

AVEO PHARMACEUTICALS INC
Form 8-K
January 04, 2017

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): December 19, 2016

AVEO Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-34655
(Commission

File Number)

04-3581650
(IRS Employer

Identification No.)

One Broadway, 14th Floor

02142

Cambridge, Massachusetts
(Address of Principal Executive Offices) **(Zip Code)**
Registrant's telephone number, including area code: (617) 588-1960

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))

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Current Report on Form 8-K and the exhibit attached hereto contain forward-looking statements of AVEO Pharmaceuticals, Inc. (AVEO , the Company , or we) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K and the attached exhibit are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, potential, will, would, could, should, continue, contemplate, strategy, or the negative of these terms or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: AVEO s plans to leverage biomarkers and pursue strategic partnerships for certain of its assets; AVEO s goals, business strategy and potential achievement of milestones; the timing, design and results of preclinical and clinical trials; the timing and outcome of meetings with and applications to regulatory authorities by AVEO and its partners; the competitive landscape and potential markets for AVEO s therapeutic candidates; AVEO s estimates for its cash runway; the timing and outcome of ongoing litigation; and the relationship of the Company with certain of its strategic partners.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements AVEO makes due to a number of important factors, including substantial risks and uncertainties relating to: AVEO s ability to successfully implement its strategic plans; AVEO s ability to successfully develop, test and gain regulatory approval of its product candidates, including its companion diagnostics; the potential safety, efficacy, tolerability and other benefits of tivozanib as a single agent or in combination with other therapies; developments, expenses and outcomes related to AVEO s ongoing shareholder litigation; AVEO s ability to obtain necessary financing required to perform its clinical trials and achieve its other goals; AVEO s ability to establish and maintain strategic partnerships; AVEO s ability to obtain and maintain intellectual property rights; competition; AVEO s dependence on its strategic partners and other third parties; adverse general economic and industry conditions; and those risk factors discussed in the Risk Factors and elsewhere in AVEO s Annual Report on Form 10-K for the year ended December 31, 2015, Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and other periodic filings AVEO makes with the SEC. All forward-looking statements contained in this Current Report on Form 8-K and the attached exhibit speak only as of the date of this Current Report, and AVEO undertakes no obligation to update any of these statements, except as required by law. You should, therefore, not rely on these forward-looking statements as representing the Company s views as of any date subsequent to the date of this Current Report.

Item 7.01. Regulation FD.

From time to time, we conduct meetings with third parties in which we utilize a corporate slide presentation. A copy of our current corporate slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The presentation includes clinical, development, collaboration and financial updates. We may amend or update this information at any time and from time to time through another Current Report on Form 8-K, a later company filing, or other means.

The information in this Item 7.01 and Exhibit 99.1 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 8.01. Other Events.

Collaboration Update - Ophthotech

In November 2014, we entered into a research and exclusive option agreement with Ophthotech Corporation (Ophthotech) pursuant to which we provided Ophthotech an exclusive option to enter into a definitive license agreement whereby we would grant Ophthotech the right to develop and commercialize tivozanib outside of Asia and the Middle East for the potential diagnosis, prevention and treatment of non-oncologic diseases or conditions of the eye in humans. Pursuant to this option agreement, we granted to Ophthotech an exclusive, royalty-free license or sublicense, as applicable, under intellectual property rights controlled by us solely to perform the research and development activities related to the use of tivozanib for the specific purposes outlined in the agreement during the option period. These activities include formulation work for ocular administration, preclinical research and the conduct of a phase 1/2a proof-of-concept clinical trial of a product containing tivozanib in patients with wet age-related macular degeneration. Under the option agreement, we are entitled to receive, among other potential payments, a one-time milestone payment of \$6.0 million on December 31, 2016; provided, however, that the milestone payment will not be payable if Ophthotech gives us a notice of termination of the option agreement within thirty (30) days after December 31, 2016. We have not yet received the milestone payment, and although we have not received formal notice of termination of the option agreement from Ophthotech, we have been informed verbally by Ophthotech that it is not going to be able to move forward with the development of tivozanib.

Litigation Update

As previously disclosed, the Company is party to two outstanding litigations stemming from disclosures surrounding the Company's failed application to the U.S. Food and Drug Administration (the FDA) for approval of tivozanib in 2012-2013.

Derivative Suit (Van Ingen, Civil Action No. 1:14-cv-11672-DJC). In April 2014, Karen J. van Ingen, a purported purchaser of AVEO stock, filed a derivative complaint allegedly on behalf of AVEO in the United States District Court for the District of Massachusetts (the Court). The complaint, filed against the Company and present and former members of the Company's board of directors, alleged breach of fiduciary duty and abuse of control between January 2012 and May 2013 with respect to allegedly misleading statements and omissions regarding tivozanib.

On December 19, 2016, the Court held a final settlement hearing on the terms of the proposed settlement, consisting of certain corporate governance changes and other non-monetary relief, and to consider the award of fees to the plaintiff's attorneys. No objections to the settlement were filed with the Court or raised at the hearing.

At the hearing, the Court indicated orally that the settlement will be approved. A formal approval order has not yet entered. The Court did not yet rule on the final amount of fees for the plaintiff's attorneys. The Company expects that such attorney's fees will be paid by insurance in the amount ordered by the Court. Until a formal approval order has been entered, there can be no complete assurance that the Court will approve the settlement.

Class Action (*In re AVEO Pharmaceuticals, Inc. Securities Litigation et al.*, No. 1:13-cv-11157-DJC). The United States District Court for the District of Massachusetts on January 3, 2017, vacated the dismissal of the purported class action lawsuit brought against the Company and certain of its former officers and members of its board of directors (Tuan Ha-Ngoc, David N. Johnston, and William Slichenmyer). The operative complaint in the action purported to be brought on behalf of shareholders who purchased the Company's common stock between May 16, 2012 and May 1, 2013, and generally alleged that the Company and certain of its present and former officers and directors violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for the Company's TIVO-1 study in an effort to lead investors to believe that the drug would receive approval from the FDA. The lawsuit seeks unspecified damages, interest, and attorneys' fees. The Company denies any allegation of wrongdoing and intends to continue to vigorously defend against this lawsuit. However, there is no assurance that the Company will be successful in its defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of the action. Moreover, the Company is unable to predict the outcome or reasonably estimate a range of possible loss at this time.

Item 9.01. Financial Statements and Exhibits.

(d) The exhibit to this Current Report on Form 8-K is listed in the Exhibit Index attached hereto.

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.

AVEO Pharmaceuticals, Inc.

Date: January 4, 2017

/s/ Michael Bailey
Michael Bailey

President and Chief Executive Officer

EXHIBIT INDEX

| Exhibit No. | Description |
|------------------------|--|
| 99.1 | Corporate Presentation Slide Deck dated January 2017 |