
**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): August 22, 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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Item 7.01. Regulation FD Disclosure

Tokai Pharmaceuticals, Inc. (“Tokai”) has determined to discontinue enrollment in its ongoing ARMOR2 expansion clinical trial of galeterone in metastatic castration-resistant prostate cancer (“mCRPC”) patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed at this time with its planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). Tokai is continuing to evaluate the unblinded data from its recently discontinued ARMOR3 clinical trial comparing galeterone to enzalutamide in treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant, and is assessing potential next steps in its galeterone program.

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; 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, it will be successfully distributed and marketed; and other factors discussed in the “Risk Factors” section of our quarterly report on Form 10-Q for the quarter ended June 30, 2016. 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.

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: August 22, 2016

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