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): January 9, 2015

TOKAI PHARMACEUTICALS, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36620**	**20-1000967**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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))

Item 1.01. Entry into a Material Definitive Agreement.

On January 9, 2015, Tokai Pharmaceuticals, Inc. (the "Company") entered into an exclusive license agreement with The Johns Hopkins University ("JHU"). Pursuant to the license agreement, JHU granted the Company an exclusive worldwide license under certain patent applications and a non-exclusive license under certain know-how, with the right to sublicense, to make, have made, use, sell, offer to sell and import certain assays to identify androgen receptor variants ("Licensed Products") for use as a companion diagnostic with galeterone. In addition, JHU granted the Company an option to negotiate an exclusive license to JHU's rights in certain improvements to the Licensed Products.

Under the terms of the license agreement, the Company is obligated to diligently develop, manufacture and sell Licensed Products. The Company is also obligated to use commercially reasonable efforts to achieve specified milestone events by specified dates. Unless the license agreement with JHU is terminated earlier as provided below, the license from JHU expires on a country-by-country basis as of the later of the expiration date of the last to expire of the claims of the patent rights licensed under the agreement in such country or ten years after the first commercial sale of a Licensed Product in such country. JHU may terminate the agreement if the Company fails to achieve such milestone events and does not cure such failure within a specified termination notice period. JHU may also terminate the agreement upon a material breach by the Company under the agreement if the Company does not cure such breach within a specified notice period or upon the Company's bankruptcy or insolvency. The Company may terminate the agreement at any time upon 90 days' notice.

In consideration for the rights granted to the Company under the license agreement, the Company made an upfront payment to JHU of $75,000 following the execution of the license agreement. The Company is obligated to pay JHU an annual minimum royalty of up to $30,000. The Company is also obligated to make milestone payments to JHU upon the achievement of specified technical and commercial milestones. If all such milestones were achieved, the total milestone payments owed to JHU would equal in the aggregate $700,000. The Company must also pay JHU single digit percentage royalties on aggregate worldwide net sales of Licensed Products (and not galeterone), including sales by sublicensees, on a Licensed Product-by-Licensed Product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable Licensed Product, in each case in the applicable country. These royalty obligations are subject to specified reductions in the event that additional licenses from third parties are required. The Company must also pay JHU 20% of all non-royalty sublicense income received from sublicensees.

Item 8.01. Other Events.

On January 12, 2015, the Company issued a press release announcing, among other things, its entry into the license agreement. A copy of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release issued by the Company on January 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: January 15, 2015

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company on January 12, 2015

Exhibit 99.1

Tokai Pharmaceuticals Provides Companion Diagnostic Update

ARMOR3-SV Remains On-Track to Begin in the First Half of the Year

CAMBRIDGE, Mass.—(BUSINESS WIRE)—Jan. 12, 2015—Tokai Pharmaceuticals, Inc. (NASDAQ: TKAI), today announced that it has entered into an agreement with the Johns Hopkins University related to the development of a companion diagnostic to determine the AR-V7 status of patients with castration-resistant prostate cancer (CRPC) for use with the Company's lead product, galeterone, which is in development for the treatment of AR-V7 positive metastatic CRPC.

Under the agreement, the Company has obtained an exclusive, worldwide license from the Johns Hopkins University to patent applications and know-how covering an assay that has been used to determine the AR-V7 status of prostate cancer patients.

AR-V7 positive prostate tumors express a truncated form of the androgen receptor (AR). These truncated ARs are missing the C-terminal end of the receptor that contains the ligand binding domain, which is known as C-terminal loss. The AR splice variant AR-V7 is the most prevalent of the splice variants that cause C-terminal loss.

Clinical data from a prospective trial at the Johns Hopkins University as well as retrospective analyses of studies at MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center have shown that AR-V7 specifically and C-terminal loss generally is associated with poor responsiveness to Zytiga® (abiraterone acetate) and Xtandi® (enzalutamide), two commonly used oral therapies for metastatic CRPC. The Company believes that galeterone has the potential to treat patients with AR-V7 based on data from preclinical studies and retrospective data in patients with C-terminal loss from the Company's Phase 2 ARMOR2 trial of galeterone.

"We are pleased to have formalized the agreement with the Johns Hopkins University to support our ongoing AR-V7 companion diagnostic program. This license adds to the intellectual property around galeterone and is a critical milestone in the development of the companion diagnostic that will be used in our 148 patient Phase 3 ARMOR3-SV trial scheduled to begin in the first half of this year," stated Jodie Morrison, president and chief executive officer of Tokai Pharmaceuticals. "It is our hope that future availability of a companion diagnostic will allow prostate cancer patients and their physicians to make more informed decisions regarding their care."

In addition, the Company announced that it has entered into an agreement with Qiagen N.V. under which Qiagen will develop a non-invasive companion diagnostic utilizing an array of novel technologies for use with galeterone. The agreement formalizes an existing collaboration under which work has been ongoing.

About Galeterone

Galeterone is a highly selective, multi-targeted, oral small molecule drug candidate being developed for the treatment of CRPC that acts by actively disrupting AR signaling, the key driver of prostate cancer growth, via multiple mechanisms of action. Galeterone combines the mechanisms of action of CYP17 inhibition and androgen receptor antagonism with an additional

mechanism of androgen receptor degradation. To Tokai's knowledge, galeterone is the only drug candidate currently in clinical trials that disrupts the AR signaling pathway at multiple points and includes a mechanism of AR degradation.

Preclinical evidence suggests galeterone's mechanism of androgen receptor degradation does not require a functional ligand binding domain to disrupt the activation of the pathway and tumor growth and thus galeterone may have activity even in the presence of C-terminal loss, such as AR-V7. In a retrospective analysis of the Phase 2 ARMOR2 trial, galeterone was associated with clinical responses in patients identified as having C-terminal loss, with 6 of 7 patients achieving a 12-week PSA50 response (the one non-responder discontinued therapy due to an adverse event unrelated to galeterone and did not receive the full treatment regimen).

About the ARMOR3-SV Clinical Trial

ARMOR3-SV is a randomized, open label Phase 3 clinical trial that will compare galeterone to Xtandi® (enzalutamide) in 148 metastatic CRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant. The primary endpoint of the trial will be radiographic progression-free survival measured from the time of patient randomization to the time of radiographic evidence of disease progression or time of death from any cause. The Company expects to commence the trial in the first half of 2015.

About Tokai Pharmaceuticals

Tokai Pharmaceuticals is a 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 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.tokaipharma.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, 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 and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether a companion diagnostic can be developed successfully and on a timely basis; 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 January 12, 2015. 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 January 12, 2015.

Source: Tokai Pharmaceuticals, Inc.
Investor Contact:
Tokai Pharmaceuticals
Lee Kalowski, 617-225-4305
Chief Financial Officer

or

Media Contact:
Pure Communications, Inc.
Susan Heins, 864-286-9597