
**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, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-36620

Tokai Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

255 State Street, 6th floor
Boston, MA
(Address of principal executive offices)

20-1000967
(I.R.S. Employer
Identification Number)

02109
(Zip Code)

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

As of April 30, 2016 there were 22,634,825 shares of Common Stock, \$0.001 par value per share, outstanding.

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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 pivotal Phase 3 clinical trial of galeterone and our efforts to complete the clinical development of galeterone for patients with AR-V7 positive metastatic castration resistant prostate cancer, or mCRPC;
- the anticipated timing, cost and conduct of additional clinical trials of, and formulation development and manufacturing activities for, galeterone;
- the development of a companion diagnostic test expected to be used commercially with galeterone;
- the timing and outcome of regulatory review of galeterone for the treatment of AR-V7 positive mCRPC;
- the development of galeterone for the treatment of prostate cancer or other indications or patient populations, and of any other future product candidates, including compounds 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. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement.

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

You should also read carefully the risk factors described in the section “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015 to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. Included in these risk factors are important factors that could cause actual results or events to differ materially from the forward-looking statements that we make.

[Table of Contents](#)**PART I—FINANCIAL INFORMATION****Item 1. Financial Statements.****Tokai Pharmaceuticals, Inc.****Balance Sheets**

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

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,303	\$ 24,023
Marketable securities	39,947	39,934
Prepaid expenses and other current assets	2,737	3,213
Total current assets	56,987	67,170
Property and equipment, net	453	489
Restricted cash	270	270
Other assets	—	45
Total assets	<u>\$ 57,710</u>	<u>\$ 67,974</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,886	\$ 1,208
Accrued expenses	4,291	4,954
Total current liabilities	6,177	6,162
Other long-term liabilities	126	88
Total liabilities	<u>6,303</u>	<u>6,250</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 22,634,825 and 22,597,144 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	23	23
Additional paid-in capital	194,253	193,194
Accumulated other comprehensive loss	(5)	(55)
Accumulated deficit	(142,864)	(131,438)
Total stockholders' equity	<u>51,407</u>	<u>61,724</u>
Total liabilities and stockholders' equity	<u>\$ 57,710</u>	<u>\$ 67,974</u>

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

Tokai Pharmaceuticals, Inc.
Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	7,931	10,559
General and administrative	3,549	2,741
Total operating expenses	<u>11,480</u>	<u>13,300</u>
Loss from operations	(11,480)	(13,300)
Interest income and other income (expense), net	54	40
Net loss	<u>\$ (11,426)</u>	<u>\$ (13,260)</u>
Net loss per share, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.59)</u>
Weighted average common shares outstanding, basic and diluted	<u>22,625,009</u>	<u>22,384,233</u>
Comprehensive loss:		
Net loss	\$ (11,426)	\$ (13,260)
Other comprehensive income:		
Unrealized gains on marketable securities	50	—
Total other comprehensive income	<u>50</u>	<u>—</u>
Total comprehensive loss	<u>\$ (11,376)</u>	<u>\$ (13,260)</u>

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

Tokai Pharmaceuticals, Inc.**Statements of Cash Flows****(In thousands)
(Unaudited)**

	Three months ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (11,426)	\$ (13,260)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,022	634
Depreciation expense	53	5
Release of reserve for loan to former advisor	—	(34)
Amortization of premium on marketable securities	37	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	521	85
Accounts payable	678	2,669
Accrued expenses	(663)	(1,158)
Other assets	—	(45)
Other long-term liabilities	38	—
Net cash used in operating activities	<u>(9,740)</u>	<u>(11,104)</u>
Cash flows from investing activities:		
Purchases of property and equipment	<u>(17)</u>	<u>(45)</u>
Net cash used in investing activities	<u>(17)</u>	<u>(45)</u>
Cash flows from financing activities:		
Repayment of notes receivable	—	34
Proceeds from exercise of common stock options	<u>37</u>	<u>21</u>
Net cash provided by financing activities	<u>37</u>	<u>55</u>
Net decrease in cash and cash equivalents	(9,720)	(11,094)
Cash and cash equivalents at beginning of period	<u>24,023</u>	<u>105,256</u>
Cash and cash equivalents at end of period	<u>\$ 14,303</u>	<u>\$ 94,162</u>

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

Tokai Pharmaceuticals, Inc.

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

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the “Company”) was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company’s lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct third mechanism – androgen receptor degradation. The Company is developing galeterone for the treatment of patients with metastatic castration resistant prostate cancer (“mCRPC”). Since its inception, the Company has devoted substantially all of its efforts to research and development, 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, formulation development and manufacturing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance capabilities.

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

The Company’s financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The Company has incurred losses and negative cash flows from operations since inception. As of March 31, 2016, the Company had an accumulated deficit of \$142,864 and had cash and investments of \$54,250. The Company believes its cash and investments balance as of March 31, 2016 will only be sufficient to enable it to fund planned operating expenses and capital expenditure requirements into the first half of 2017. The Company will need to obtain substantial additional funding in order to complete the development of, and to commercialize, galeterone for patients with AR-V7 positive mCRPC and in other indications and patient populations, submit a new drug application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for galeterone, conduct other ongoing and planned clinical trials of galeterone, and develop or commercialize any future product candidates. If the Company is unable to raise capital when needed or on acceptable terms, it may be forced to delay, reduce, terminate or eliminate its product development programs and commercialization efforts. 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.

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

Tokai Pharmaceuticals, Inc.**Notes to the Financial Statements**
(Amounts in thousands, except share and per share data)
(Unaudited)**2. Summary of Significant Accounting Policies***Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Marketable Securities

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

At March 31, 2016, marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Certificates of Deposit (due within one year)	\$ 14,884	\$ —	\$ —	\$ 14,884
United States Treasury Notes (due within one year)	25,068	—	(5)	25,063
Total	<u>\$ 39,952</u>	<u>\$ —</u>	<u>\$ (5)</u>	<u>\$ 39,947</u>

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

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

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.

Tokai Pharmaceuticals, Inc.

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

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

	Fair Value Measurements at March 31, 2016 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	\$ —	\$ 13,415	\$ —	\$ 13,415
Marketable securities:				
Certificates of Deposit	—	14,884	—	14,884
United States Treasury Notes	—	25,063	—	25,063
Total	<u>\$ —</u>	<u>\$ 53,362</u>	<u>\$ —</u>	<u>\$ 53,362</u>

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

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

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common share equivalents consist of shares issuable upon the exercise of stock options and unvested restricted common stock unit awards using the treasury stock method. Because the inclusion of potential common share equivalents would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

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

	March 31, 2016	December 31, 2015
Stock options to purchase common stock	3,035,315	2,861,011
Unvested restricted common stock units	34,128	40,953
	<u>3,069,443</u>	<u>2,901,964</u>

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40)*. The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote

Tokai Pharmaceuticals, Inc.

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

disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. This standard will be effective for the annual period ending after December 15, 2016, and for annual periods and interim periods within annual periods beginning thereafter. Early adoption is permitted. This guidance relates to footnote disclosure only and the adoption will not impact the Company's financial position, results of operations or liquidity.

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

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

3. Accrued Expenses

Accrued expenses consisted of the following:

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
Accrued research and development expenses	\$ 3,139	\$ 3,188
Accrued professional fees	614	699
Accrued payroll and related expenses	459	900
Accrued other	79	167
	<u>\$ 4,291</u>	<u>\$ 4,954</u>

4. Income Taxes

The Company did not provide for any income taxes for the three months ended March 31, 2016 or 2015. The Company had gross deferred tax assets of \$51,028 at December 31, 2015, which increased by approximately \$4,000 at March 31, 2016. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 2016 and December 31, 2015, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

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

Tokai Pharmaceuticals, Inc.**Notes to the Financial Statements**
(Amounts in thousands, except share and per share data)
(Unaudited)**5. Stock-Based Compensation**

The Company grants stock-based awards under its 2014 Stock Incentive Plan and is authorized to issue, but has not issued as of March 31, 2016, common stock under its 2014 Employee Stock Purchase Plan. The Company also has outstanding stock options under its 2007 Stock Incentive Plan, but is no longer granting awards under this plan. As of March 31, 2016, 1,854,879 shares of common stock were available for issuance under the 2014 Stock Incentive Plan. As of March 31, 2016, 225,000 shares of common stock were available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded stock-based compensation expense related to stock options and restricted common stock units in the following expense categories of its statements of operations:

	Three Months Ended March 31,	
	2016	2015
Research and development	\$ 211	\$ 168
General and administrative	811	466
	<u>\$ 1,022</u>	<u>\$ 634</u>

6. Commitments and Contingencies*Leases*

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

Prior to April 2015, the Company leased office space in Cambridge, Massachusetts, and obtained certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. The Company recorded exit costs of \$133 in connection with the termination of the Cambridge lease, which are included in rent expense during the three months ended March 31, 2015.

During the three months ended March 31, 2016 and 2015, the Company recognized \$174 and \$306, respectively, of rental expense related to office space.

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

2016	\$ 420
2017	839
2018	489
	<u>\$1,748</u>

Restricted Cash and Letters of Credit

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

Tokai Pharmaceuticals, Inc.

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

Intellectual Property Licenses

The Company has a master license agreement with the University of Maryland, Baltimore (“UMB”). Pursuant to the license agreement, UMB granted an exclusive, worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen steroids, including galeterone, for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted the Company a first option to receive an exclusive license to UMB’s rights in certain improvements to the licensed products. The Company has exercised its option and acquired exclusive rights to licensed improvements under four amendments to the license agreement. The Company is obligated to pay UMB an annual maintenance fee of \$10 each year until the first commercial sale of a product developed using the licensed technology. The Company is also obligated to make milestone payments of an additional \$50 for the filing of each additional investigational new drug application filed for a licensed product, aggregate milestone payments of up to \$150 associated with the development of a licensed product for a particular non-prostate disease indication, and a \$100 milestone payment upon the approval by the FDA of each NDA for a licensed product. There were no milestones achieved during the three months ended March 31, 2016 or 2015.

The Company must also pay UMB a low-single digit percentage royalty on aggregate worldwide net sales of licensed products, including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. The royalty obligations are subject to specified reductions in the event that additional licenses need to be obtained from third parties or in the event of specified competition from third-party products licensed by UMB. Minimum annual royalty payments to UMB are \$50 beginning in the year following the year in which the first commercial sale occurs. The Company must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents. As of March 31, 2016 the Company has not yet developed a commercial product using the licensed technologies, nor has it entered into any sublicense agreements for the technologies.

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

In consideration for the rights granted to the Company under the license agreement, the Company made an upfront payment to Johns Hopkins of \$75 following the execution of the license agreement, which was recognized as research and development expense during the 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. During the year ended December 31, 2015, the Company expensed \$50 related to the achievement of two of these milestones. The Company has not achieved any other milestones and therefore no additional liabilities for such milestone payments have been recorded in the Company’s financial statements.

The Company must also pay Johns Hopkins single digit percentage royalties on aggregate worldwide net sales of licensed products (but not galeterone), including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. These royalty obligations are subject to specified reductions in the event that additional licenses from third parties are required. The Company must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse Johns Hopkins for patent costs. As of March 31, 2016, the Company has not yet developed a commercial product using the licensed technologies.

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(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 “CDx Agreement”). Pursuant to the CDx Agreement, Qiagen has agreed to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. Qiagen has also developed under the CDx Agreement a clinical trial assay that is being used in the Company’s pivotal Phase 3 clinical trial of galeterone in order to identify mCRPC patients whose tumor cells express AR-V7, and that may be used in future clinical trials of galeterone.

Subject to the terms of the CDx Agreement, the Company paid Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test, which was recognized as research and development expense during the three months ended March 31, 2015. The Company also pays Qiagen fees for the development of the AR-V7 clinical trial assay and is obligated to pay a contingent milestone payment of \$1,000 upon Qiagen obtaining pre-market approval of the companion diagnostic test. 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. The Company will not, however, receive any revenues from future sales, if any, of the companion diagnostic test.

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 financial statements as of March 31, 2016.

7. 401(k) Plan

The Company has a 401(k) plan available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the Board of Directors. Since January 1, 2016, the Company has made matching contributions for the plan year ending December 31, 2016 at a rate of 100% of each employee’s contribution up to a maximum matching contribution of 3% of the employee’s eligible plan compensation and at a rate of 50% of each employee’s contribution in excess of 3% up to a maximum of 5% of the employee’s eligible plan compensation.

For the three months ended March 31, 2016, the Company made matching contributions of \$45 for the plan year ending December 31, 2016.

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

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

Overview

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

We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in approximately 148 treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant. We refer to this clinical trial as ARMOR3-SV. We believe that the AR-V7 splice variant is the most common form of C-terminal loss, or the loss of the portion of the androgen receptor that contains the ligand-binding domain. C-terminal loss generally, and AR-V7 specifically, has been associated with poor response to commonly-used oral therapies for mCRPC. ARMOR3-SV is, to our knowledge, the first precision-medicine based pivotal clinical trial in prostate cancer. Selection of patients with AR-V7 is made using a clinical trial assay developed by our collaborator, Qiagen Manchester Limited, or Qiagen. We believe that the design of ARMOR3-SV is aligned with feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect to complete enrollment in ARMOR3-SV by the end of 2016 and to have top-line data available from the study by mid-2017. We have been given fast track designation by the FDA for galeterone for the treatment of mCRPC.

As of March 31, 2016, galeterone has been well tolerated in prostate cancer patients and healthy volunteers in clinical trials. In these trials, which included patients whose tumor cells did not express AR-V7, 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, have been observed in prostate cancer patients treated with galeterone. Therefore, and subject to the availability of resources, we anticipate expanding the clinical development of galeterone in other indications or patient populations.

Our planned expansion of the galeterone clinical development program is focused on mCRPC patients who have shown resistance following treatment with either Xtandi or Zytiga® (abiraterone acetate). During the first quarter of 2016, we began enrolling patients in an expansion of an arm of our ongoing Phase 2 clinical trial of galeterone, referred to as ARMOR2, in mCRPC patients who have developed acquired resistance to Xtandi. We also expect to evaluate galeterone beginning in mid-2016 in men whose mCRPC rapidly progressed after initial treatment with either Xtandi or Zytiga. We plan to evaluate these “rapid progressors” for the presence of AR-V7 without it being a criterion for participation.

We have worldwide development and commercialization rights to galeterone. To maximize the value of these rights, we intend to build a urology- and oncology-focused specialty sales and marketing organization in the United States to support the commercialization of galeterone. We intend to commercialize galeterone outside the United States through collaborations with third parties.

Since our inception in March 2004, we have devoted substantially all of our resources to developing our product candidates, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations primarily through our initial public offering of our common stock, and prior to our initial public offering, through private placements of our redeemable convertible preferred stock and convertible promissory notes. In September 2014, we completed the initial public offering of our common stock through the issuance and sale of 6,480,000 shares of our common stock at a price to the public of \$15.00 per share, resulting in net proceeds of \$87.1 million after deducting underwriting discounts and commissions and offering expenses. In October 2014, we issued and sold an additional 540,000 shares of our common stock as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock at the public offering price of \$15.00 per share, and received additional net proceeds of \$7.5 million after deducting underwriting discounts and commissions.

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We have never generated any revenue and have incurred net losses in each year since our inception. Our net loss was \$11.4 million for the three months ended March 31, 2016 and \$45.1 million for the year ended December 31, 2015. As of March 31, 2016, we had an accumulated deficit of \$142.9 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 ARMOR3-SV and other clinical trials, non-clinical studies and formulation development and manufacturing activities required to support the submission of a new drug application, or NDA, to the FDA for galeterone for AR-V7 positive mCRPC;
- develop a companion diagnostic test for use with galeterone in collaboration with Qiagen;
- conduct planned additional clinical trials of galeterone in mCRPC patients who have shown resistance following treatment with either Xtandi or Zytiga;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer;
- explore the use of galeterone for the treatment of other 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, 2016, we had cash and investments of \$54.3 million. We expect that our existing cash and investments will only be sufficient to enable us to fund our planned operating expenses and capital expenditure requirements into the first half of 2017. We will need to obtain substantial additional funding in order to complete the development of, and to commercialize, galeterone for patients with AR-V7 positive mCRPC and in other indications and patient populations, submit an NDA to the FDA for galeterone, conduct other ongoing and planned clinical trials of galeterone, 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. 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.

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Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, include the following:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- third-party contract costs relating to development of a companion diagnostic test for use with galeterone, including the AR-V7 clinical trial assay being used to identify eligible patients for ARMOR3-SV;
- personnel costs, including salaries, related benefits and stock-based compensation for personnel engaged in research and development functions;
- consulting fees paid to third parties;
- costs related to compliance with regulatory requirements;
- payments made under our third-party licensing agreements; and
- allocated facility-related costs.

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

Research and development activities 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 \$7.9 million for the three months ended March 31, 2016 and \$10.6 million for the three months ended March 31, 2015. We expect that our research and development expenses will increase as we conduct ARMOR3-SV, other clinical trials, and additional NDA-enabling activities for galeterone, and develop any future product candidates.

We are currently conducting ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone, and are expanding our clinical development program for galeterone. We cannot determine with certainty the duration and completion costs of ARMOR3-SV, our expanded program for galeterone, or any future clinical trials of any future product candidates we develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our ongoing clinical trials as well as any additional clinical trials and other research and development activities that we may conduct;
- future clinical trial results;
- uncertainties in clinical trial design and patient enrollment rate;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

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General and Administrative Expenses

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

We expect that our general and administrative expenses will continue to increase in future periods as we establish capabilities that would enable the potential commercialization of galeterone for the treatment of mCRPC and of any future product candidates, and as a result of increased 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 Income and Other Income (Expense), net

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

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 2015, we had federal and state net operating loss carryforwards of \$27.9 million and \$24.2 million respectively. Our federal and state net operating loss carryforwards begin to expire in 2024 and 2030, respectively. We also had federal and state research and development tax credit carryforwards of \$1.0 million and \$0.4 million, respectively, as of December 31, 2015, which begin to expire in 2025 and 2023, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of \$96.1 million that we have capitalized for income tax purposes as of December 31, 2015.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

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

[Table of Contents](#)**Results of Operations****Comparison of the Three Months Ended March 31, 2016 and 2015**

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	7,931	10,559	(2,628)
General and administrative	3,549	2,741	808
Total operating expenses	11,480	13,300	(1,820)
Loss from operations	(11,480)	(13,300)	1,820
Interest income and other income (expense), net	54	40	14
Net loss	<u>\$(11,426)</u>	<u>\$(13,260)</u>	<u>\$ 1,834</u>

Research and Development Expenses

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Galeterone for prostate cancer	\$6,042	\$ 9,272	\$(3,230)
Other early-stage development programs and additional indications for galeterone	323	103	220
Unallocated research and development expenses	1,566	1,184	382
Total research and development expenses	<u>\$7,931</u>	<u>\$ 10,559</u>	<u>\$(2,628)</u>

The decrease in research and development expenses associated with our galeterone for prostate cancer program for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 was due primarily to decreased costs associated with the development of our AR-V7 clinical trial assay of \$2.3 million and decreased manufacturing costs of \$1.7 million, partially offset by an increase in costs of clinical trials of \$0.7 million. Costs associated with the development of our AR-V7 clinical trial assay for the three months ended March 31, 2015 included a one-time fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the assay and related companion diagnostic test as well as higher assay development costs. The decrease in manufacturing costs was primarily due to a large purchase of raw materials in the three months ended March 31, 2015 for use in manufacturing process optimization and validation studies required to support the submission of an NDA for galeterone. The increase in clinical trial costs for the three months ended March 31, 2016 primarily related to ARMOR3-SV, which was initiated in the second quarter of 2015.

General and Administrative Expenses

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,926	\$ 1,243	\$ 683
Professional and consultant fees	1,089	974	115
Facility related and other	534	524	10
Total general and administrative expenses	<u>\$ 3,549</u>	<u>\$ 2,741</u>	<u>\$ 808</u>

The increase in personnel related costs for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 was primarily due to an increase in headcount in the general and administrative function associated with operating as a public company including an increase in stock-based compensation expense of \$0.3 million related to this increase in headcount.

[Table of Contents](#)**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 through the issuance and sale of 6,480,000 shares of our common stock at a price to the public of \$15.00 per share, resulting in net proceeds of \$87.1 million after deducting underwriting discounts and commissions and offering expenses. In October 2014, we issued and sold an additional 540,000 shares of our common stock as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock at the public offering price of \$15.00 per share and received additional net proceeds of \$7.5 million after deducting underwriting discounts and commissions.

Cash Flows

As of March 31, 2016, our principal sources of liquidity were cash and investments of \$54.3 million.

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

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$(9,740)	\$(11,104)
Cash used in investing activities	(17)	(45)
Cash provided by financing activities	37	55
Net decrease in cash and cash equivalents	<u>\$(9,720)</u>	<u>\$(11,094)</u>

Operating activities. During the three months ended March 31, 2016, cash used in operating activities consisted of our net loss of \$11.4 million, partially offset by net non-cash charges of \$1.1 million and by net cash provided by changes in our operating assets and liabilities of \$0.6 million. Our net non-cash charges during the period consisted almost entirely of stock-based compensation expense of \$1.0 million. Cash provided by changes in our operating assets and liabilities consisted primarily of a decrease in prepaid expenses and other current assets of \$0.5 million during the three months ended March 31, 2016.

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, 2015.

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, 2016 and 2015 related to purchases of property and equipment.

Financing activities. During the three months ended March 31, 2016, net cash provided by financing activities was attributable to proceeds from the exercise of stock options. During the three months ended March 31, 2015, net cash provided by financing activities was due to the repayment of notes receivable and proceeds from the exercise of stock options.

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Capital 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 ARMOR3-SV and other clinical trials, non-clinical studies, and formulation development and manufacturing activities required to support the submission of an NDA to the FDA for galeterone for AR-V7 positive mCRPC;
- develop a companion diagnostic test for use with galeterone in collaboration with Qiagen;
- conduct planned additional clinical trials of galeterone in mCRPC patients who have shown resistance following treatment with either Xtandi or Zytiga;
- develop galeterone for the treatment of other indications and patient populations in prostate cancer;
- 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, 2016, we had cash and investments of \$54.3 million. We expect that our existing cash and investments will only be sufficient to enable us to fund our planned operating expenses and capital expenditure requirements into the first half of 2017. We will need to obtain substantial additional funding in order to complete the development of, and to commercialize, galeterone for patients with AR-V7 positive mCRPC and in other indications and patient populations, submit an NDA to the FDA for galeterone, conduct other ongoing and planned clinical trials of galeterone, 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.

We have based these estimates 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 galeterone is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of galeterone.

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

- the progress and results of ARMOR3-SV and our efforts to complete the clinical development of galeterone and conduct other non-clinical, formulation development and manufacturing activities required to submit an NDA to the FDA and marketing authorization applications to regulatory authorities outside of the United States;
- the progress and results of any additional clinical trials of galeterone that we decide to conduct in other indications and patient populations, including in our planned trials in patients whose mCRPC has progressed after treatment with either Xtandi or Zytiga;
- the timing and outcome of regulatory review of galeterone for the treatment of AR-V7 positive mCRPC and in any other indication or patient population, and of any other future product candidates;
- the progress and results of the development of a companion diagnostic test for use with galeterone in collaboration 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;

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- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States; and
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To this end, in October 2015, we filed and the SEC declared effective a shelf registration statement registering an aggregate of \$150 million in various equity and debt securities. We have not issued or sold any securities under this registration statement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that require liens to be placed on our property and include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute our common stockholders' ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market galeterone that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

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, 2015.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Fluctuation Risk

Our cash and investments as of March 31, 2016 consisted of cash, money market accounts, certificates of deposit and government bonds. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

Item 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, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that

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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, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

There have been no material changes in the Company's risk factors from those previously disclosed in Part I, Item 1A, "*Risk Factors*" in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 10, 2016.

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

Use of Proceeds from Initial Public Offering

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

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

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

As of March 31, 2016, we estimate that we have used approximately \$60.4 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 marketable securities and money market accounts. There has been no material change in our planned use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC on September 17, 2014 pursuant to Rule 424(b)(4) under the Securities Act.

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.

Date: May 10, 2016

TOKAI PHARMACEUTICALS, INC.

By: /s/ Lee H. Kalowski

Lee H. Kalowski
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on September 26, 2014).
101*†	Fourth Amendment to Master License Agreement between the Registrant and the University of Maryland, Baltimore, dated as of March 15, 2016.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

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

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.

FOURTH AMENDMENT TO LICENSE AGREEMENT

This Fourth Amendment to License Agreement (“**Fourth Amendment**”) is effective as of the date of the last signature on the signature page hereto and is between the UNIVERSITY OF MARYLAND, BALTIMORE (“**UMB**”), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, and TOKAI PHARMACEUTICALS, INC., a Delaware corporation (“**Company**”). Company and UMB are referred to collectively as the “**Parties**” and each as a “**Party**.”

BACKGROUND

B.1 UMB and Company entered into a Master License Agreement, effective as of May 9, 2006, as amended (“**MLA**”), under which Company received an exclusive worldwide license to practice the Patent Rights. (Any capitalized term which is not otherwise defined in this Fourth Amendment shall have the meaning set forth in the MLA.)

B.2 A valuable invention generally known as “*Novel AR and Mnk-eIF4E Modulating Agents and Uses Thereof*” (UMB docket #VN-2015-009) (the “**Pancreatic Cancer Invention**”) has been made by Vincent C. O. Njar, Ph.D., Puranik Purushottamachar, Ph.D., and Andrew K. Kwegyir-Afful (*all employees of UMB*). The Pancreatic Cancer Invention constitutes an Improvement pursuant to the MLA.

B.3 Research described in the Pancreatic Cancer Invention was funded in part by National Institutes of Health Grants CA195694 and CA129379.

B.4 Company has duly exercised its Option to receive a license to the Improvement, pursuant to Section 3.6 of the MLA. The Parties have negotiated in good faith to enter into this Fourth Amendment under the MLA, such that the Pancreatic Cancer Invention will henceforth constitute a Licensed Improvement on the terms and conditions set forth in this Fourth Amendment.

The Parties agree to amend the MLA as set forth herein.

NOW THEREFORE, the Parties agree as follows:

1. Article 2 (*Definitions*) of the MLA is hereby amended by adding the following definitions:

“**Pancreatic Cancer Licensed Product**”: Any product constituting an Initial Licensed Product, Oral Prodrug Licensed Product, ER Stress Response Licensed Product or ARDA Licensed Product (including without limitation any Combination Product): whose manufacture, use, Sale, or import would infringe, or any process whose practice would infringe, the Pancreatic Cancer Patent Rights.

“**Pancreatic Cancer Patent Rights**”: The Patent Rights set forth in Part E of **Schedule A**.

2. Schedule A (*Patent Rights*) of the MLA is hereby amended by adding the following:

PART E: PANCREATIC CANCER PATENT RIGHTS

- U.S. Provisional Patent Appl'n 62/058,856, titled "*Novel AR and Mnk-eIF4E Modulating Agents and Uses Thereof*," filed 10/2/2014 (converted);
- International Patent Appl'n PCT/US2015/053653, titled "*Novel AR and Mnk-eIF4E Modulating Agents and Uses Thereof*," filed 10/2/2015.

3. Schedule B (*Due Diligence Milestones*) of the MLA is hereby amended by adding the following:

PANCREATIC CANCER LICENSED PRODUCTS

- (1) *Within [**] months after the Effective Date*: Filing of IND with the FDA (or foreign equivalent, and if legally required) for a Pancreatic Cancer Licensed Product.
- (2) *Within [**] months after IND approval by the FDA (or foreign equivalent)*: Commence Phase 1 Clinical Trial (if legally required) for a Pancreatic Cancer Licensed Product.
- (2) *Within [**] months after completion of Phase 1 Clinical Trial*: Commence Phase 2 Clinical Trial of a Pancreatic Cancer Licensed Product.
- (3) *Within [**] months after completion of Phase 2 Clinical Trial*: Commence Phase 3 Clinical Trial of a Pancreatic Cancer Licensed Product.
- (4) *Within [**] months after completion of Phase 3 Clinical Trial*: Filing of NDA with the FDA (or foreign equivalent) for a Pancreatic Cancer Licensed Product.
- (5) *Within [**] months after marketing approval by the FDA (or foreign equivalent)*: First Commercial Sale of a Pancreatic Cancer Licensed Product.

4. Section 5.3 (*Milestone Payments*) is hereby deleted in its entirety, and replaced with the following:

5.3 Milestone Payments. Company shall pay to UMB the following milestone payments:

<u>Milestone</u>	<u>Payment</u>	<u>Due Date</u>
On submission of each IND for a Licensed Product to the U.S. FDA:	U.S. \$ 50,000.00	Paid May 7, 2010 for first IND; due within [**] days following submission of each subsequent IND
On approval of each NDA or BLA for a Licensed Product by the U.S. FDA:	U.S. \$100,000.00	Within [**] days following receipt of approval
Upon issuance of the first patent citing U.S. Provisional Patent Application No. 61/039,133 as priority	U.S. \$ 40,000.00	Paid August 5, 2012
Upon first-in-human dosing of a patient (i.e., dosing of first patient in a Phase 1 Clinical Trial or, for Galeterone, a Phase 2 Clinical Trial) with a Pancreatic Cancer Licensed Product	U.S. \$ [**]	Within [**] days following achievement
Upon dosing of first patient in the first Phase 3 Clinical Trial of a Pancreatic Cancer Licensed Product	U.S. \$ [**]	Within [**] days following achievement

5. Section 10.2.2 (*Diligence Default*) is hereby deleted in its entirety, and replaced with the following:

10.2.2 Diligence Default.

(a) In the event of any default or material breach of Section 4.3 (*Due Diligence Milestones*) due to Company failing to timely achieve a milestone set forth on **Schedule B**, as such milestones may from time to time be amended as contemplated by Section 4.1.3 hereof and then in effect, and the failure is not cured within [**] days of written notice thereof, UMB may terminate the license granted under this Agreement to the category of Patent Rights to which such milestone relates.

(b) However, if that failure cannot be cured by the exercise of due diligence within [**] days of written notice, then the time for cure shall be extended for the time reasonably necessary to effect the cure (the extension not to exceed an additional [**] days), provided that Company promptly commences to cure within said period and at all times thereafter proceeds diligently to cure the failure.

(c) The termination of the license granted hereunder for any category of Patent Rights to which such milestone relates shall not affect the license granted hereunder for any other Patent Rights as to which such milestone does not relate.

(d) The withholding by a regulatory agency of marketing or other approval in spite of Company's Commercially Reasonable Efforts to obtain the approval shall not constitute a default or material breach of Section 4.3 (*Due Diligence Milestones*).

6. In consideration of the license granted under this Fourth Amendment, Company agrees to pay a one-time, non-refundable license fee of Ten Thousand Dollars (\$10,000.00) to UMB within ten (10) business days of the execution of this Fourth Amendment by both Parties.

7. Except as specifically modified in this Fourth Amendment, all terms and conditions of the MLA (including without limitation the royalty rate and other payment obligations of Company) shall remain in full force and effect.

[Signatures on following page]

IN WITNESS WHEREOF, each Party has caused this Fourth Amendment to be executed under seal by its duly authorized representative.

UNIVERSITY OF MARYLAND, BALTIMORE

By: /s/ Jay A. Perman (SEAL)

Name: Jay A. Perman, M.D.

Title: President

Date: March 15, 2016

TOKAI PHARMACEUTICALS, INC.

By: /s/ John McBride (SEAL)

Name: John McBride

Title: COO

Date: December 17, 2015

CERTIFICATIONS

I, Jodie P. Morrison, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

By: /s/ Lee H. Kalowski

Lee H. Kalowski
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jodie P. Morrison, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

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

**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, 2016 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 10, 2016

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

