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): April 2, 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** **(Address of Principal Executive Offices)**	**02142** **(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 contains forward-looking statements of AVEO Pharmaceuticals, Inc. ("AVEO," "we", "our" or "us") that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K 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," "promising," "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; and the European Medicines Agency's (the "EMA") potential regulatory actions regarding tivozanib.

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 and the EMA 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; 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 U.S. Securities and Exchange Commission (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 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.

In August 2017, the European Commission granted marketing authorization for tivozanib to our licensee, EUSA Pharma (UK) Limited ("EUSA"), in all 28 countries of the European Union, Norway and Iceland. Tivozanib is sold under the brand name FOTIVDA and is approved for the first-line treatment of adult patients with advanced or metastatic renal cell carcinoma ("RCC") and for adult patients who are vascular endothelial growth factor receptor and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC.

As previously disclosed, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, as part of its post-authorization monitoring procedures, requested the topline data results from our TIVO-3 trial. In addition, the CHMP requested data analyses to explain the discordance between the final progression-free survival ("PFS") results (HR 0.73) and the preliminary OS results (HR 1.12) in the TIVO-3 trial.

Following its review, the CHMP has determined that the analyses of various factors that may have impacted the preliminary OS data do not fully explain the discordance, and that more mature OS data is required prior to drawing a conclusion. Similar to the FDA, the CHMP accepted the proposal to conduct an additional interim OS analysis in August 2019. The CHMP further provided that regulatory action should be considered if the August 2019 interim OS analysis confirms a negative trend in OS.

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: April 3, 2019

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