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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

OR

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

For the transition period from _____ to _____

Commission file number: 001-36620

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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, 2017 there were 22,641,651 shares of Common Stock, $0.001 par value per share, outstanding.

Tokai Pharmaceuticals, Inc.

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FORWARD-LOOKING STATEMENTS

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

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

- our board of directors' review of strategic alternatives and our pending transaction with Otic Pharma Ltd as a result of such review;
- the results of our analysis of the unblinded study data from ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone that we announced our plan to discontinue in July 2016 following the recommendation of the trial's independent data monitoring committee, and our evaluation of potential paths forward for galeterone and our ARDA (androgen receptor degradation agents) program;
- costs associated with the discontinuation of the ARMOR3-SV trial, as well as estimated cost savings from the July 2016 workforce reduction and trial discontinuation;
- the anticipated timing, cost and conduct of additional clinical trials of, and formulation development and manufacturing activities for, galeterone;
- the development of galeterone for the treatment of prostate cancer or other indications or patient populations, and of any other future product candidates, including compounds under our ARDA program that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation;
- our plans to seek to enter into collaborations for the commercialization of galeterone and any other future product candidates;
- the potential benefits of any future collaboration;
- the rate and degree of market acceptance and clinical utility of our products;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statement.

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

You should also read carefully the risk factors described in the section "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Tokai Pharmaceuticals, Inc.

Balance Sheets

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

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 24,400	$ 23,223
Marketable securities	—	4,175
Restricted cash	—	150
Prepaid expenses and other current assets	1,231	1,995
Total current assets	25,631	29,543
Property and equipment, net	80	98
Restricted cash	120	120
Total assets	$ 25,831	$ 29,761
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 276	$ 430
Accrued expenses	2,143	2,389
Total current liabilities	2,419	2,819
Long-term liabilities	48	84
Total liabilities	2,467	2,903
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 22,641,651 shares issued and outstanding at March 31, 2017 and December 31, 2016	23	23
Additional paid-in capital	196,604	196,233
Accumulated other comprehensive loss	—	(1)
Accumulated deficit	(173,263)	(169,397)
Total stockholders' equity	23,364	26,858
Total liabilities and stockholders' equity	$ 25,831	$ 29,761

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,	
	2017	2016
Revenue	$ —	$ —
Operating expenses:		
Research and development	306	7,931
General and administrative	3,586	3,549
Total operating expenses	3,892	11,480
Loss from operations	(3,892)	(11,480)
Interest income and other income, net	26	54
Net loss	$ (3,866)	$ (11,426)
Net loss per share, basic and diluted	$ (0.17)	$ (0.51)
Weighted average common shares outstanding, basic and diluted	22,641,651	22,625,009
Comprehensive loss:		
Net loss	$ (3,866)	$ (11,426)
Other comprehensive income:		
Unrealized gains on marketable securities	1	50
Total other comprehensive income	1	50
Total comprehensive loss	$ (3,865)	$ (11,376)

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,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (3,866)	$ (11,426)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	371	1,022
Depreciation expense	17	53
Impairment of property and equipment	1	—
Amortization of premium on marketable securities	1	37
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	764	521
Accounts payable	(154)	678
Accrued expenses	(246)	(663)
Other long-term liabilities	(36)	38
Net cash used in operating activities	(3,148)	(9,740)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	4,175	—
Purchases of property and equipment	—	(17)
Change in restricted cash	150	—
Net cash provided by (used in) investing activities	4,325	(17)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	—	37
Net cash provided by financing activities	—	37
Net increase (decrease) in cash and cash equivalents	1,177	(9,720)
Cash and cash equivalents at beginning of period	23,223	24,023
Cash and cash equivalents at end of period	$ 24,400	$ 14,303

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

In July 2016, the Company announced its plan to discontinue ARMOR3-SV, its pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve mCRPC patients whose prostate tumors expressed the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee ("DMC"). The Company conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and its ARDA program. Based on data reviewed, there is a substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. All patients enrolled in the ARMOR3-SV clinical trial have been discontinued. Following the announcement regarding the discontinuation of the ARMOR3-SV trial, the Company reduced its workforce in the third quarter of 2016 by approximately 60%.

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

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

On December 21, 2016, the Company entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic") and the shareholders of Otic (the "Selling Shareholders") pursuant to which, among other things, each Selling Shareholder agreed to sell to the Company, and the Company agreed to purchase from each Selling Shareholder, all of the ordinary and preferred shares of Otic (the "Otic Shares") owned by such Selling Shareholder (the "Otic Transaction"). See "Note 9. Share Purchase Agreement" for further information regarding the Otic Transaction. The Company amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of the Company's common stock among the Selling Shareholders and to extend to May 31, 2017, the date after which the Company or Otic may terminate the Share Purchase Agreement.

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

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

Tokai Pharmaceuticals, Inc.

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

The Company's common stock is currently listed for quotation on the NASDAQ Global Market. On March 8, 2017, the Company received a deficiency letter from the Listing Qualifications Department of the NASDAQ Stock Market notifying the Company that, for the last 30 consecutive business days prior to the date of the letter, the bid price for its common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the NASDAQ Global Market. The Company has been provided an initial period of 180 calendar days, or until September 4, 2017, to regain compliance with the listing requirements. If, at any time before September 4, 2017, the bid price for the Company's common stock closes at $1.00 or more for a minimum of 10 consecutive business days it may be eligible to regain compliance with the minimum bid requirement. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that the Company complies with NASDAQ's continued listing standards. The Company is seeking approval of a reverse stock split at its upcoming Special Meeting of Stockholders to be held on May 9, 2017 in connection with the Otic Transaction. The Company expects that the reverse stock split, if approved, would help it regain compliance with the listing standards.

If the Company's common stock is delisted by NASDAQ, the common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for the Company to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, the common stock and could result in a decrease in the trading price of the Company's common stock. In addition, there can be no assurance that the common stock would be eligible for trading on any such alternative exchange or markets.

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, 2017, the Company had an accumulated deficit of $173,263 and had cash and cash equivalents of $24,400. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, and that the Company does not successfully consummate the Otic Transaction, the Company expects its cash and cash equivalents as of March 31, 2017 to be sufficient to fund operations through at least the first half of 2018. While the Company has entered into the Share Purchase Agreement, its operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, the Company will need to continue its review of strategic alternatives including evaluating potential paths forward for galeterone and its ARDA program. If the Otic Transaction is consummated or if the Company determines to pursue an alternate strategy, its future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by management. If the Company determines to further develop galeterone, proceed with its ARDA program, or both, the Company will need to obtain substantial additional funding. Because of the significant uncertainty regarding its future plans, the Company is not able to accurately predict the impact of a potential change on its business strategy and future funding requirements. If its cash and cash equivalents are not sufficient to fund its approved strategy and the Company is unable to raise capital when needed or on acceptable terms, the Company may be forced to delay, reduce, terminate or eliminate its product development programs and commercialization efforts.

The balance sheet at December 31, 2016 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, 2017 and for the three months ended March 31, 2017 and 2016 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, 2016 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 3, 2017. 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, 2017 and results of operations and cash flows for the three months ended March 31, 2017 and 2016 have been made. The results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2017.

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

At March 31, 2017, there were no marketable securities.

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificates of Deposit (due within one year)	$ 1,175	$ —	$ —	$ 1,175
United States Treasury Notes (due within one year)	3,001	—	(1)	3,000
Total	$ 4,176	$ —	$ (1)	$ 4,175

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)
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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, 2017 and December 31, 2016:

	Fair Value Measurements at March 31, 2017 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	$ —	$ 22,943	$ —	$ 22,943
Total	$ —	$ 22,943	$ —	$ 22,943

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

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

Net Loss Per Share

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

The following common share equivalents outstanding as of March 31, 2017 and 2016 were excluded from the computation of diluted net loss per share for the three months ended March 31, 2017 and 2016 because they had an anti-dilutive impact:

	March 31,	
	2017	2016
Stock options to purchase common stock	1,855,741	3,035,315
Unvested restricted common stock units	—	34,128
	1,855,741	3,069,443

Recently Issued or Adopted Accounting Pronouncements

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

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that the statement of cash flows explains the change during the period in the total of cash, cash equivalents, and

Tokai Pharmaceuticals, Inc.

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(Amounts in thousands, except share and per share data)
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amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. ASU 2016-18 will be effective for the first interim period within fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on the Company's statement of cash flows.

Effective January 1, 2017, the Company adopted ASU No. 2016-09, *Compensation – Stock Compensation* ("ASU 2016-09") issued by the FASB in March 2016. 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. Accordingly, the Company elected to account for forfeitures as they occur rather than apply a forfeiture rate to stock-based compensation. The impact of the election to account for forfeitures as they occur was not material. Additionally, upon adoption on January 1, 2017, the Company's gross deferred tax assets and corresponding valuation allowance each increased by $1,400 related to tax deductions from the exercise of stock options that previously would have been credited to additional paid-in-capital when realized.

3. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2017	December 31, 2016
Accrued professional fees	$ 1,105	$ 871
Accrued research and development expenses	623	907
Accrued payroll and related expenses	186	394
Accrued other	229	217
	$ 2,143	$ 2,389

4. Income Taxes

The Company did not provide for any income taxes in the three months ended March 31, 2017 or 2016. The Company had gross deferred tax assets of $65,643 at December 31, 2016, which increased by approximately $1,000 at March 31, 2017 due to the Company's net operating loss. In addition, in connection with the adoption of ASU No. 2016-09 as of January 1, 2017, as more fully described above in "Note 2. Recently Issued and Adopted Accounting Pronouncements", the deferred tax asset and the corresponding valuation allowance also increased by $1,400. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at each of March 31, 2017 and December 31, 2016, 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, 2017 or December 31, 2016. As of March 31, 2017 and December 31, 2016, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since December 31, 2013 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

5. Stock-Based Compensation

The Company grants stock-based awards under its 2014 Stock Incentive Plan and is authorized to issue, but has not issued as of March 31, 2017, 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, 2017, 3,967,421 shares of common stock were available for issuance under the 2014 Stock Incentive Plan. As of March 31, 2017, 451,416 shares of common stock were available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded

Tokai Pharmaceuticals, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
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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	
	2017	2016
Research and development	$ 24	$ 211
General and administrative	347	811
	$ 371	$ 1,022

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 was subject and subordinate to a prime lease between the Sublandlord and the prime landlord. The term of the sublease commenced on April 1, 2015 and expired on December 31, 2016. In June 2015, the Company entered into a lease (the "New Lease") for the existing space with the prime landlord (the "Landlord"), which effectively extends the term until July 31, 2018. Payment escalations specified in the lease agreements are accrued such that rent expense per square foot is recognized on a straight-line basis over the terms of occupancy.

During the three months ended March 31 2017 and 2016, the Company recognized $175 and $174, respectively, of rental expense related to office space.

As of March 31, 2017, future minimum lease payments under the noncancelable office lease are as follows:

Remainder of 2017	$ 629
2018	489
	$1,118

Restricted Cash and Letters of Credit

The Company held a money market account as of March 31, 2017 and December 31, 2016 to collateralize a credit card account with its bank. As of March 31, 2017, the balance of the money market account was $50, which was classified as long-term restricted cash. As of December 31, 2016, the balance of the money market account was $200, of which $150 was classified as current restricted cash and $50 was classified as long-term restricted cash. 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, 2017 and December 31, 2016.

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

Tokai Pharmaceuticals, Inc.

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(Unaudited)

an annual maintenance fee of $10 each year until the first commercial sale of a product developed using the licensed technology. The Company is also obligated to make milestone payments of an additional $50 for the filing of each additional investigational new drug application filed for a licensed product, aggregate milestone payments of up to $150 associated with the development of a licensed product for a particular non-prostate disease indication, and a $100 milestone payment upon the approval by the U.S. Food and Drug Administration ("FDA") of each new drug application ("NDA") for a licensed product. There were no milestones achieved during the three months ended March 31, 2017 and 2016.

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, 2017 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 in 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. The Company expensed $50 related to the achievement of two of these milestones in 2015. 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, 2017, the Company has not yet developed a commercial product using the licensed technologies.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers, which provide, among other things, that the Company will indemnify such directors and executive officers to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred material costs as a result of the indemnification agreements described above. In addition, the Company maintains directors and officers insurance coverage. The Company is unable to predict if any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows and has not accrued any material liabilities related to such possible obligations in its financial statements as of March 31, 2017.

Tokai Pharmaceuticals, Inc.

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Legal Proceedings

On August 1, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against the Company, Jodie P. Morrison, and Lee H. Kalowski, entitled Doshi v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-06106 ("Doshi Action"). The plaintiff seeks to represent a class of purchasers of Company securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about the Company's clinical trials for its drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, two lead plaintiff motions were filed by two shareholders. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against the Company, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company's initial public offering ("IPO"), entitled Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al., No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), the Company's registration statement for its IPO made false and misleading statements and omissions about the Company's clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of Company common stock in and/or traceable to the Company's IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of forum non conveniens, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction. On February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.

On September 29, 2016, two purported stockholders of the Company filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against the Company, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company's IPO, entitled Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-11963 ("Garbowski Action"). The lawsuit alleges that the defendants and the Company's registration statement for its IPO made false and misleading statements and omissions about the Company's clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of Company common stock in or traceable to the Company's IPO as well as a class of purchasers of Company common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, a lead plaintiff motion was filed by one of the lead plaintiff candidates in the Doshi Action, who later refiled his motion on December 13, 2016. The same lead plaintiff candidate also filed a motion to consolidate the Doshi and Garbowski Actions for all purposes.

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

In connection with the Otic Transaction, two putative securities class actions have been filed in the U.S. District Court for the District of Massachusetts against the Company, Jodie P. Morrison, Seth L. Harrison, Stephen Buckley, Jr., Cheryl L. Cohen, David A. Kessler, and Joseph A. Yanchik, III. The two complaints are captioned as follows: *Bushansky v. Tokai Pharmaceuticals, Inc., et al.*,

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No. 1:17-cv-10621-DPW (filed April 11, 2017), and *Wilson v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10645-DPW (filed April 14, 2017). Each lawsuit alleges that the Company's definitive proxy statement on Schedule 14A filed with the SEC on April 7, 2017 (the "Definitive Proxy Statement") made false and misleading statements and omissions in connection with the Otic Transaction, in violation of the Exchange Act and Rule 14a-9, promulgated thereunder. Each plaintiff seeks to represent a class of all persons and entities that own the Company's common stock. Each lawsuit seeks, among other things, preliminary and permanent injunctions of the Otic Transaction unless the Company discloses certain information requested by plaintiff, rescission and unspecified damages if the Otic Transaction is consummated, and attorneys' fees. The Company refers to these two actions collectively as the "Stockholder Litigation." The Company believes that no supplemental disclosures are required under applicable laws. However, to avoid the risk of the Stockholder Litigation delaying or adversely affecting the closing of the Otic Transaction and to minimize the expense of defending the Stockholder Litigation, and without admitting any liability or wrongdoing, the Company made certain disclosures that supplement and revise those contained in the Definitive Proxy Statement. The Company and the other named defendants deny that they have committed or assisted others in committing any violations of law or breaches of duty to Company stockholders, and expressly maintain that they have complied with their fiduciary and other legal duties and have provided the litigation-related supplemental disclosures solely to try to eliminate the burden and expense of further litigation, to put the claims that were or could have been asserted to rest, and to avoid any possible delay to the closing of the Otic Transaction that might arise from further litigation. Nothing in the litigation-related supplemental disclosures shall be deemed an admission of the legal necessity or materiality under applicable laws of any of the litigation-related supplemental disclosures.

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

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, 2017, the Company has made matching contributions for the plan year ending December 31, 2017 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, 2017 and 2016, the Company made matching contributions of $19 and $45, respectively.

8. Related Party Transaction

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

9. Share Purchase Agreement

On December 21, 2016, the Company entered into the Share Purchase Agreement with Otic and the Selling Shareholders pursuant to which, among other things, each Selling Shareholder agreed to sell to the Company, and the Company agreed to purchase from each Selling Shareholder, all of the Otic Shares owned by such Selling Shareholder. Immediately following the closing of the Otic Transaction, the Selling Shareholders are expected to own approximately 60% of the Company's outstanding common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing). Consummation of the Otic Transaction is subject to certain closing conditions, including, among other things, approval by the Company's stockholders at its upcoming Special Meeting of Stockholders to be held on May 9, 2017. The Share Purchase Agreement contains certain termination rights for both the Company and Otic, and further provides that, upon termination of the Share Purchase Agreement under specified circumstances, the Company may be required to pay Otic a termination fee of $1,000, or Otic may be required to pay the Company a termination fee of $1,500. Upon the delivery of a fairness opinion of the Otic Transaction, the Company owes its strategic advisor $500. An additional $500 is

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due to its strategic advisor upon consummation of the transaction with Otic. The Company has expensed $500 during the three months ended March 31, 2017 related to the delivery of the fairness opinion. The Company determined the $500 due upon delivery of the fairness opinion should have been accrued as of December 31, 2016. The impact of this error was not material to the financial statements for the year ended December 31, 2016. The subsequent correction was made in the financial statements for the three months ended March 31 2017 and was not material. There can be no assurances that the Otic Transaction will be consummated. The Company amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of the Company's common stock among the Selling Shareholders, to update the manner in which Otic options and warrants are converted and to extend to May 31, 2017, the date after which the Company or Otic may terminate the Share Purchase Agreement.

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

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, 2016 included in our Annual Report on Form 10-K that was filed with the SEC on March 3, 2017. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q and the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 3, 2017, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

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

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

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

Following the announcement regarding the discontinuation of the ARMOR3-SV trial, in July 2016 we announced that our board of directors approved a plan to reduce the size of our workforce by approximately 60% to a total of 10 full-time equivalent employees. The workforce reduction, which was completed in September 2016, was designed to reduce our operating expenses while we conducted a review of development options for galeterone and the ARDA program.

In September 2016, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to our business strategy and future operations. As part of this process, which was conducted in parallel with a review of development options for galeterone and the ARDA program, our board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets. As a result of this process, in December 2016, we entered into a share purchase agreement, or the Share Purchase Agreement, with Otic Pharma, Ltd., or Otic, and the shareholders of Otic named therein, or the Selling Shareholders, pursuant to which, among other things, each Otic shareholder agreed to sell to us, and we agreed to purchase from each Otic shareholder, all of the ordinary and preferred shares of Otic in exchange for shares of our common stock. We refer to this transaction as the Otic Transaction. We amended and restated the Share Purchase Agreement on March 2, 2017 to update the allocation of shares of our common stock among the Selling Shareholders, to update the manner in which Otic options and warrants are converted and to extend to May 31, 2017, the date after which we or Otic may terminate the Share Purchase Agreement. As a result of the Otic Transaction, Otic will become our wholly owned subsidiary and the Otic shareholders are expected to own approximately 60% of our common stock (62% if all of Otic's outstanding options and warrants are exercised prior to closing). See "Note 9. Share Purchase Agreement" of the Notes to the Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for further information regarding the Otic Transaction.

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

We cannot provide any commitment regarding when or if the Otic Transaction or the Stock Purchase Agreement will be consummated as, among other conditions, the issuance of shares of our common stock in the Otic Transaction and under the Stock Purchase Agreement are subject to the approval of our stockholders. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements.

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

We have never generated any revenue and have incurred net losses in each year since our inception. Our net loss was $3.9 million for the three months ended March 31, 2017 and $38.0 million for the year ended December 31, 2016. As of March 31, 2017, we had an accumulated deficit of $173.3 million. This deficit has resulted principally from costs incurred in connection with research and development activities, general and administrative costs associated with our operations and in-licensing our product candidates. If the Otic Transaction is not consummated, and we determine to further develop galeterone, proceed with our ARDA program, or both, we anticipate that we will continue to incur significant expenses if and as we:

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

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

As of March 31, 2017, we had cash and cash equivalents of $24.4 million. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, and that we do not successfully consummate the Otic Transaction, we expect our cash and cash equivalents as of March 31, 2017 to be sufficient to fund operations through at least the first half of 2018. While we have entered into the Share Purchase Agreement, our operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements. If our cash and cash equivalents are not sufficient to fund our approved strategy and we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, terminate or eliminate our product development programs and our commercialization efforts.

Financial Operations Overview

Revenue

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

Operating Expenses

The majority of our operating expenses consist of research and development activities and general and administrative costs.

Research and Development Expenses

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

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

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

Research and development activities have been central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the

increased size and duration of later-stage clinical trials. To date, we have focused substantially all of our research and development efforts on the development of galeterone. We incurred total research and development expenses of $0.3 million for the three months ended March 31, 2017 and $7.9 million for the three months ended March 31, 2016. We anticipate that overall research and development expenses will decrease in the near future compared to prior periods due to the discontinuation of our ARMOR3-SV clinical trial and discontinuation of enrollment in our ARMOR2 expansion trial pending our review of potential paths forward for galeterone and our ARDA program. However, if the Otic Transaction is not consummated and we determine to further develop galeterone, proceed with our ARDA program, or both, following our review of development options, we anticipate that we would continue to incur significant research and development expenses as we conduct clinical trials and NDA-enabling activities for galeterone or future product candidates.

In July 2016 we announced our decision to discontinue ARMOR3-SV, our pivotal Phase 3 clinical trial of galeterone, following the recommendation of the trial's independent data monitoring committee and ceased enrollment in this trial. Although the trial has been discontinued, we anticipate that we will have some continuing expenses related to the wind-down of the trial in 2017. We conducted a review of unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and our ARDA program. Based on data reviewed, there is a substantial likelihood that we will not pursue the development of galeterone in AR-V7 positive mCRPC patients in the future. We cannot determine with certainty the duration and completion costs of any future clinical trials of galeterone, if any, or any future product candidates we develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

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

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

General and Administrative Expenses

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

Interest Income and Other Income, net

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

Income Taxes

Since our inception in 2004, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 2016, we had federal and state net operating loss carryforwards of $38.2 million and $34.3 million respectively. Our federal and state net operating loss carryforwards begin to expire in 2024 and 2030, respectively. We also had federal and state research and development tax credit carryforwards of $1.3 million and $0.5 million, respectively, as of December 31, 2016, which begin to expire in 2025 and 2028, respectively. Our federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of $121.2 million that we have capitalized for income tax purposes as of December 31, 2016.

Critical Accounting Policies and Significant Judgments and Estimates

Our 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, 2016, 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, 2016.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2016

The following table summarizes our results of operations for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,		
	2017	2016	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	306	7,931	(7,625)
General and administrative	3,586	3,549	37
Total operating expenses	3,892	11,480	(7,588)
Loss from operations	(3,892)	(11,480)	7,588
Interest income and other income, net	26	54	(28)
Net loss	$(3,866)	$(11,426)	$ 7,560

Research and Development Expenses

	Three Months Ended March 31,		
	2017	2016	Change
	(in thousands)		
Galeterone for prostate cancer	$ 90	$ 6,042	$(5,952)
Other early-stage development programs and additional indications for galeterone	15	323	(308)
Unallocated research and development expenses	201	1,566	(1,365)
Total research and development expenses	$ 306	$ 7,931	$(7,625)

The decrease in research and development expenses associated with our galeterone for prostate cancer program for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was due primarily to a decrease in the costs of clinical trials of $4.1 million and a decrease in manufacturing costs of $1.3 million. The decrease in clinical trials and manufacturing costs was due to the discontinuation of the ARMOR3-SV clinical trial announced in July 2016 following the recommendation of the trial's independent data monitoring committee. The decrease in unallocated research and development expenses was primarily due to a decrease in personnel related costs as a result of the workforce reduction that occurred in the third quarter of 2016.

General and Administrative Expenses

	Three Months Ended March 31,		
	2017	2016	Change
	(in thousands)		
Professional and consultant fees	$ 2,004	$ 1,089	915
Personnel related (including stock-based compensation)	878	1,926	$(1,048)
Facility related and other	704	534	170
Total general and administrative expenses	$ 3,586	$ 3,549	$ 37

The increase in professional and consultant fees for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was primarily due to strategic advisor, legal and accounting fees associated with the Otic Transaction as well as legal fees related to the outstanding litigation against us and certain of our directors and officers. The decrease in personnel related costs for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 was primarily due to the workforce reduction that occurred in the third quarter of 2016.

Liquidity and Capital Resources

Since our inception in March 2004, we have not generated any revenue and have incurred recurring net losses. We anticipate that we will continue to incur losses for at least the next several years. We expect that we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

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

Cash Flows

As of March 31, 2017, our principal sources of liquidity were cash and cash equivalents of $24.4 million.

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

	March 31,	
	2017	2016
	(in thousands)	
Cash used in operating activities	$(3,148)	$(9,740)
Cash provided by (used in) investing activities	4,325	(17)
Cash provided by financing activities	—	37
Net increase (decrease) in cash and cash equivalents	$ 1,177	$(9,720)

Operating activities. During the three months ended March 31, 2017, cash used in operating activities consisted of our net loss of $3.9 million, partially offset by net non-cash charges of $0.4 million and by net cash provided by changes in our operating assets and liabilities of $0.3 million. Our net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash provided by changes in our operating assets and liabilities consisted primarily of a decrease in prepaid expenses and other current assets of $0.8 million partially offset by a decrease in accounts payable and accrued expenses of $0.4 million during the three months ended March 31, 2017.

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 primarily 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.

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

Investing activities. During the three months ended March 31, 2017, proceeds from maturities of marketable securities were $4.2 million. Restricted cash related to our corporate credit cards also decreased by $0.2 million during the three months ended March 31, 2017.

We used a small amount of cash during the three months ended March 31, 2016 related to purchases of property and equipment.

Financing activities. During the three months ended March 31, 2016, cash provided by financing activities was attributable to proceeds from the exercise of stock options.

Capital Requirements

As of March 31, 2017, we had cash and cash equivalents of $24.4 million. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, and that we do not successfully consummate the Otic Transaction, we expect our cash and cash equivalents as of March 31, 2017 to be sufficient to fund operations through at least the first half of 2018. While we have entered into the Share Purchase Agreement, our operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction is not consummated, we will need to continue our review of strategic alternatives including evaluating potential paths forward for galeterone and our ARDA program. If the Otic Transaction is consummated or if we determine to pursue an alternate strategy, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If the Otic Transaction is not consummated and we determine to further develop galeterone, proceed with our ARDA program, or both, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change on our business strategy and future funding requirements. If our cash and cash equivalents are not sufficient to fund our approved strategy and we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, terminate or eliminate our product development programs and our commercialization efforts.

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

- our determination regarding potential paths forward for galeterone and our ARDA program;
- our analysis of the available unblinded data from ARMOR3-SV;
- the scope, progress and results of any additional clinical trials of galeterone that we decide to conduct;
- the timing and outcome of regulatory review of galeterone and of any other future product candidates;
- the cost of commercialization activities, including product sales, marketing, manufacturing and distribution, for galeterone and our future product candidates for which we receive regulatory approval;
- the development of future product candidates, including our plans to seek to acquire or in-license additional compounds or technologies;
- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of our product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- our ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States; and
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To this end, in October 2015, we filed and the Securities and Exchange Commission, or the SEC, declared effective a shelf registration statement registering an aggregate of $150 million in various equity and debt securities. Pursuant to General Instruction I.B.5 of Form S-3, however, in no event will we sell securities pursuant to such registration statement with a value of more than one-third of the aggregate market value of our common stock held by non-affiliates in any 12 calendar month period, so long as the aggregate market value of our common stock held by non-affiliates is less than $75 million. We have not issued or sold any securities under this registration statement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that require liens to be placed on our property and include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute our common stockholders' ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market galeterone that we would otherwise prefer to develop and market ourselves.

Our common stock is currently listed for quotation on the NASDAQ Global Market. On March 8, 2017, we received a deficiency letter from the Listing Qualifications Department of the NASDAQ Stock Market notifying us that, for the last 30 consecutive business days prior to the date of the letter, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the NASDAQ Global Market. We have been provided an initial period of 180 calendar days, or until September 4, 2017, to regain compliance with the listing requirements. If, at any time before September 4, 2017, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days we may be eligible to regain compliance with the minimum bid requirement. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that we comply with NASDAQ's continued listing standards. We are seeking approval of a reverse stock split at our upcoming Special Meeting of Stockholders to be held on May 9, 2017 in connection with the Otic Transaction. We expect that the reverse stock split, if approved, would help us regain compliance with the listing standards.

If our common stock is delisted by NASDAQ, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, the common stock and could result in a decrease in the trading price of our common stock. In addition, there can be no assurance that the common stock would be eligible for trading on any such alternative exchange or markets.

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, 2016.

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 cash equivalents as of March 31, 2017 consisted of cash and money market accounts. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. As we hold only cash and money market accounts, 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, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On August 1, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against us, Jodie P. Morrison, and Lee H. Kalowski, entitled Doshi v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-06106 ("Doshi Action"). The plaintiff seeks to represent a class of purchasers of our securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about our clinical trials for our drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, two lead plaintiff motions were filed by two shareholders. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against us, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our initial public offering ("IPO"), entitled Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al., No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of our common stock in and/or traceable to our IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of forum non conveniens, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction. On February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.

On September 29, 2016, two purported stockholders filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our IPO, entitled Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-11963 ("Garbowski Action"). The lawsuit alleges that the defendants and our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of our common stock in or traceable to our IPO as well as a class of purchasers of our common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, a lead plaintiff motion was filed by one of the lead plaintiff candidates in the Doshi Action, who later refiled his motion on December 13, 2016. The same lead plaintiff candidate also filed a motion to consolidate the Doshi and Garbowski Actions for all purposes.

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

In connection with the Otic Transaction, two putative securities class actions have been filed in the U.S. District Court for the District of Massachusetts against us, Jodie P. Morrison, Seth L. Harrison, Stephen Buckley, Jr., Cheryl L. Cohen, David A. Kessler, and Joseph A. Yanchik, III. The two complaints are captioned as follows: *Bushansky v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10621-DPW (filed April 11, 2017), and *Wilson v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10645-DPW (filed April 14, 2017). Each lawsuit alleges that our definitive proxy statement on Schedule 14A filed with the SEC on April 7, 2017 (the "Definitive Proxy Statement") made false and misleading statements and omissions in connection with the Otic Transaction, in violation of the Exchange Act and Rule 14a-9, promulgated thereunder. Each plaintiff seeks to represent a class of all persons and entities that own our common stock. Each lawsuit seeks, among other things, preliminary and permanent injunctions of the Otic Transaction unless we disclose certain information requested by plaintiff, rescission and unspecified damages if the Otic Transaction is consummated, and attorneys' fees. We refer to these two actions collectively as the "Stockholder Litigation." We believe that no supplemental disclosures

are required under applicable laws. However, to avoid the risk of the Stockholder Litigation delaying or adversely affecting the closing of the Otic Transaction and to minimize the expense of defending the Stockholder Litigation, and without admitting any liability or wrongdoing, we made certain disclosures that supplement and revise those contained in the Definitive Proxy Statement. We and the other named defendants deny that we have committed or assisted others in committing any violations of law or breaches of duty to our stockholders, and expressly maintain that we have complied with our fiduciary and other legal duties and have provided the litigation-related supplemental disclosures solely to try to eliminate the burden and expense of further litigation, to put the claims that were or could have been asserted to rest, and to avoid any possible delay to the closing of the Otic Transaction that might arise from further litigation. Nothing in the litigation-related supplemental disclosures shall be deemed an admission of the legal necessity or materiality under applicable laws of any of the litigation-related supplemental disclosures.

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

Item 1A. Risk Factors.

Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2016. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2016. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in our Annual Report on Form 10-K for the year ended December 31, 2016.

An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid. In addition, if we fail to meet the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock.

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

On March 8, 2017, we received a deficiency letter from the Listing Qualifications Department of the NASDAQ Stock Market notifying us that, for the last 30 consecutive business days prior to the date of the letter, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the NASDAQ Global Market. We have been provided an initial period of 180 calendar days, or until September 4, 2017, to regain compliance with the listing requirements. If, at any time before September 4, 2017, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days we may be eligible to regain compliance with the minimum bid requirement. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that we comply with NASDAQ's continued listing standards. We are seeking approval of a reverse stock split at our upcoming Special Meeting of Stockholders to be held on May 9, 2017 in connection with the Otic Transaction. We expect that the reverse stock split, if approved, would help us regain compliance with the listing standards.

If our common stock is delisted by NASDAQ, our common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, the common stock and could result in a decrease in the trading price of our common stock. In addition, there can be no assurance that the common stock would be eligible for trading on any such alternative exchange or markets.

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

Our stock price has been and in the future may be subject to substantial volatility. The stock market in general and the market for biotechnology companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock traded within a range of a high price of $30.00 per share and a low price of $0.57 per share for the period beginning September 17, 2014, our first day of trading on The NASDAQ Global Market, through

April 30, 2017. Our stock price experienced significant volatility in July 2016 after we announced our plan to discontinue our ARMOR3-SV clinical trial. As a result of this volatility, our stockholders could incur substantial losses. The market price for our common stock may be influenced by many factors, including the outcome of the Otic Transaction. In connection with the Otic Transaction, two putative securities class actions have been filed in the U.S. District Court for the District of Massachusetts against us, Jodie P. Morrison, Seth L. Harrison, Stephen Buckley, Jr., Cheryl L. Cohen, David A. Kessler, and Joseph A. Yanchik, III. The two complaints are captioned as follows: *Bushansky v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10621-DPW (filed April 11, 2017), and *Wilson v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10645-DPW (filed April 14, 2017). Each lawsuit alleges that our definitive proxy statement on Schedule 14A filed with the SEC on April 7, 2017 (the "Definitive Proxy Statement") made false and misleading statements and omissions in connection with the Otic Transaction, in violation of the Exchange Act and Rule 14a-9, promulgated thereunder. Each plaintiff seeks to represent a class of all persons and entities that own our common stock. Each lawsuit seeks, among other things, preliminary and permanent injunctions of the Otic Transaction unless we disclose certain information requested by plaintiff, rescission and unspecified damages if the Otic Transaction is consummated, and attorneys' fees. We refer to these two actions collectively as the "Stockholder Litigation." We believe that no supplemental disclosures are required under applicable laws. However, to avoid the risk of the Stockholder Litigation delaying or adversely affecting the closing of the Otic Transaction and to minimize the expense of defending the Stockholder Litigation, and without admitting any liability or wrongdoing, we made certain disclosures that supplement and revise those contained in the Definitive Proxy Statement. We and the other named defendants deny that we have committed or assisted others in committing any violations of law or breaches of duty to our stockholders, and expressly maintain that we have complied with our fiduciary and other legal duties and have provided the litigation-related supplemental disclosures solely to try to eliminate the burden and expense of further litigation, to put the claims that were or could have been asserted to rest, and to avoid any possible delay to the closing of the Otic Transaction that might arise from further litigation. Nothing in the litigation-related supplemental disclosures shall be deemed an admission of the legal necessity or materiality under applicable laws of any of the litigation-related supplemental disclosures.

The market price for our common stock may be influenced by many factors, including:

- our analysis of available unblinded data from our ARMOR3-SV trial and our determination as to the potential paths forward in the development of galeterone and our ARDA program;
- results of clinical trials of galeterone and our future product candidates or those of our competitors;
- the success of competitive products or technologies;
- potential approvals of galeterone or other future product candidates for marketing by the FDA or equivalent foreign regulatory authorities or our failure to obtain such approvals;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize galeterone or other future product candidates;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to galeterone or any of our future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in the "Risk Factors" discussion contained in our Annual Report on Form 10-K for the year ended December 31, 2016.

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

On August 1, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against us, Jodie P. Morrison, and Lee H. Kalowski, entitled Doshi v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-06106 ("Doshi Action"). The plaintiff seeks to represent a class of purchasers of our securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about our clinical trials for our drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, two lead plaintiff motions were filed by two shareholders. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against us, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our initial public offering ("IPO"), entitled Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al., No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 ("Securities Act"), our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of our common stock in and/or traceable to our IPO. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of forum non conveniens, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction. On February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.

On September 29, 2016, two purported stockholders filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of our IPO, entitled Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al., No. 1:16-cv-11963 ("Garbowski Action"). The lawsuit alleges that the defendants and our registration statement for our IPO made false and misleading statements and omissions about our clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of our common stock in or traceable to our IPO as well as a class of purchasers of our common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. On September 30, 2016, a lead plaintiff motion was filed by one of the lead plaintiff candidates in the Doshi Action, who later refiled his motion on December 13, 2016. The same lead plaintiff candidate also filed a motion to consolidate the Doshi and Garbowski Actions for all purposes.

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

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

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, 2017, we estimate that we have used approximately $90.2 million of the net proceeds from our initial public offering to fund the clinical development of galeterone and for working capital and other general corporate purposes. We currently have the unused proceeds from the offering invested in money market accounts. Following our announcement in July 2016 to discontinue the ARMOR3-SV clinical trial, we are currently evaluating the potential use of the remaining net proceeds from our initial public offering.

Item 6. Exhibits.

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

SIGNATURES

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

TOKAI PHARMACEUTICALS, INC.

Date: May 3, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
2.1	Amended and Restated Share Purchase Agreement dated as of March 2, 2017 by and among the Registrant, Otic Pharma, Ltd. and shareholders of Otic Pharma, Ltd. named therein (incorporated by reference to Exhibit 2.1 to the Registrant's Annual Report on Form 10-K (File No. 001-36620) filed on March 3, 2017) (All Schedules have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any schedules to the Securities and Exchange Commission upon request.)
10.1	Stock Purchase Agreement, dated as of January 31, 2017, by and among the Registrant and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-36620) filed on February 3, 2017)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

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

Exhibit 31.1

CERTIFICATIONS

I, Jodie P. Morrison, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 3, 2017

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

Exhibit 31.2

CERTIFICATIONS

I, John S. McBride, certify that:

1. I have reviewed this 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 3, 2017

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2017 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 3, 2017

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tokai Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John S. McBride, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 3, 2017

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