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 5, 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") 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," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," "seek," "look forward," "advance," "goal," "strategy," 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 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; AVEO's plans regarding the potential efficacy, safety and tolerability profile of tivozanib, including with respect to overall survival; AVEO's expectation regarding submitting updated informed consent forms ("ICFs") to the FDA and using them obtain consent from patients in ongoing and future trials; and the timing and outcome of meetings with and applications to regulatory authorities by AVEO.

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 as it relates to the TIVO-3 trial and tivozanib; AVEO's ability to successfully file an NDA for tivozanib on the timeline it anticipates, or at all; 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; competitive factors; and those risks discussed in the sections 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 Securities and Exchange Commission in the future. All forward-looking statements contained in this Current Report on Form 8-K 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 AVEO's views as of any date subsequent to the date of this Current Report.

Item 8.01. Other Events

As disclosed on January 31, 2019, and following a meeting with the U.S. Food and Drug Administration ("FDA" or "Agency"), AVEO Oncology ("Company" or "AVEO") announced its decision to accept the FDA's recommendation not to submit a New Drug Application ("NDA") for tivozanib with preliminary overall survival ("OS") results from the Company's Phase 3 TIVO-3 trial. The FDA had indicated that these preliminary OS results did not allay their concerns about the potential detriment in OS outlined in the complete response letter dated June 6, 2013. The Company also announced its plan to designate an August 2019 OS analysis as interim, rather than final, in order to allow time for the OS data to mature.

On February 5, 2019, AVEO received final minutes from that meeting with the FDA. The minutes reflect both a summary of the meeting and decisions or recommendations made by the Agency after the meeting. The minutes reflect the Company's agreement not to submit an NDA at this time. In the minutes, the FDA notes that the Company may decide to submit a formal interim analysis with an appropriate statistical error allocation at a later date; requests that the Company provide any OS analysis performed to the FDA; and recommends that the Company not conduct any exploratory OS updates. The minutes also reflect the FDA's request that the Company submit any revision to the TIVO-3 statistical analysis protocol to the Agency for review. Finally, the FDA asked the Company to submit updated informed consent forms ("ICFs") to the Agency for review that will be used to obtain consent from patients in ongoing and future trials. The revised ICFs will include information about all of the tivozanib clinical trial OS outcomes to date.

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.

Date: February 6, 2019

AVEO Pharmaceuticals, Inc.

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