

AVEO PHARMACEUTICALS INC
Form 8-K
June 15, 2016

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): June 10, 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 Form 8-K and the exhibit attached hereto contain forward-looking statements of AVEO Pharmaceuticals, Inc. (AVEO, we or the Company) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K and the attached exhibit are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will continue, contemplate, or the negative of these terms or other similar 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 and business strategy; 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 for AVEO's therapeutic candidates; AVEO's ability to demonstrate tivozanib's safety and efficacy as a combination therapy and AVEO's estimates for its cash runway.

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; developments, expenses and outcomes related to AVEO's ongoing shareholder litigation, including the risk that the Company may be required to incur substantial costs to settle such 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 most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q, and its other periodic filings AVEO makes with the SEC. All forward-looking statements contained in this Form 8-K and the attached exhibit speak only as of the date hereof, 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 Form 8-K.

Item 1.02 Termination of Material Definitive Agreement.

The Company was given notice by JSC Pharmstandard-Ufimskiy Vitamin Plant (Pharmstandard), effective as of June 10, 2016, (the Notice) of its exercise of its right to terminate the License Agreement, dated as of August 4, 2015, by and between the Company and Pharmstandard (the Agreement). Pursuant to the terms of the Agreement and the Notice, the termination of the Agreement will be effective on September 9, 2016. In the Notice, Pharmstandard advised the Company that it was exercising its right to terminate because, in its reasonable opinion, due to economic and market changes in Russia the commercial viability of the licensed product under the existing contract terms does not justify continued development by Pharmstandard. The Company has previously disclosed that Pharmstandard was seeking to renegotiate its obligation to make milestone payments under the Agreement due to adverse economic conditions. The Company and Pharmstandard were unable to come to an agreement on revised terms.

Under the Agreement, Pharmstandard is responsible for the development and commercialization of tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States (the Licensed Territories).

Upon termination of the Agreement, among other things, the licenses to tivozanib granted by the Company to Pharmstandard will terminate, all product rights and regulatory documents will be transferred to AVEO, Pharmstandard will no longer be responsible for the development and commercialization of tivozanib, and Pharmstandard will have no further payment obligations under the Agreement except with respect to payments that accrued prior to the effective date of the termination.

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None of the milestone or other potential payments to the Company under the Agreement have been included in the Company's cash forecasts. Accordingly, termination of Agreement will have no impact on the Company's cash forecasts as disclosed in its press releases and filings with the SEC. The Company plans to seek a new partner for the development and commercialization of tivozanib in the Licensed Territories. The Company expects that the marketing authorization application for tivozanib submitted in December 2015 by Pharmstandard in Russia will be withdrawn and that any future application for marketing approval in Russia will involve a new submission.

Item 7.01 Regulation FD

From time to time, the Company conducts meetings with third parties in which it utilizes a corporate slide presentation. The Company has updated its corporate slide presentation to reflect, among other things, the termination of the Agreement. A copy of the current corporate slide presentation, dated June 14, 2016, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company 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 in 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 9.01 Financial Statements and Exhibits.

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: June 15, 2016

By: /s/ Michael Bailey
Michael Bailey

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Corporate Presentation Slide Deck, dated June 14, 2016