
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 10, 2014

TOKAI PHARMACEUTICALS, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36620
(Commission
File Number)

20-1000967
(IRS Employer
Identification No.)

One Broadway, 14th floor
Cambridge, MA 02142
(Address of Principal Executive Offices) (Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On November 10, 2014, Tokai Pharmaceuticals, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2014. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall 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 liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release of Tokai Pharmaceuticals, Inc., dated November 10, 2014

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 hereunto duly authorized.

TOKAI PHARMACEUTICALS, INC.

Date: November 10, 2014

By: /s/ Lee H. Kalowski
Lee H. Kalowski
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Tokai Pharmaceuticals, Inc., dated November 10, 2014



Tokai Pharmaceuticals Reports Third Quarter 2014 Financial Results

Company Successfully Completed Initial Public Offering

CAMBRIDGE, Mass., November 10, 2014 – Tokai Pharmaceuticals, Inc. (NASDAQ: TKAI), a clinical-stage biopharmaceutical company focused on developing novel therapies for prostate cancer and other hormonally driven diseases, today reported company highlights and financial results for the quarter ended September 30, 2014.

“This has been an exciting year for Tokai, both operationally and in the clinic,” stated Jodie Morrison, president and chief executive officer at Tokai. “We successfully completed our initial public offering, strengthened our balance sheet and made great progress with our lead product candidate, galeterone, for the potential treatment of patients with castration resistant prostate cancer. Over the last year we have refined our initial registration strategy to focus on advancing galeterone into late-stage development in patients with androgen receptor splice variants that are expected to show poor response to currently available secondary hormonal treatment options, with plans to initiate a pivotal Phase 3 clinical trial, ARMOR3-SV, in the first half of 2015. In addition, we committed to deepening our pipeline, including advancing our Androgen Receptor Degrading Agents program. We look forward to reporting key updates on these efforts as we go forward.”

Recent Business Highlights

- **Completed Initial Public Offering (IPO):** On September 23, 2014, Tokai announced that it had completed its IPO of common stock raising \$97.2 million, before underwriting discounts and commissions and offering expenses. Subsequent to the close of the quarter, Tokai completed the sale of an additional 540,000 shares pursuant to the underwriters’ partial exercise of their option to purchase additional shares, resulting in additional gross proceeds of \$8.1 million.
- **Reported Interim Results from Ongoing ARMOR2 Trial:** At the European Society for Medical Oncology (ESMO) 2014 congress, data presented from ARMOR2, the company’s ongoing Phase 2 clinical trial evaluating galeterone as a treatment for patients with castration resistant prostate cancer (CRPC) demonstrated clinically meaningful reductions in prostate-specific antigen (PSA) levels, a marker of prostate cancer growth. Expanded clinical data in patients with C-terminal loss as well as additional preclinical data were also presented, providing further support for galeterone’s potential activity in CRPC patients whose tumors express androgen receptor (AR) splice variants, which are believed to be associated with resistance to hormonal agents commonly used to treat CRPC patients.

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- **Strengthened Leadership Team:** During the third quarter of 2014, Tokai announced the appointment of Lee Kalowski as Chief Financial Officer and Daniel Dransfield, Ph.D. as Vice President, Head of Translational Medicine.

Financial Results

- **Cash and cash equivalents** as of September 30, 2014, were \$105.5 million compared to \$31.8 million at December 31, 2013.
- **Research and development (R&D) expenses** were \$2.8 million in the third quarter of 2014 compared to \$2.7 million in the third quarter of 2013.
- **General and administrative (G&A) expenses** were \$3.6 million in the third quarter of 2014 compared to \$0.7 million in the third quarter of 2013. G&A expenses in the third quarter of 2014 included a one-time fee of \$1.1 million paid to a financial advisor upon the closing of the company's IPO in connection with strategic and financial advisory services unrelated to the IPO. G&A expenses in the third quarter of 2014 also included a one-time stock-based compensation charge of \$0.9 million related to the acceleration of vesting of options upon the closing of the Company's IPO.
- **Net Loss** was \$6.4 million in the third quarter of 2014 compared to a net loss of \$3.4 million in the third quarter of 2013.

Upcoming Activities

- **Clinical Update:** Updated interim results from ARMOR2 will be presented in an oral presentation at the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, Spain on Wednesday, November 19, 2014.
- **Corporate Presentations:** Tokai management will present at the 2014 Credit Suisse Healthcare Conference in Phoenix, Arizona on Tuesday, November 11, 2014 at 9:30 a.m. (ET) and at the Stifel 2014 Healthcare Conference in New York City on Tuesday, November 18, 2014 at 8:35 a.m. (ET). Live webcasts of these presentations can be accessed under the "Calendar of Events" page within the Investors & Media section of the company's website at www.tokaipharma.com. Replays of the webcasts will be archived on the Tokai website for two weeks following the date of the presentation.

About Tokai Pharmaceuticals

Tokai Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing novel therapies for prostate cancer and other hormonally driven diseases. The company's lead drug candidate, galeterone, is a highly selective, multi-targeted, oral small molecule drug candidate being developed for the treatment of patients with castration-resistant prostate cancer. The company's Androgen Receptor Degrading Agents (ARDA) drug discovery program is

focused on the identification and evaluation of compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation and are targeted to patients with androgen receptor signaling diseases, including prostate cancer. For more information on the company and galeterone, please visit www.tokai-pharma.com.

Forward-looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, intellectual property, cash resources, financial position and projected costs, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether the Company's cash resources will be sufficient to fund the Company's continuing operations for the period anticipated; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the Company can establish companion diagnostics arrangements for its planned Phase 3 trial; whether galeterone will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; whether, if galeterone obtains such approval, it will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of the Company's Registration Statement on Form S-1. In addition, the forward-looking statements included in this press release represent the Company's views as of November 10, 2014. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to November 10, 2014.

TOKAI PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share information)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,825	2,704	10,773	7,852
General and administrative	3,599	661	6,428	2,348
Total operating expenses	<u>6,424</u>	<u>3,365</u>	<u>17,201</u>	<u>10,200</u>
Loss from operations	(6,424)	(3,365)	(17,201)	(10,200)
Other income (expense), net	34	—	113	—
Net loss	<u>(6,390)</u>	<u>(3,365)</u>	<u>(17,088)</u>	<u>(10,200)</u>
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(79)
Net loss attributable to common stockholders	<u>(6,390)</u>	<u>(3,365)</u>	<u>(17,088)</u>	<u>(10,279)</u>
Basic and diluted net loss per share	\$ (2.71)	\$ (6.82)	\$ (15.19)	\$ (26.36)
Basic and diluted weighted average number of common shares outstanding	<u>2,357,236</u>	<u>493,299</u>	<u>1,124,627</u>	<u>390,001</u>

TOKAI PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEET DATA
(in thousands)

	September 30,	December 31,
	2014	2013
Cash and cash equivalents	\$ 105,464	\$ 31,753
Total current assets	106,724	32,178
Working capital	101,352	29,969
Total assets	106,983	32,287
Total stockholders' equity (deficit)	101,611	(55,267)

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