
**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): July 26, 2016

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.)

255 State Street, 6th Floor
Boston, Massachusetts 02109
(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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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements in this Form 8-K about our future expectations, plans and prospects, including statements about our 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 our cash resources will be sufficient to fund our continuing operations for the period anticipated; whether, if we determine to move forward with the development of galeterone, necessary regulatory and ethics approvals to commence additional clinical trials for galeterone can be obtained, and whether data from early clinical trials of galeterone will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of galeterone, whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if galeterone obtains such approval, whether it will be successfully distributed and marketed; and other factors discussed in the “Risk Factors” section of our annual report on Form 10-K for the year ended December 31, 2015. Any forward-looking statements contained in this Form 8-K speak only as of the date hereof and not of any future date, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 2.02. Results of Operations and Financial Condition.

On July 26, 2016, we announced that our cash and cash equivalents as of June 30, 2016 was \$43.9 million.

Item 8.01 Other Events

On July 26, 2016, we announced that we plan to discontinue the ARMOR3-SV clinical trial, our pivotal Phase 3 study comparing galeterone to enzalutamide in treatment-naïve metastatic castration-resistant prostate cancer (“mCRPC”) patients whose prostate tumors express AR-V7, following the recommendation made by the trial’s independent Data Monitoring Committee (“DMC”) on July 25, 2016.

Based on a review of all safety and efficacy data, the DMC determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival (“rPFS”) for galeterone versus enzalutamide in AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. ARMOR3-SV is the first pivotal clinical trial in mCRPC to prospectively select AR-V7 positive patients, a population we believe represents an unmet medical need and has an aggressive disease course.

We plan to analyze the unblinded study data in detail to evaluate potential paths for galeterone and our pipeline. We plan to present data from the trial in a scientific forum once fully available and analyzed.

We also intend to evaluate our ongoing ARMOR2 expansion in mCRPC patients with acquired resistance to enzalutamide, and our planned study in patients who rapidly progress on either enzalutamide or abiraterone acetate. We plan to allow all patients currently enrolled in the ARMOR2 and ARMOR3-SV trials to continue on therapy following consultation with their physicians and study investigators. The appropriate health authorities and clinical study investigators are being notified that ARMOR3-SV is being discontinued.

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: July 26, 2016

By: /s/ Gerald E. Quirk

Gerald E. Quirk
Executive Vice President, Business Operations
and General Counsel