AVEO PHARMACEUTICALS INC
Form 8-K
February 15, 2019

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): February 15, 2019

AVEO Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-34655**	**04-3581650**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Broadway, 14th Floor

Cambridge, Massachusetts **02142**
(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:

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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, seek, look forward, advance, goal, opportunity 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 goals and business strategy, prospects, plans and objectives; AVEO s plans regarding potentially submitting a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for tivozanib; the timing, design and results of preclinical and clinical trials, including AVEO s plans to conduct, and expectations regarding the timing and potential results of, interim and final overall survival analyses for the Phase 3 TIVO-3 study of tivozanib in RCC; 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 plans regarding the potential efficacy, safety and tolerability profile of tivozanib, including with respect to overall survival; 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, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy and clinically meaningful benefit of AVEO s product candidates, including, in particular, tivozanib; AVEO s ability to successfully file an NDA for tivozanib; AVEO s and its collaborators ability to successfully enroll and complete clinical trials; and AVEO s ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements. AVEO faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO s ability to maintain compliance with regulatory requirements applicable to its product candidates; AVEO s ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates; AVEO s ability to successfully implement its strategic plans; AVEO s ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the development and commercialization of tivozanib; unplanned capital requirements; adverse general economic and industry conditions; and those risks discussed in the section titled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources included in AVEO s quarterly and annual reports on file with the SEC and in other filings that AVEO may make with the SEC in the future. 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, and specifically disclaims any 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 detailed analysis of our Phase 3 TIVO-3 study of tivozanib in RCC and collaboration and financial updates.

We may amend or update the information in this slide presentation 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.

(d) Exhibits

99.1 Corporate Presentation Slide Deck dated February 2019

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: February 15, 2019

By: /s/ Michael Bailey
Michael Bailey
President and Chief Executive Officer