supplied to QIAGEN by Tokai, or generated in any Clinical Trial (including, for example, all patient data), or generated by the Contract Laboratories for or on behalf of either or both Parties in the course of the Project under this Agreement, or generated by QIAGEN using the Materials shall be owned as follows:

(a) Tokai shall own all **"Clinical Data,"** which is defined as [**] derived from any Materials, all as generated by or on behalf of either Party or both Parties during the course of performing the Activities under a Project or Schedule. Tokai shall be free to use the Clinical Data for any purpose. QIAGEN, as far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Clinical Data to Tokai, and if it not in a legal position to so assign, QIAGEN hereby grants to Tokai an exclusive, worldwide, irrevocable, perpetual, fully paid-up license to use the Clinical Data for any purpose. QIAGEN shall promptly provide to Tokai copies of or access to all Clinical Data held by QIAGEN and its Affiliates, and all related supporting documentation, information, results and analyses with respect to QIAGEN's the Activities under a Project or Schedule, when and as such Clinical Data become available.

(b) Tokai shall own all "**Biomarker Data**," which is defined [**] generated under the Project, all as generated by or on behalf of either Party or both Parties during the course of performing the Activities under a Project or Schedule. Tokai shall be free to use the Biomarker Data for any purpose. QIAGEN, as far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Biomarker Data to Tokai and if it not in a legal position to so assign, QIAGEN hereby grants to Tokai an exclusive, world-wide, irrevocable, perpetual, fully paid-up license to use the Biomarker Data for any purpose.

(c) QIAGEN shall own all "**Analytical Performance Data**," which is defined as [**], all as generated by or on behalf of either Party or both Parties during the course of performing the activities under the Project and Schedule for the QIAGEN IVD. QIAGEN shall be free to use the Analytical Performance Data for any purpose. Tokai, as far as it is in the legal position to do so, hereby assigns all of its right, title and interest in and to such Analytical Performance Data to QIAGEN and if it not in a legal position to so assign, Tokai hereby grants to QIAGEN an exclusive, worldwide, irrevocable, perpetual, fully paid-up license to use the Analytical Performance Data for all purposes.

(d) Tokai hereby grants to QIAGEN a non-exclusive, world-wide, royalty-free license and right of reference to the Clinical Data and Biomarker Data, with the right to sublicense to QIAGEN's Affiliates or any third party developing, obtaining Regulatory Approval for, manufacturing or selling the QIAGEN IVD under the Development Project on behalf of QIAGEN, for the sole and limited purpose of, and only to the extent required to carry out its Activities under the Development Project and subsequent Commercialization of the QIAGEN IVD developed within the Development Project for use with the Tokai Product. QIAGEN shall not use the Clinical Data or Biomarker Data for any purpose other than permitted in this Section 7.2 for as long as such Clinical Data or Biomarker Data constitutes Confidential Information.

(e) QIAGEN hereby grants Tokai a non-exclusive license and right of reference to the Analytical Performance Data for the sole and limited purpose of, and only to the extent required to (i) carry out the Activities under the Project and (ii) research, develop and/or obtain Regulatory Approval for, and make, have made, use, sell, offer for sale, import, export and commercialize Tokai Products. The license shall not be sub-licensable except to any of Tokai's Affiliates or any third party researching, developing, obtaining Regulatory Approval for, making, having made, using, selling, offering for sale, importing, exporting or commercializing the Tokai Product, whether alone or in collaboration with Tokai or any of its Affiliates.

(f) As between the Parties, all right, title and interest in and to the Material is and shall remain the property of Tokai.

7.3 Foreground Intellectual Property. Subject to Section 7.1 paragraph 3, the Parties agree that any Foreground Intellectual Property shall be treated as follows:

7.3.1 Tokai Foreground Intellectual Property. Tokai shall exclusively own all right, title and interest in and to any Foreground Intellectual Property relating to [**], (iii) improvements to the Tokai Background Intellectual Property, and (iv) all Foreground Intellectual Property other than QIAGEN Foreground Intellectual Property that is made or conceived solely by employees, consultants, contractors and agents of Tokai and its Affiliates (hereinafter "**Tokai Foreground Intellectual Property**"). Tokai hereby grants to QIAGEN a non-exclusive, world-wide, royalty-free license, with the right to sublicense, under the Tokai Foreground Intellectual Property solely to carry out the Activities under the applicable Project, including subsequent Commercialization of a QIAGEN IVD developed within a Project for use with the applicable Tokai Product.

7.3.2 QIAGEN Foreground Intellectual Property. QIAGEN shall exclusively own all right, title and interest in and to any Foreground Intellectual Property relating to [**], (ii) improvements of QIAGENs Background Intellectual Property concerning the QIAGEN IVD Platform, and (iii) all Foreground Intellectual Property other than Tokai Foreground Intellectual Property that is made or conceived solely by employees, consultants, contractors and agents of QIAGEN and its Affiliates (hereinafter "**QIAGEN Foreground**

Intellectual Property"). QIAGEN hereby grants to Tokai an irrevocable, perpetual, non-exclusive, world-wide, fully paid-up license, with the right to sublicense, under the QIAGEN Foreground Intellectual Property for carrying out the Activities under the respective Project and to Commercialize the Tokai Product with (x) a QIAGEN IVD or (y) an IVD solely (1) in the event of a termination of this Agreement by Tokai pursuant to Section 10.2 or (2) in any Market for which QIAGEN declines to seek Regulatory Approval for the QIAGEN IVD.

7.3.3 Joint Foreground Intellectual Property. The Parties shall jointly own an equal, undivided interest in and to any Foreground Intellectual Property, other than Tokai Foreground Intellectual Property and QIAGEN Foreground Intellectual Property, that is made or conceived jointly by employees, consultants, contractors and agents of Tokai and its Affiliates and by employees, consultants, contractors and agents of QIAGEN and its Affiliates (hereinafter "**Joint Foreground Intellectual Property**"). In the event that a jurisdiction requires consent of co-owners for one co-owner to grant license rights under or otherwise exploit Joint Foreground Intellectual Property, each Party hereby grants to the other Party and its Affiliates a sublicensable right and license to exploit such Joint Foreground Intellectual Property without a requirement of accounting other than as set forth in this Agreement.

7.3.4 Protection of Foreground Intellectual Property. The Parties will inform each other about any Foreground Intellectual Property without unreasonable delay after it has been conceived by their employees, agents or consultants. The Parties shall take all legally required steps to ensure and effect the allocation of the Foreground Intellectual Property as provided in Sections 7.3.1 through 7.3.3 at the sole expense of the Party owning the Foreground Intellectual Property according to Sections 7.3.1 through 7.3.3 and, the other Party shall provide reasonable assistance and all necessary documentation and declarations to perfect the rights in the Foreground Intellectual Property (*e.g.*, documents for proof of chain of title). Each Party will provide the other Party with thirty (30) days prior notice before pursuing patent protection on the Foreground Intellectual Property allocated to it according to Sections 7.3.1 through 7.3.3. Tokai shall be responsible for the preparation, filing, prosecution and maintenance of the Tokai Foreground Intellectual Property and Joint Foreground Intellectual Property. QIAGEN shall be responsible for the preparation, filing, prosecution and maintenance of the QIAGEN Foreground Intellectual Property.

7.4 Defence and Enforcement. Each Party shall promptly notify the other Party in the event it becomes aware of any third party activities that may constitute infringement of any Intellectual Property that is subject to this Agreement, and/or of any third party claims or allegations contesting the validity and/or enforceability of any such Intellectual Property. QIAGEN shall have the right, but no obligation, to control, enforce, and defend worldwide, at its own expense, Intellectual Property rights in QIAGEN Background Intellectual Property and QIAGEN Foreground Intellectual Property. Tokai shall have the right, but no obligation, to control, enforce, and defend worldwide, at its own expense, Intellectual Property rights in Tokai Background Intellectual Property and Tokai Foreground Intellectual Property. With respect to any Joint Foreground Intellectual Property, the Parties will promptly thereafter consult and cooperate to determine a course of action, which may include, without limitation, the commencement of legal action by any or all of the Parties to terminate or otherwise address such infringement, misappropriation or misuse, and/or to defend the Joint Foreground Intellectual Property.

7.5 Patent Term Restoration. The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for United States patents and patent applications. The Parties shall cooperate with each other, including without limitation to provide necessary information and assistance as another Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Foreground Intellectual Property.

7.6 Trademarks.

7.6.1 Tokai shall have the sole right to select, register and maintain the Tokai Trademarks at its own expense, and shall own and retain all right, title and interest in and to such Tokai Trademarks, and all goodwill associated with or attached to the Tokai Trademarks arising out of the use thereof by Tokai, its Affiliates and third party licensees shall inure to the benefit of Tokai. Only Tokai will be authorized to initiate at its own discretion legal proceedings against any infringement or threatened infringement of the Tokai Trademarks. Tokai shall be responsible for the registration, hosting, maintenance and defence of the Tokai Domain Names. For the avoidance of doubts, Tokai is allowed to register such Domain Names in its own name, to host on its servers, maintain and defend these Domain Names and use them for websites.

7.6.2 QIAGEN shall have the sole right to select, register and maintain the QIAGEN Trademarks at its own expense, and shall own and retain all right, title and interest in and to such QIAGEN Trademarks, and all goodwill associated with or attached to the QIAGEN Trademarks arising out of the use thereof by QIAGEN, its Affiliates and third party licensees shall inure to the benefit of QIAGEN. Only QIAGEN will be authorized to initiate at its own discretion legal proceedings against any infringement or threatened infringement of the QIAGEN Trademarks. QIAGEN shall be responsible for the registration, hosting, maintenance and defence of the QIAGEN Domain Names. For the avoidance of doubt, QIAGEN is allowed to register such Domain Names in its own name, to host on its servers, maintain and defend these Domain Names and use them for websites.

7.6.3 The Parties recognize the exclusive ownership of each other Party's Trademarks, logotype or trade dress furnished by such Party for use in connection with the marketing, sale or distribution of the Product as defined in this Agreement. The Parties shall not, either while this Agreement is in effect, or at any time thereafter, register, use or challenge or assist others to challenge the other Party's Trademarks, logotype and trade dress furnished by each Party for use in connection with the marketing of the products as defined in this Agreement or attempt to obtain any right in or to any such name, logotype, trademarks or trade dress confusingly similar for the marketing of the products as defined in this Agreement or any other goods and products, notwithstanding that such goods or products have a different use or are dissimilar to the products as defined in this Agreement.

7.6.4 Each Party hereby grants to the other Party a non-exclusive, world-wide, sub-licensable, non-transferable and royalty-free license under its Trademarks relevant for a Project to the extent such license is necessary for the other Party to carry out its Activities under the respective Project, including subsequent Commercialization by QIAGEN in accordance with Section 8 of this Agreement of the QIAGEN IVD developed in the respective Project for use with the respective Tokai Product and subsequent Commercialization by Tokai of the Tokai Product with the QIAGEN IVD under this Agreement.

7.7 Third Party Intellectual Property Licenses

7.7.1 Licenses relevant for the Tokai Product

For the avoidance of doubt, Tokai shall be solely responsible, at its own discretion and expense, for obtaining and maintaining any licenses or other rights to access or use any other third party Intellectual Property that is necessary for the development, manufacture, use or Commercialization of any Tokai Product, including but not limited to treatment decisions derived from a diagnostic result and/or patient selection and/or stratification and/or biomarkers. QIAGEN agrees to cooperate reasonably with Tokai to assist Tokai's acquisition of any licenses that it is obligated to obtain pursuant to Section 7.6.1; provided, however, that such cooperation shall not include the undertaking of any financial obligations such as the payment of royalties, milestones or the like, unless otherwise agreed between the Parties.

7.7.2 Licenses relevant for the QIAGEN IVD.

QIAGEN shall be solely responsible, at its own discretion and expense, for obtaining and maintaining any licenses or other rights to access or use any third party Intellectual Property related to:

(i) [**]

(ii) [**],

(iii) [**],

to the extent necessary for the development, manufacture, use or Commercialization by QIAGEN of such QIAGEN IVD pursuant to this Agreement.

8. Commercialization of the QIAGEN IVD as Companion Diagnostic; Supply of IVDs

8.1 General Principles. The Parties agree that the ultimate goal of each Project conducted under this Agreement is the Commercialization of a QIAGEN IVD used in connection with the Tokai Product. The determination of whether and to which extent and in which countries or territories the Tokai Product shall be Commercialized shall be within Tokai's sole discretion. To the extent Tokai Commercializes a Tokai Product in certain countries or territories, QIAGEN shall Commercialize the corresponding QIAGEN IVD in each Major Market, and may Commercialize such QIAGEN IVD in such other markets included in the Project Schedule.

8.2 QIAGEN's Commercialization Obligations. QIAGEN shall be responsible to Commercialize or have Commercialized by a subcontractor the QIAGEN IVD according to the terms and conditions herein. Within the timeframe set forth in the relevant Schedule, QIAGEN shall prepare and the Parties (acting through the JSC) shall agree upon a commercialization plan ("**Commercialization Plan**") for launch, marketing and sale of the QIAGEN IVD in the Markets in accordance with its customary commercial practices. For clarity, any activities that are: (a) outside the scope of QIAGEN's customary commercial practices; or (b) that are tailored to, or necessarily connected to the same activities for, the Tokai Product, the Parties shall mutually agree on the plan and funding for such activities in the Commercialization Plan. Each Commercialization Plan shall, among other things, [**]. Without limiting the foregoing, QIAGEN shall use commercially reasonable and diligent efforts to: (a) ensure the availability of the QIAGEN IVD for purchase in the Markets for use in connection with the initiation and ongoing treatment of patients with the Tokai Product and (b) collaborate with Tokai to seek any necessary reimbursement approvals for the QIAGEN IVD from Governmental Authorities and other third party payors in each of the Major Markets. In addition, while QIAGEN shall be entitled to establish the price to be charged for the QIAGEN IVD, it shall price the QIAGEN IVD in a manner consistent with market norms for the pricing of companion diagnostic products.

8.3 Regulatory Approvals. QIAGEN shall be responsible for obtaining and maintaining, [**], Regulatory Approvals for the QIAGEN IVD in any Major Markets identified by Tokai in a Project Schedule, as well as any other Markets that are mutually agreed by the Parties in a Project Schedule. Tokai shall be responsible for obtaining Regulatory Approvals for the Tokai Product. Without limiting the foregoing, QIAGEN shall use commercially reasonable and diligent efforts to: [**], (e) at Tokai's request, permit Tokai to participate in scheduled meetings with Governmental Authorities in each Major Market regarding development of the Tokai Product for use with the QIAGEN IVD, (f) obtain Regulatory Approval of the QIAGEN IVD in each Major Market and (g) support any efforts of Tokai to obtain Regulatory Approval for the Tokai Product for use with the QIAGEN IVD in each Major Market.

8.4 Manufacture and Supply of IVDs. QIAGEN shall be solely responsible for, and shall use commercially reasonable and diligent efforts to, manufacture QIAGEN IVDs. QIAGEN shall manufacture the QIAGEN IVDs in compliance with cGMP requirements. Until commercial launch of a QIAGEN IVD, QIAGEN shall ensure that adequate supplies of QIAGEN IVDs (or prototypes), are made available to Tokai, any Contract Laboratories and any Clinical Trial sites according to the terms set forth in the Schedule. Subject to receiving sufficient notice of required quantities from Tokai, QIAGEN shall ensure that it maintains sufficient inventories of each QIAGEN IVD as is necessary for the complete conduct of the Clinical Trials of the applicable Tokai Product and Tokai shall pay costs of all remaining quantities which cannot be used for commercialization by QIAGEN. QIAGEN shall be responsible for the transfer of the QIAGEN IVD or the prototypes thereof to the Contract Laboratories involved in the Clinical Trials. Within a commercially reasonable time prior to launch of a Tokai Product, with reasonable advance written notice by Tokai of such launch, QIAGEN will build up and maintain at its own cost an inventory of QIAGEN IVDs which shall be sufficient to satisfy the Commercialization requirement.

8.5 Commercialization Term and Viability of the QIAGEN IVD.

(a) Once Tokai commercially launches the Tokai Product in a Market that is a Major Market, QIAGEN shall make the QIAGEN IVD commercially available in that Major Market and use commercially reasonable and diligent efforts to Commercialize the QIAGEN IVD in that Major Market. QIAGEN shall also Commercialize the QIAGEN IVD in any Market other than Major Markets that were agreed in a Project Schedule and for which Tokai funded the applicable Regulatory Approvals.

(b) QIAGEN shall be responsible for Commercializing the QIAGEN IVD in each Market for as long as there are Valid Claims in that particular Market (the "**Commercialization Term**"). However, QIAGEN may be sooner released from this obligation on a Market by Market basis as follows. In the event QIAGEN reasonably determines that it is not commercially reasonable to Commercialize a QIAGEN IVD in a Market other than a Major Market (it being understood that QIAGEN shall at all times keep the QIAGEN IVD commercially available in a Major Market if the labelling for the Tokai Product in such Major Market requires that an IVD be administered to a potential patient prior to a physician prescribing the applicable Tokai Product), QIAGEN shall provide Tokai with twelve (12) months' written notice, which notice shall include a detailed summary of the basis therefor. During such twelve (12) month period, QIAGEN shall use commercially reasonable efforts to procure alternative channels of distribution and make available or procure the making available of the QIAGEN IVD in such quantities and upon commercially reasonable terms in each case as necessary to reasonably enable Tokai to market the Tokai Product in conjunction with the QIAGEN IVD. [**]. Such supply obligation shall expire upon expiration of the Commercialization Term.

9. Management

9.1 Joint Steering Committee. Within [**] days after the Effective Date, the Parties shall form a Joint Steering Committee (the "**JSC**") to facilitate the transfer of information and coordinate processes related to the development, Regulatory Approval and Commercialization of the Tokai Products and the QIAGEN IVDs being the subject of this Agreement. The JSC shall be composed of three (3) representatives appointed by each Party. Each representative shall be appointed (and may be replaced at any time) by a Party upon prior written notice to the other Party. These representatives shall have appropriate experience, knowledge, and ongoing familiarity with the Projects in their then current phases. [**].

9.2 Responsibilities. The JSC's responsibilities shall include, but not be limited to, the following functions:

- Facilitating the transfer of information and data related to the Commercialization and Regulatory Approval process;
- Facilitating the cooperation of the Parties, when requested, to provide information and support;

- Facilitating coordinated interpretation of data;
- Establishing the JCC and determine how the JCC shall operate;
- Approving each Commercialization Plan (subject to execution of the Commercial Plan by authorized signatories of the Parties); and
- Taking such other actions as may be specifically allocated to the JSC by the Parties from time to time.

9.3 Meetings. The JSC shall meet (either in person, telephonically or via video conference) not less than once per calendar quarter or at such greater frequency as agreed by the respective committee members. Meetings of the JSC shall be at such locations as the Parties agree. Additional representatives of the Parties may from time to time be invited to attend JSC meetings, subject to the other Party's prior consent which shall not be unreasonably withheld. The chair of the JSC shall alternate between a representative of Tokai and a representative of QIAGEN. All decisions of the JSC require the approval of a majority of each Party's representatives to the JSC.

9.4 Joint Project Team.

Within [**] days after last signature of this Agreement the Parties will, in addition to the JSC, form a joint project team (the "**Joint Project Team**" or "**JPT**"), which shall be responsible for facilitating the operational tasks and providing updates on the status of the Development Project. Members of the JPT can include but shall not be limited to representatives with expertise in research biology, translational medicine, clinical, regulatory, and/or product development. Each Party will designate a representative as JPT Lead. Such JPT shall meet, either in person, via telephone or video conferences, on a regular basis, however, at least once per month. [**].

9.5 Joint Project Team Responsibilities.

The JPT's primary responsibilities shall include, but shall not be limited to, the following functions or roles:

- Serving as technical lead and principal point of contact for all matters set forth in the Schedules;
- Overseeing project planning and progress and coordinating all activities set forth in the Schedules;
- Recommending updates to the Schedules including tactics and risk mitigation to the JSC;
- Leading meetings (at least monthly) to facilitate review and coordinated interpretation of data, information sharing, and timeline monitoring;

- Facilitating issue resolution at the Team level and escalating issues to the JSC; and
- Coordinating with the Alliance Managers to provide input to the agenda, preparing thoroughly for meetings, attending meetings and ensuring follow up on action items.

9.6 Alliance Manager.

To manage the Activities under the Agreement, an alliance manager for each Party (the "**Alliance Manager**") shall be appointed by each Party. The Alliance Manager will be an associated member of the JSC and:

- Serve as central point of contact;
- Manage the administrative aspects related to the Agreement;
- Manage and coordinate the different Activities under the contract and ensure appropriate communication and information among the Parties;
- Ensure, together with the JPT, JCC and JSC, that timelines and milestones are defined appropriately and linked with respective payment schedules; and
- Support the resolution of conflicts.

9.7 Joint Commercialization Committee. At least [**] prior to the date on which the first Regulatory Approval of a Tokai Product is expected, the Parties will form a joint commercialization team (the "**JCC**"), which shall be responsible for:

- Facilitating the transfer of information and coordination of processes related to the Commercialization of the Tokai Product and QIAGEN IVD;
- Reviewing each Commercialization Plan prior to submission to the JSC for approval;
- Coordinating planned sales and marketing activities, including launch strategies for the Markets, sales force activities, marketing strategies, alignment of package inserts, instructions for use, data sheets, marketing material, publications, training activities, reimbursement strategies, sharing of market research information and use of advisory boards/key opinion leaders; and
- Forecasting and measuring sales and distribution data to ensure adequate supply of the QIAGEN IVD in each Market.

The JCC shall be constituted and shall operate as the JSC determines. [**].

10. Term and Termination

10.1 Term. This Agreement shall come into force on the Effective Date and shall continue until the expiration or termination of any and all Projects that have been executed within the Initiation Period, or until this Agreement terminated in accordance with this Article 10 ("Term").

10.2 Termination for Cause

10.2.1 Material Breach

(a) This Agreement

Either Party may terminate this Agreement immediately upon sixty (60) days' prior written notice if the other party commits a material breach of the Agreement and fails to cure such breach within the notice period. For clarity, a breach that is specific to a Project shall not serve to terminate this Agreement, but shall be addressed as set forth below. Any termination of this Agreement shall automatically terminate any Project Schedules, Commercialization Plans, or related agreements that may be in effect, unless the Parties agree otherwise in writing.

(b) A Project

Either Party may terminate a Project (Schedule or Commercialization Plan, as the case may be) immediately upon sixty (60) days' prior written notice if the other party commits a material breach of the Schedule and fails to cure such breach within the notice period.

10.2.2 Insolvency or Bankruptcy. Either Party may terminate this Agreement and any Schedules immediately by written notice to the other Party, if the other Party becomes insolvent, makes or has made an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against it (except for involuntary bankruptcies which are dismissed within ninety (90) days) or has a receiver or trustee appointed for substantially all of its property.

10.3 Termination without Cause. Tokai may terminate this Agreement or a Schedule for any Project, for any reason or no reason, at any time upon one hundred eighty (180) days' prior written notice to QIAGEN.

10.4 Effects of Termination. In the event of a termination for cause under Section 10.2 or without cause under Section 10.3, with regard to the terminated Project(s):

(i) the Parties shall promptly meet to prepare a close-out Schedule,

(ii) Tokai shall make a final payment to QIAGEN for: (A) a pro rata portion of any future milestone payments where work was properly performed toward the agreed milestone(s) prior to the date of the termination notice; (B) any project-specific inventory of the QIAGEN IVD maintained in accordance with this Agreement; (C) any pass-through costs that were already paid, or ordered and unable to be cancelled, by QIAGEN pursuant to the Schedule or as otherwise authorized by Tokai;

(iii) upon settlement of all financial obligations of Tokai to QIAGEN, Tokai shall have the right to issue a last order within 14 calendar days as of the effective date of termination and QIAGEN shall transfer to Tokai, within the normal lead time for the quantity ordered after receipt of such last order from Tokai, the quantities of QIAGEN IVDs as ordered by Tokai to enable Tokai to complete the respective Clinical Trial(s), whereas Tokai shall pay for such QIAGEN IVDs the price equalling the market price QIAGEN offers to its third party customers for such types of IVDs;

(iv) all licenses to Background Intellectual Property granted by either Party under this Agreement shall terminate (for the terminated Project, or this Agreement, if terminated in its entirety) upon the effective date of such termination; and

(v) finally, **only in the event of a termination by Tokai for material breach of this Agreement by QIAGEN under Section 10.2 (and specifically not where Tokai terminates this Agreement without cause) or for the bankruptcy or insolvency of QIAGEN under Section 10.2**, all licenses to Data and Foreground Intellectual Property granted by either Party under Sections 7.2 and 7.3 shall survive any expiration or termination of this Agreement.

10.5 Wind-down Costs

In the event of a termination for cause by QIAGEN under Section 10.2 or termination without cause by Tokai under Section 10.3, with regard to the terminated Project(s), Tokai shall reimburse QIAGEN's costs in winding down the Project, which shall be calculated as follows: An amount equal to the number of QIAGEN personnel who were actively engaged in performing Activities in support of the Development Project at the time of termination, multiplied by the percentage of their time allocated to the Development Project at that time, multiplied by a daily FTE rate of US$[**] for the period of Business Days from the date of notice of termination until the date the QIAGEN personnel are reallocated to other activities or projects, not to exceed [**] days.

10.6 Return of Materials and Confidential Information. At the earlier of completion or termination of a particular Project (or this Agreement as a whole), and except as otherwise permitted herein, each Party shall destroy, or return at the other Party's expense and election, Materials and Confidential Information of the other Party. A Party may retain one copy of Confidential Information of the other Party for the purpose of evidence. The return or destruction of Materials and Confidential Information will not affect the receiving Party's obligation to observe the confidentiality and non-use restrictions set out in this Agreement. The provisions of this Section 10.5 shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the receiving Party according to provisions of mandatory law.

10.7 Survival. Termination or expiration of this Agreement will not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder at law or

in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation arising hereunder. Sections 3 [Materials and Records], 5 [Payment], 6 [Confidentiality], 7.2 [Assignment and License Back of Data], 7.3.2 [QIAGEN Foreground Intellectual Property], 7.3.3 [Joint Foreground Intellectual Property], 10.4 [Effects of Termination], 10.5 [Wind-down Costs], 10.6 [Return of Materials and Confidential Information], 10.7 [Survival], 11.4.3, 11.5 [Disclaimers] 12 [Indemnification, Liability and Insurance], and 13 [Miscellaneous], shall survive any termination or expiration of this Agreement. In addition, any other provisions which by their nature are understood to survive the termination or expiration of this Agreement shall so survive.

11. Warranties and Disclaimers

11.1 General Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date that: (i) it is a corporation duly organized, validly existing, and in good standing under applicable laws, rules and regulations, (ii) it has obtained all necessary consents, approvals and authorizations of all governmental authorities (both inside and outside the Markets) and other persons required to be obtained by it in connection with this Agreement, (iii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part, and (iv) it has, to its knowledge, the right to grant the applicable rights and licenses provided for under this Agreement.

11.2 No Inconsistent Agreements. Each Party hereby represents, warrants and covenants to the other Party that during the Term of a Project it will not grant or convey to any third party any right, license or interest in any Intellectual Property that is inconsistent with the rights and licenses expressly granted to the other Party under this Agreement with respect to the relevant Project.

11.3 No Debarment Nor Prohibited Payments. Each Party hereby certifies that it will not employ or otherwise use and has not employed or used in any capacity the services of any person (i) debarred by, or (ii) to the best of the respective Party's knowledge, currently subject to a debarment procedure by US Food and Drug Administration (FDA) under Title 21 United States Code Section 335a or any other competent authority in performing any activities under this Agreement. Each Party further represents and warrants that in connection with the subject matter of this Agreement: (i) none of its employees, agents, officers or directors is a Foreign Official as defined in the U.S. Foreign Corrupt Practices Act, (ii) it will not make, accept or request any payment, either directly or indirectly, of money or other assets to any third party where such payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010, (iii) regardless of legality, it shall neither make, accept nor request any such payment for the purpose of improperly influencing the decisions or actions of any third party, and (iv) it shall report any suspected or actual violation of this Section 11.3 to the other Party upon becoming aware of the same.

11.4 Compliance.

11.4.1 Each Party shall perform all work performed as part of the contractual relationship with the other Party in a manner consistent with all applicable laws and regulations, including, but not limited to, all applicable anti-bribery and antitrust laws. To the extent related to this Agreement, each Party represents and warrants that it has not made or provided, and will not make or provide, any payment or benefit, directly or indirectly, to government officials, customers, business partners, healthcare professionals or any other person in order to secure an improper benefit or unfair business advantage, affect private or official decision-making, affect prescription behaviour, or induce someone to breach professional duties or standards.

11.4.2 Each Party will immediately report to the other Party in writing any suspected or detected violation of the above principles in connection with the other Party's business and, in such cases, will cooperate fully with the other Party in reviewing the matter. In the event that a Party believes, in good faith, that the other Party has violated any of the above principles; then such Party shall have the unilateral right to terminate the contractual relationship with the other Party with immediate effect.

11.4.3 During the Term and for the one (1) year period following the termination or expiration of this Agreement, each Party through a mutually agreeable, independent third-party auditor, upon reasonable advance notice to and at the auditing Party's sole expense, shall have the right during normal business hours to examine and review such books, records, and other documents and materials, except individual salary information, for the sole purpose of verifying whether the other Party has complied with the compliance obligations stated in this Section 11.4.

11.5 Disclaimers. THE REPRESENTATIONS AND WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ANY AND ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, OR STATUTORY, AND EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES OR REPRESENTATIONS, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS.

12. Indemnification, Liability and Insurance

12.1 Indemnification by QIAGEN. QIAGEN shall defend, indemnify and hold harmless each of Tokai, its Affiliates and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "**Tokai Indemnitee**") from and against any and all third party claims, suits, actions, demands or judgments (collectively, "**Claims**") to the extent that such Claims arise, directly or indirectly out of or in connection with this Agreement, and any and all resultant liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees) ("**Liabilities**") to the extent that such Claims and Liabilities arise out of, or in connection with: (i) a QIAGEN Indemnitee's negligence or willful misconduct, (ii) a QIAGEN Indemnitee's violation of applicable law, rule or regulation, (iii) the breach by QIAGEN of any of its representations, warranties and/or covenants under Article 11, (iv)

personal injury or death caused by QIAGEN's use, storage or handling of the Materials in violation of this Agreement, (v) personal injury or death caused by the use or administration of a QIAGEN IVD hereunder and (vi) the infringement of third party Intellectual Property as a result of the Commercialization of any QIAGEN IVD (other than third party Intellectual Property covering biomarkers); provided, however, that QIAGEN's obligations under this Section 12.1 shall be excused to the extent that such Liabilities arise out of a Claim to which a QIAGEN Indemnitee is entitled to indemnification under Section 12.2.

12.2 Indemnification by Tokai Pharmaceuticals. Tokai shall defend, indemnify and hold harmless each of QIAGEN, its Affiliates, and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "**QIAGEN Indemnitee**") from and against any and all Claims to the extent that such Claims arise, directly or indirectly out of or in connection with this Agreement, and any and all resultant Liabilities, to the extent that such Claims and Liabilities arise out of, or in connection with: (i) a Tokai Indemnitee's negligence or willful misconduct, (ii) a Tokai Indemnitee's violation of applicable law, rule or regulation, (iii) the breach by Tokai of any of its representations, warranties and or covenants under Article 11, and (iv) personal injury or death caused by the use or administration of a Tokai Product, (v) medical malpractice occurring in connection with the Clinical Trials of a Tokai Product, and (vi) the infringement of third party Intellectual Property as a result of the Commercialization of any Tokai Product alone, or third party Intellectual Property covering biomarkers as a result of the Commercialization of the QIAGEN IVD; provided, however, that Tokai's obligations under this Section 12.2 shall be excused to the extent that such Liabilities arise out of a Claim to which a Tokai Indemnitee is entitled to indemnification under Section 12.1.

12.3 Procedure. A Party seeking indemnification under Section 12.1 or Section 12.2 (an "**Indemnitee**"), shall notify the other Party (the "**Indemnitor**") upon becoming aware of any Claim that may be subject to indemnification under this Article 12. Failure to provide such notice shall not constitute a waiver or release of the Indemnitee's rights to indemnification, except to the extent that such delay or failure materially prejudices the Indemnitor. The Indemnitor shall have the right, (but not the obligation) to control the defense and disposition (including, without limitation, settlement, litigation or appeal) of any such claim. The Indemnitee shall cooperate reasonably with the Indemnitor and its legal representatives in connection with the investigation and defense of any Claim and/or Liability covered by this Article 12. Indemnitor shall not settle any indemnified claim hereunder in a manner that establishes liability on the part of any Indemnitee, without the express written consent of such Indemnitee. The Indemnitor shall have no obligation to indemnify any Indemnitee with respect to any claim settled without the prior written consent of the Indemnitor.

12.4 Limitation of Damages. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER SIMILAR DAMAGES (INCLUDING ANY CLAIMS FOR LOST PROFITS OR REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT; PROVIDED, HOWEVER, THAT THIS SHALL NOT LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO ANY THIRD PARTY CLAIMS UNDER THIS ARTICLE 12.

12.5 Insurance. During the Term and until completion of the last Project conducted under this Agreement, each Party shall maintain a comprehensive commercial general liability insurance program as is customary for diagnostic or pharmaceutical companies (as the case may be), including product liability insurance with coverage limits not less than US$[**] for each occurrence and in the aggregate. Tokai also will maintain clinical trials liability coverage with limits not less than US$[**] for each occurrence and in the aggregate, and will name QIAGEN as an additional insured. All insurers utilized to confirm coverage within Section 12.5 shall be rated A, Class VII or better by A.M. Best Company in a form satisfactory to both Parties. Upon request, each Party will provide to the other Party respective insurance certificates. For clarification, the insurance coverage required herein may be provided through any reasonable structure of local and global insurance programs.

13. Miscellaneous

13.1 Force Majeure. Neither Party shall be liable for failure or delay in performance under this Agreement due to causes such as an act of God, strike, lockout or other labor dispute, civil commotion, sabotage, fire, flood, explosion, acts of any government, any other similar causes not within the reasonable control of the Party affected (a "**Force Majeure Event**"). In the event either Party is unable to perform any of its obligations hereunder due to a Force Majeure Event, such Party shall promptly notify the other Party. Performance hereunder shall be promptly resumed after the applicable Force Majeure Event has been remedied.

13.2 Notice. All notices under this Agreement shall be in writing and shall be sent by registered or certified mail, postage prepaid, or by overnight courier service, to the attention of the Legal Department in the case of QIAGEN, and to the attention of the Chief Operating Officer in the case of Tokai, in each case at the addresses of the respective Parties set forth in the first paragraph of this Agreement.

13.3 Governing Law and Disputes.

13.3.1 Law. The formation, existence, performance, validity and all aspects of this Agreement shall be governed by and construed in all respects in accordance with the laws of the State of the New York, USA without regard to its rules on conflicts of laws.

13.3.2 Dispute Resolution. Prior to arbitration, the parties shall seek informal resolution of disputes. The process shall be initiated with written notice of one party to the other, describing the dispute with reasonable particularity followed with a written response within [**] calendar days of receipt of notice. Each party shall promptly designate an executive with requisite authority to resolve the dispute. The informal procedure shall commence within [**] calendar days of the date of response. If the dispute is not resolved within [**] business days of the date of commencement of the procedure, either party may proceed to binding arbitration without recourse to the ordinary courts of law according to the American Arbitration Association (the "**Rules**"). The seat of arbitration shall be New

York, New York USA. The number of arbitrators shall be three (3). The arbitrators shall be appointed in accordance with the Rules. The language to be used in the arbitration proceedings shall be English. If any arbitration is brought for the enforcement of this Agreement, or because of any alleged dispute, breach, default or misrepresentation in connection with any of the provisions of this Agreement, the successful or prevailing party shall be entitled to recover reasonable attorneys' fees and other costs incurred therein, in addition to any other relief to which it or they may be entitled. Notwithstanding anything to the contrary in this Section, if either Party in its sole judgment believes that any such breach of this Agreement could cause it irreparable harm, such Party (i) will be entitled to seek equitable relief in order to avoid such irreparable harm, and (ii) will not be required to follow the procedures set forth in this Section 13.3.2 with respect to seeking such relief.

13.4 Entire Agreement. This Agreement sets out the entire agreement and understanding between the Parties regarding the subject matter of this Agreement and supersedes all prior discussions, arrangements and agreements, whether oral or in writing or which may be inferred from the conduct of the Parties, including without limitation the Initiation Agreement dated October 29, 2014 between the Parties.

13.5 Validitv/Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision which shall remain in full force and effect. The Parties undertake to replace such invalid or unenforceable provision by a valid and enforceable provision which accomplishes as far as possible the purpose and the intent of the invalid or unenforceable provision.

13.6 Assignment. This Agreement may be freely assigned by either Party to any of its' Affiliates. This Agreement shall not be assigned by either Party to a third party, except (i) with the other Party's prior written approval, which approval shall not be withheld unreasonably, or (ii) by reason of any merger, acquisition, reorganization, or consolidation to any successor in interest of the business to which this Agreement relates. Other than as provided by this Section 12.6, any attempt by either Party to effect an assignment without the consent of the other Party will be void and without effect.

13.7 Waiver; Modification of Agreement. No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances. Any amendments to this Agreement shall be made in writing; the same applies for any waiver or amendment of this written form clause.

13.8 Relationship of the Parties. The relationship of the Parties is that of independent contractors.

13.9 Independent Development. Nothing in this Agreement will be construed as restricting either Party's ability to acquire, license, develop, manufacture or distribute for itself, or have others acquire, license, develop, manufacture or distribute for such Party, similar technology performing the same or similar functions as the technology contemplated by this Agreement, or to market and distribute such similar technology in addition to, or in lieu of, the technology contemplated by this Agreement, provided, however, that such activities of such Party comply with all provisions herein.

13.10 Execution In Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (.pdf) sent by electronic mail shall be deemed to be original signatures.

13.11 No Third Party Beneficiaries. No person other than Tokai or QIAGEN (and their respective affiliates and assignees) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

[*signature page follows*]

IN WITNESS WHEREOF, QIAGEN and Tokai, intending to be legally bound, have executed this Agreement at the dates indicated below by their respective duly authorized representatives.

Tokai Pharmaceuticals, Inc.	**QIAGEN Manchester Limited**
By: /s/ John McBride	By: /s/ Douglas Liu
Name: John McBride	Name: Douglas Liu
Title: CEO	Title: Senior VP Global Operations
Date: January 12, 2015	Date:

Companion Diagnostics

PROJECT WORK PLAN

Between TOKAI PHARMACEUTICALS, INC.
One Broadway, 14th Floor
Cambridge, MA 02142
hereinafter " **TOKAI** "

and QIAGEN Manchester Limited
Skelton House, Lloyd Street North
Manchester, M15 6SH,
England
hereinafter "**QIAGEN**"

This Project Schedule 1 (this "**Schedule**") is dated March 13, 2015 (the "Schedule Effective Date"), and is incorporated into the Master Collaboration Agreement dated January 12, 2015 by and between TOKAI and QIAGEN (for the purposes of this Schedule, the "**MCA**"), and describes a Project to be conducted under the terms of the MCA, including, without limitation, a list of Activities, the TOKAI Compound ("Galeterone") and the QIAGEN IVD development timelines, Deliverables, Markets and other terms applicable to a Development Project. The Project was initiated under an Initiation Agreement dated October 29, 2014 ("Initiation Agreement"), which shall be superseded by this Schedule. All capitalized terms used and not expressly defined in this Schedule will have the meanings given to them in the MCA.

This Schedule is divided into the following seven (7) sections:

1. Background
2. Activities
3. Deliverables
4. Timeline
5. Key Assumptions and Requirements
6. Compensation
7. Additional Terms

1. BACKGROUND

The party's MCA establishes a legal framework for their collaborations in the field of development and commercialization of *in vitro* diagnostics and/or companion diagnostics for TOKAI Compounds.

TOKAI wishes to have QIAGEN develop and commercialize a companion diagnostic to identify patients carrying Androgen Receptor Exon 9 Xq12 (AR-V7) splice variant in Castration Resistant Prostate Cancer (CRPC) for treatment with the TOKAI Compound (for purposes of this Schedule, the "**QIAGEN IVD**").

The scope of this Project is for development of the QIAGEN IVD necessary for co-development and clinical validation together with the TOKAI Compound, designated for approval and Commercialization in the US, EU, Canada and Australia. While Japan is not included within the scope of this Project due to an evolving regulatory landscape in this country, at TOKAI's request the Parties shall negotiate diligently and in good faith the terms under which the scope of this Project would be expanded to include potential Commercialization of the QIAGEN IVD together with the TOKAI Compound in Japan.

2. Activities

TOKAI responsibilities

In relation to the development of the QIAGEN IVD, TOKAI shall be responsible for the following:

- TOKAI shall solely be responsible for the clinical testing of Galeterone and proper use of the QIAGEN IVD by the central laboratories in connection with such clinical testing.
- TOKAI shall provide QIAGEN clinical data, including sample and patient demographic data, regarding the use of the QIAGEN IVD as well as patient outcome data to the extent such data is available and necessary, as reasonably determined by QIAGEN, for QIAGEN regulatory filings for the QIAGEN IVD and for planning of further QIAGEN IVD development activities at QIAGEN in the performance of the Development Project. TOKAI will be responsible for contracting out the clinical sample testing to and providing oversight of a suitable GCP-compliant central laboratory clinical testing site ("**Laboratory Site**") and QIAGEN will support the selection, training and qualification of this vendor. For clarification, notwithstanding any provision in the MCA, the parties expressly agree that Tokai shall be responsible for the Milestone Payments set forth below and costs set forth in Attachment 3 which relate to applications for Regulatory Approval of the QIAGEN IVD.

- TOKAI will make reasonable efforts to provide any clinical samples necessary for QIAGEN IVD development and verification/validation. QIAGEN will work with its approved procurement service providers to source appropriate samples. Sample costs will be passed through to TOKAI.

QIAGEN responsibilities

Subject to and without limiting the terms and conditions of the Agreement, QIAGEN shall be responsible for the development of the QIAGEN IVD as follows.

- QIAGEN shall lead the development and PMA submission with FDA's Center for Devices and Radiological Health (CDRH) for the QIAGEN IVD. QIAGEN shall inform and coordinate with TOKAI on all CDRH-related matters and support TOKAI in discussions with FDA's Center for Drug Evaluation and Research (CDER) for Galeterone.
- Subject to the involvement of TOKAI as described above, QIAGEN shall be responsible for the design, development and regulatory approval of the QIAGEN IVD in accordance with this Schedule, including the development of suitable and necessary protocols for the QIAGEN IVD.
- QIAGEN shall be responsible for manufacturing, supply and delivery of the QIAGEN IVD, including all components for the QIAGEN IVD, subject to any intellectual property considerations set forth in Section 7 below.
- QIAGEN shall be responsible for the preparation of the PMA documentation and site readiness required for submission of the PMA for the QIAGEN IVD.
- QIAGEN shall be responsible for the intended use and applicable package insert, and the pricing, reimbursement and market access of the QIAGEN Kit, subject to the applicable terms of the MCA.

3. **DELIVERABLES**

Stage 1 Feasibility

[**]. Stage 1 of development is covered under the initiation agreement between QIAGEN and TOKAI which was executed on October 29, 2014.

Stage 2 Clinical Trial Assay labelled Investigational Use Only ("IUO")

[**]. An IUO labelled Clinical Trial Assay ("CTA") (with or without and IDE) is required in H1 2015. [**]

Stage 4 CDx Development and Validation

The fourth stage of development will cover all of the activities needed for the development and approval of a CDx assay in the USA, Canada, EU and Australia. This stage will include all Design Verification and Clinical Validation Studies

Stage 5 CDx Approval and Product Implementation

Product Implementation into the US will follow approval of the PMA approval and agreement on the device labelling with CDRH

For the EU development data used to support the US PMA application will be used to generate a technical file in compliance with the Essential Requirements Checklist. The MHRA shall be notified of the new product under the self-certification scheme. Appropriate labeling and translations will be prepared as necessary for EU countries accepting the CE Mark.

For Canada it is also assumed that data used to support the US PMA application will be used to complete the necessary requirements as established by Health Canada for successful submission and approval. Product Implementation will follow and establish the product in the Canadian market with appropriate labelling and translations as necessary.

For Australia it is also assumed that data used to support the US PMA application will be used to complete the necessary requirements as established by the Australian Therapeutic Goods Administration (TGA) for successful submission and approval. Product Implementation will follow.

Contractual Milestone Description

The Project Agreement will be delivered on a completed milestone based model. The following descriptions provide a high level overview of the work package and the deliverable for acceptance and completion.

Milestone 1: Assessment of Technology for Transfer

This milestone will involve site-visit preparation, evaluation and assessment of the existing work undertaken by Dr. Jun Luo and associates at Johns Hopkins University ("JHU") for information exchange.

Evidence of Milestone Achievement: Short report on findings and recommendations for technology transfer.

Note: This Milestone 1 was completed under the Initiation Agreement.

Milestone 2: Design Control Planning (CDx)

This milestone represents the initial activities associated with the Companion Diagnostic Development process for the AR-V7 splice variant [inclusive of AR-FL] assay.

For this milestone, the following design control documents will be signed off and provided as evidence of Milestone achievement:

[**].

Milestone 3: Feasibility; Conversion of AR-V7 [inclusive of AR-FL] splice variant assay to a QIAGEN format & formulation for use on the Rotor-Gene Q MDx

[**].

Milestone 5: Clinical Trial Assay Build Completion (Including CTA QC and Control Specifications)

This milestone entails activities required to complete development of the Clinical Trial Assay for use in Phase III Clinical Trial. The assay is planned to be presented to CDRH under an Investigational Device Exemption application. The following work packages will be competed;

[**].

Milestone 6: Lab Set-up for Clinical Trial Testing (6a,6b, & 6c US, EU & Asia)

[**]

Milestone 8: Completion of Design Inputs; Design Input Lock and Design & Development Plan (CDx)

[**].

Milestone 9: Completion of Assay Optimization and Specification Setting for CDx

[**].

Milestone 10: Prototype Batch Manufacturing (CDx) – needed for assay performance studies

[**]

Milestone 12: CDx Assay Performance Studies Complete

[**]

Milestone 13: Assay Software Available

[**]

Milestone 14: Completion of Verification Batches (Pilot Batches)

[**]

Milestone 15: System Design Lock;

[**]

Milestone 17: Design Output and Design Verification Lock (Completion of Verification)

[**]

Milestone 20: PMA Approval

This milestone will be triggered upon successful approval of the companion diagnostic

Evidence of Milestone Achievement; Receipt of successful notification letter by CDRH

Milestone 21: Product Implementation

[**].

4. **TIMELINE**

TOKAI—Updated Gantt Chart Based on start date of 28th October 2014

[**]

5. **KEY ASSUMPTIONS AND REQUIREMENTS**

Tokia and QIAGEN each recognize that this Schedule has been prepared on the basis of a number of Key Assumptions as described in this Section 5. During the course of the Development Project, a change in an assumption upon which this Schedule is based may require a change to modify the scope of the project, and the Parties agree to address such changes in good faith pursuant to the process provided under Section 2.3 of the MCA. **Regulatory**

An IDE may be required by FDA. This shall be dependent on FDA's response to the Risk Determination Document.

Study Estimates

Tokia estimates screening approximately [**] patients to enroll a total of 150 AR-V7 positive patients into the clinical trial. Patient screening and selection is planned to begin as soon as possible in H1 2015

Clinical Samples

TOKAI will work with Johns Hopkins University and other parties to supply QIAGEN with clinical samples to support the development and verification of the AR-V7 assay

- QIAGEN will make all best efforts to procure representative samples for development and analytical validation of the assay. However, the availability of samples containing specific splice variants cannot be guaranteed.

    (1) QIAGEN shall not be held responsible for any delays caused by insufficient supply or other issues with the third party sample providers.

    (2) Any such samples shall be considered "pass-through costs" and shall be paid in full by *TOKAI* upon invoice from QIAGEN.

- The development of any specialized sample material *e.g*. cell lines containing specific splice variants are not included in this project plan and costing. The development of specialized sample material would be considered as pass through costs to TOKAI. These pass through costs are outlined as estimated in Attachment 2.

- Samples from the AR-V7 trial need to be retained for the purposes of any bridging studies.

Territory

The Territory for this Development Project shall include the Markets listed on Attachment 1 to this Schedule.

6. MILESTONE PAYMENTS

The following Milestones and Deliverables shall be completed by QIAGEN to the satisfaction of TOKAI in accordance with the terms of Section 2 of the MCA. Payment for completed Milestones will be made in accordance with Section 5 of the MCA and with the additional process as follows: (1) Tokai shall approve or dispute milestone completion within [**] business days of receiving QIAGEN's report; (2) Tokai agree to review milestone four within [**] business days of receiving QIAGEN's report; (3) if Tokai fails to approve or dispute the milestone completion within such time period, the milestone completion shall be considered approved; (4) if Tokai disputes the milestone completion, the parties shall work in good faith to timely resolve the dispute.

Milestone	Description	Completion Date (Est)	Payment (USD)
1	Assessment of Technology for Transfer	[**]	[**]
2	Design Control Planning	[**]	[**]
3	Feasibility Testing for AR-V7	[**]	[**]
	Full CDx Milestones		
4	[**]	[**]	[**]
5	Clinical Trial Assay Build Complete (Controls and QC)	[**]	[**]
6a	Lab set up for IUO Testing – US	[**]	[**]
6b	Lab set up for IUO Testing – EU	[**]	[**]
6c	Lab set up for IUO Testing – Australia	[**]	[**]
7	[**]	[**]	[**]
8	Design Input Lock & DDP	[**]	[**]
9	Completion of Assay Optimization and Specification Setting for CDx	[**]	[**]
10	Prototype Batch Manufacture	[**]	[**]
11	[**]	[**]	[**]

12	CDx Performance Studies Complete	[**]	[**]
13	Assay Software Available	[**]	[**]
14	Completion of Verification Batches (Pilot Batches)	[**]	[**]
15	System Design Lock	[**]	[**]
16	[**]	[**]	[**]
17	Design Output and Verification Lock Completion of Assay Verification	[**]	[**]
18	[**]	[**]	[**]
19	[**]	[**]	[**]
20	PMA Approval	[**]	$1,000,000
21	Product Implementation	[**]	[**]
Total			[**]

[**].

7. **ADDITIONAL TERMS**

7.1 Project Term

The Project Term of this Project shall commence on the Schedule Effective Date and continue until all commercialization obligations expire under Section 8 of the MCA, unless sooner terminated by either Party under the terms of the MCA.

7.2 Technology and Intellectual Property Considerations

(a) Circulating Tumor Cells Technology Access Fee

[**].

(ii) Scope of Technology Access

In exchange for the Technology Access Fee described above and notwithstanding anything in Section 7 of the to the contrary, QIAGEN will grant, and hereby does grant, TOKAI the exclusive right to have QIAGEN utilize the CTC Technology in the field of companion diagnostics for the TOKAI Compound. For clarity, the CTC Technology shall be considered the "Background Intellectual Property" of QIAGEN under the MCA.

(iii) Technology Access Fee

The Technology Access Fee shall be US $[**]. QIAGEN shall invoice Tokai for this amount promptly upon [**]. TOKAI shall pay the invoice within [**] days of receipt. [**]

(b) JHU Sublicense

(i) **"JHU License**" shall mean that certain Exclusive License Agreement dated January 9, 2015 between The Johns Hopkins University ("JHU") and TOKAI, a copy of which is attached hereto as Attachment 4.

(ii) The Licensed Patents and Licensed Know-How (each as defined in the JHU License) shall be considered TOKAI's Background Intellectual Property.

(iii) QIAGEN specifically acknowledges and agrees that, in accepting the grant of certain of the licenses under the MCA, it shall be sublicensed under the Licensed Patents and Licensed Know-How and, as such, QIAGEN shall be subject to and shall assume certain terms and conditions of the JHU License (as such agreement may be amended from time to time and communicated to QIAGEN) as if those terms and conditions were imposed on QIAGEN itself. These terms and conditions include, without limitation, due diligence, reporting and recordkeeping, indemnification, maintenance of insurance non-use of JHU's name, and audit rights. In addition, QIAGEN may not sublicense the Licensed Patents and Licensed Know-How sublicensed to QIAGEN without TOKAI's and JHU's consent. QIAGEN shall also have no right to prosecute the Licensed Patents or to defend or enforce the Licensed Patents. In the event of any conflict or inconsistency between any applicable provision of this Agreement and the provisions of the JHU License, the provisions of the JHU License shall prevail. Without limiting the foregoing, QIAGEN shall be subject to Sections 7, 8, 10.3 and 12.2 of the JHU License, which terms are incorporated by reference herein.

(iv) QIAGEN acknowledges and agrees that TOKAI may provide JHU an unredacted copy of the sections within the MCA and this Project Agreement which are strictly related to the sublicensing of third party intellectual property, and to disclose such information related to the conduct of the Project to the extent reasonably necessary for TOKAI to fulfil its reporting obligations to JHU under the JHU License. In the event TOKAI is required to disclose QIAGEN's Confidential Information to JHU in order to fulfil its obligations under the JHU License, TOKAI shall provide QIAGEN with advance notice of any such disclosures. TOKAI will reasonably consider any comments that QIAGEN may have on the scope of such disclosure.

(v) For so long as QIAGEN is commercializing a QIAGEN IVD, it shall provide TOKAI, within [**] days following completion of each calendar quarter, a written report detailing, on a country by country basis, aggregate Net Revenues (as defined in the JHU License) of each QIAGEN IVD during the preceding calendar quarter in sufficient detail for TOKAI to calculate and remit royalties due to JHU under the JHU License. Such reports shall be considered the highly confidential information of QIAGEN and shall not be disclosed or used for any purpose other than calculating the royalty obligation under the JHU License. Without limiting the foregoing, such reports shall include Net Sales Revenues (as defined in the JHU License) and all deductions and adjustments that may be applicable to a calculation of Net Revenues. QIAGEN shall make itself reasonably available to answer any questions that TOKAI may have on the foregoing royalty reports in sufficient time for TOKAI to fulfill its reporting and payment obligations to JHU.

(vi) TOKAI shall be responsible for the timely payment of all royalty obligations to JHU under the JHU License. TOKAI shall defend, indemnify and hold harmless QIAGEN for any third party costs, claims, or liabilities directly resulting from TOKAI's failure to make royalty payments under the JHU License (except to the extent such failure is the result of QIAGEN failing to fulfil its reporting obligations to TOKAI under this Agreement).

(vii) TOKAI shall at all times comply with the JHU License to maintain such license in full force and effect during the term of this Agreement. TOKAI shall defend, indemnify and hold harmless QIAGEN for any third party costs, claims or liabilities directly resulting from TOKAI's failure to comply with the JHU License (except to the extent such failure is the result of QIAGEN failing to fulfil its obligations to TOKAI under this Agreement).

IN WITNESS WHEREOF, QIAGEN and TOKAI, intending to be legally bound, have executed this Agreement at the dates indicated below by their respective duly authorized representatives.

TOKAI Pharmaceuticals, Inc.		**QIAGEN Manchester Limited**	
By:	_____	By:	/s/ Douglas Liu
Name:		Name:	Douglas Liu
Title:		Title:	Senior VP Global Operations QIAGEN
Date:	_____	Date:	12 March 2015

Attachment 1

Territory

United States

European Union

Canada

Australia

Attachment 2

Name	Description	Payment (USD)
Sample Procurement	Procurement of CRPC samples for development and verification; may require customized project to be established with a procurement service provider to prospectively collect and ship samples	[**]
Non GMP Raw materials	Non GMP oligos, Extraction Kits, PCR reagents	[**]
[**]	[**]	[**]
PAX gene tubes and extractions	[**]	[**]
GMP Raw materials	GMP reagents [**]	[**]
Long oligonucleotides	[**]	[**]
In vitro transcripts	[**]	[**]
Cell Line Control Materials	Procurement and culture of AR–V7 cell lines for development.	[**]
Development of reference method for accuracy	A comparator method may be required to determine the Sensitivity and specificity of the assay. The requirements will be determined by discussions with CDRH	[**]
IP	[**]	[**]
Materials Management Fee	Covers the development of specifications for any incoming materials such as: samples, goods receipt, labelling, database entry for internal tracking and storage Final amount is dependent on final PTEs costs.	[**]
Total (Estimate)		[**]

Attachment 3

Registration:

The parties expressly agree that Tokai shall fund all regulatory filings set forth in this Project Agreement, despite any conflicting terms in the MCA.

Territory	Requirements	Costs	Preparation	Review Clock
Canada	Product implementation together with IVD registration activities and submission fees for Health Canada (Assumes no additional data generation)	[**]	[**]	4-5 Months according to Health Canada Guidance
EU- CE Mark	Product implementation with IVD registration activities for self-certification and updated filing with notified bodies (Assumes no additional data generation)	[**]	[**]	n/a – products currently self-certified* * Subject to existing requirements and subject to change with new updates as they materialize.
Australia	Product implementation with IVD registrational activities and submission fees for Australian Therapeutic Goods Administration (TGA) (Assumes no additional data generation)	[**]	[**]	7-12 months according to TGA Guidance

Attachment 4

JHU License

Incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014

Exhibit 31.1

CERTIFICATIONS

I, Jodie P. Morrison, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: May 12, 2015

By: /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 Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: May 12, 2015

By: /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 Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2015 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: May 12, 2015

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2015 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: May 12, 2015

By: /s/ Lee H. Kalowski
Lee H. Kalowski
Chief Financial Officer
(Principal Financial and Accounting Officer)