AVEO PHARMACEUTICALS INC
Form 8-K
November 03, 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): November 3, 2017

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 (*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))
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 , 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 are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, potential, could, should, would, seek, look forward, adva 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: clinical, regulatory and commercial plans of AVEO and its partner EUSA Pharma to progress the development of FOTIVDA® (tivozanib); the role and expected benefits of tivozanib and other tyrosine kinase inhibitors on a stand-alone basis, or in combination with or following immunotherapy; the expected enrollment of the TiNivo trial and presentation of TiNivo results; expectations about the potential for additional payments by EUSA Pharma; the value of AVEO s partnerships in advancing its pipeline; and AVEO s strategy, prospects, plans and objectives, including as they pertain specifically to tivozanib. AVEO has based its expectations and estimates on assumptions that may prove to be incorrect. As a result, readers are cautioned not to place undue reliance on these expectations and estimates.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including substantial risks and uncertainties relating: to AVEO s ability to enter into and maintain its third party collaboration agreements, and its ability, and the ability of its licensees and other partners, to achieve development and commercialization objectives under these arrangements; and AVEO s ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies the safety, efficacy and clinically meaningful benefit of AVEO s product candidates, including tivozanib. AVEO faces other risks relating to its business as well, including risks relating to its ability to successfully enroll and complete clinical trials, including the TIVO-3 and TiNivo trials; AVEO s ability to achieve and maintain compliance with all 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 and technologies; developments, expenses and outcomes related to AVEO s ongoing shareholder litigation; 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 risk factors discussed in the Risk Factors and elsewhere in AVEO s Annual Report on Form 10-K for the year ended December 31, 2016 and other periodic filings AVEO makes with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date of this Current Report. AVEO anticipates that subsequent events and developments may cause its views to change, 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.

On November 3, 2017, results of AVEO s ongoing phase 1 portion of the TiNivo study, a phase 1/2 multicenter trial of tivozanib (FOTIVDA®) in combination with Bristol-Myers Squibb s nivolumab (OPDIVO®), an immune checkpoint, or PD-1, inhibitor, for the treatment of advanced renal cell carcinoma (RCC) are being presented at the 16th International Kidney Cancer Symposium in Miami, Florida, in an oral presentation titled TiNivo: A Phase Ib Dose Escalation Trial of Tivozanib and Nivolumab in Renal Cell Carcinoma by Laurence Albiges, M.D., Ph.D., Head, Genitourinary Unit, Institute Gustave Roussy, and a lead investigator of the study.

The phase 1 portion of the trial enrolled six patients, three with previously untreated metastatic RCC and three who had received first-line treatment. RCC tumor histology included five clear cell (one with sarcomatoid features) and one papillary. Tivozanib was administered to patients in two escalating dose cohorts (1.0 mg/QD and 1.5 mg/QD) in

combination with nivolumab at a constant 240 mg every 2 weeks. The combination was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities. The most common adverse events (any grade) were hypertension, asthenia and decreased appetite. No grade 4 adverse events were reported. Two grade 3 events were reported beyond cycle 1 (stomatitis and increased ALT), which did not lead to study discontinuation and were managed concurrently. Unconfirmed best response to date includes a 67% (4/6) partial response (PR) rate and a 100% disease control rate (PR + stable disease). Enrollment of approximately 20 patients in the phase 2 portion of the trial is ongoing.

AVEO is encouraged by the promising preliminary tolerability and activity results from the TiNivo trial, and believes that they begin to underscore the unique potential of tivozanib-immunotherapy combinations. The Company expects to present the results of the phase 2 portion of the TiNivo trial in the first half of 2018, and anticipates initiating additional combination studies in the next year.

The information in this Item 7.01 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.

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: November 3, 2017

By: /s/ Michael Bailey
Michael Bailey

President and Chief Executive Officer