# 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): March 12, 2015

# 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)

| follo | 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 wing 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))  |

### Item 2.02. Results of Operations and Financial Condition.

On March 12, 2015, Tokai Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 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 March 12, 2015

# **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: March 18, 2015 By: /s/ Lee H. Kalowsl

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

# EXHIBIT INDEX

Exhibit No.

No. Description

99.1 Press Release of Tokai Pharmaceuticals, Inc., dated March 12, 2015



### Tokai Pharmaceuticals Reports Fourth Quarter and Full Year 2014 Financial Results

**CAMBRIDGE**, Mass., March 12, 2015 – 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 and year ended December 31, 2014.

"We are excited by the recent heightened attention on AR-V7 in prostate cancer and interest in our ARMOR3-SV galeterone registration trial at the 2015 Genitourinary Cancers Symposium (ASCO-GU)," stated Jodie Morrison, President and Chief Executive Officer of Tokai Pharmaceuticals. "We remain on track to begin ARMOR3-SV in the first half of the year as we work to complete development of our AR-V7 clinical trial assay and continue trial center start up. We ended 2014 with over \$105 million in cash, which we expect will provide us with sufficient funding into 2017, enabling us to take galeterone as a wholly-owned worldwide asset through topline data due by late 2016."

#### **Recent Business Highlights**

- Presented ARMOR3-SV Poster and Supported ASCO-GU CME Event: At the 2015 Genitourinary Cancers Symposium (ASCO-GU) on February 26-27, Tokai presented the protocol and rationale for the ARMOR3-SV Phase 3 trial and supported a CME event discussing AR-V7 in prostate cancer
- Announced Selection of AR-V7 Assay and Companion Diagnostic Development Partner: In January 2015, Tokai announced that it had
  obtained an exclusive, worldwide license from the Johns Hopkins University related to patent applications and know-how covering an assay that
  has been used to determine the AR-V7 status of prostate cancer patients for use with galeterone and announced a collaboration with Qiagen to
  develop a non-invasive AR-V7 companion diagnostic for use with galeterone. Qiagen initiated development of the AR-V7 assay as a companion
  diagnostic in October 2014 and the Company expects the AR-V7 assay to be available for use for its planned ARMOR3-SV trial in the first half
  of 2015
- Expanded Board of Directors: During the first quarter of 2015, Tokai announced the appointment of Stephen Buckley, Jr. to its board of directors
- Reported Interim Results from Ongoing ARMOR2 Trial: At the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer
  Therapeutics in November 2014, Tokai presented updated interim results from the ongoing Phase 2 ARMOR2 trial evaluating galeterone as a
  treatment for patients with castration-resistant prostate cancer (CRPC). Data demonstrating PSA50 reductions, time to PSA progression and
  duration of therapy suggests efficacy in patients with C-terminal loss, a segment of the population linked to poor responsiveness to hormonal
  agents commonly used to treat CRPC.

#### **Financial Results**

- Cash and cash equivalents as of December 31, 2014 was \$105.3 million compared to \$31.8 million at December 31, 2013.
- Research and development expenses were \$3.8 million in the fourth quarter of 2014 compared to \$4.3 million in the fourth quarter of 2013 and \$14.6 million for the full year 2014 compared to \$12.2 million for the full year 2013.
- General and administrative expenses were \$2.5 million in the fourth quarter of 2014 compared to \$1.2 million in the fourth quarter of 2013 and \$8.9 million for the full year 2014 compared to \$3.5 million for the full year 2013.
- Net Loss was \$6.2 million for the fourth quarter of 2014 compared to \$5.5 million for the fourth quarter of 2013 and \$23.3 million for the full year 2014 compared to \$15.8 million for the full year 2013.

#### 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 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 <a href="https://www.tokaipharma.com">www.tokaipharma.com</a>.

#### 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, 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 galeterone will advance through the clinical trial process on the anticipated timeline, including whether ARMOR3-SV will be initiated when anticipated; whether a companion diagnostic can be developed successfully and on a timely basis; whether the results of ARMOR3-SV will warrant submission for regulatory approval of galeterone and whether such submission will receive approval

from the United States Food and Drug Administration or equivalent foreign regulatory agencies; 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 quarterly report on Form 10-Q for the quarter ended September 30, 2014. In addition, the forward-looking statements included in this press release represent the Company's views as of March 12, 2015. The Company anticipates that subsequent events and developments may 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 March 12, 2015.

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

|   | Three Months Ended December 31, |           |      |         | Year Ended<br>December 31, |          |      |          |
|---|---------------------------------|-----------|------|---------|----------------------------|----------|------|----------|
|   |                                 | 2014      |      | 013     | 2014                       |          |      | 2013     |
| Revenue   | \$                              |           | \$   |         | \$                         |          | \$   |          |
| Operating expenses:   |                                 |           |      |         |                            |          |      |          |
| Research and development  |                                 | 3,804     |      | 4,349   |                            | 14,577   |      | 12,201   |
| General and administrative  |                                 | 2,457     |      | 1,200   |                            | 8,885    | _    | 3,548    |
| Total operating expenses  |                                 | 6,261     |      | 5,549   |                            | 23,462   |      | 15,749   |
| Loss from operations  |                                 | (6,261)   | (    | (5,549) |                            | (23,462) | - (  | (15,749) |
| Other income  |                                 | 53        |      | 24      |                            | 166      |      | 24       |
| Net loss  |                                 | (6,208)   | (    | (5,525) |                            | (23,296) | - (  | (15,725) |
| Accretion of redeemable convertible preferred stock to redemption value |                                 |           |      | (15)    |                            |          |      | (94)     |
| Net loss attributable to common stockholders                            | \$                              | (6,208)   | \$ ( | (5,540) | \$                         | (23,296) | \$ ( | (15,819) |
| Basic and diluted net loss per share                                    | \$                              | (0.28)    | \$ ( | (11.23) | \$                         | (3.60)   | \$   | (38.02)  |
| Basic and diluted weighted average number of common shares outstanding  | 22                              | 2,328,994 | 49   | 3,299   | 6.                         | ,469,289 | 4    | 116,037  |

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

|  | Decem     | December 31, |  |  |
|--|-----------|--------------|--|--|
|  | 2014      | 2013         |  |  |
| Cash and cash equivalents              | \$105,256 | \$ 31,753    |  |  |
| Total assets                           | 107,744   | 32,287       |  |  |
| Working capital                        | 103,268   | 29,969       |  |  |
| Redeemable convertible preferred stock | _         | 85,345       |  |  |
| Total stockholders' equity (deficit)   | 103,501   | (55,267)     |  |  |

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