AVEO PHARMACEUTICALS INC
Form 8-K
December 21, 2015

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): December 18, 2015

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		**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))

Item 1.01. Entry into a Material Definitive Agreement.

EUSA License Agreement

On December 18, 2015 (the Effective Date), AVEO Pharmaceuticals, Inc., a Delaware corporation (AVEO), entered into a License Agreement (the License Agreement) with EUSA Pharma (UK) Limited, a company registered in England and Wales (EUSA). Under the License Agreement, AVEO has granted to EUSA the exclusive, sublicensable right to develop, manufacture and commercialize tivozanib in the territories of Europe (excluding Russia, Ukraine and the Commonwealth of Independent States), Latin America (excluding Mexico), Africa, Australasia and New Zealand (together, the Licensed Territories) for all diseases and conditions in humans, excluding non-oncologic diseases or conditions of the eye.

Under the License Agreement, EUSA is required to make research and development funding payments to AVEO of (a) $2.5 million within fifteen (15) days of the Effective Date, and (b) $4 million upon the grant by the European Medicines Agency (EMA) of marketing approval for tivozanib for treatment of renal cell carcinoma. AVEO is eligible to receive additional research funding from EUSA, including up to $20 million if EUSA elects to utilize data generated by AVEO s planned phase 3 study in third line renal cell carcinoma, and up to $2 million for a potential phase 1 combination study with a checkpoint inhibitor. AVEO will be entitled to receive milestone payments of $2 million per country upon reimbursement approval for renal cell carcinoma in each of France, Germany, Italy, Spain and the United Kingdom, and an additional $2 million for the grant of marketing approval in three of the following five countries: Argentina, Australia, Brazil, South Africa and Venezuela. AVEO would also be eligible to receive a payment of $2 million in connection with EUSA s filing with the EMA for marketing approval for tivozanib for the treatment of each of up to three additional indications and $5 million per indication in connection with the EMA s grant of marketing approval for each of up to three additional indications, as well as potentially up to $335 million upon EUSA s achievement of certain sales thresholds. AVEO will also be eligible to receive tiered double digit royalties on net sales, if any, of licensed products in the Licensed Territories ranging from a low double digit up to mid-twenty percent depending on the level of annual net sales.

EUSA is obligated to use commercially reasonable efforts to develop and commercialize tivozanib throughout the Licensed Territories. With the exception of certain support to be provided by AVEO prior to the grant of marketing approval by the EMA, EUSA has responsibility for all activities and costs associated with the further development, manufacture, regulatory filings and commercialization of tivozanib in the Licensed Territories. EUSA is obligated to use commercially reasonable efforts to file an application with the EMA for approval of marketing authorization for tivozanib for the treatment of renal cell carcinoma, with a target filing date of March 7, 2016 or earlier.

The term of the License Agreement commenced on the Effective Date and will continue on a product-by-product and country-by-country basis until the later to occur of (a) the expiration of the last valid patent claim for such product in such country, (b) the expiration of market or regulatory data exclusivity for such product in such country or (c) the 10th anniversary of the Effective Date. Either party may terminate the License Agreement in the event of the bankruptcy of the other party or a material breach by the other party that remains uncured, following receipt of written notice of such breach, for a period of (a) thirty (30) days in the case of breach for nonpayment of any amount due under the License Agreement, and (b) ninety (90) days in the case of any other material breach. EUSA may terminate the License Agreement at any time upon one hundred eighty (180) days prior written notice. In addition, AVEO may terminate the License Agreement upon thirty (30) days prior written notice if EUSA challenges any of the patent rights licensed under the License Agreement.

A percentage of any milestone and royalty payments received by AVEO are due to Kyowa Hakko Kirin Co., Ltd. (formerly Kirin Brewery Co., Ltd.) (KHK) as a sublicensing fee under the license agreement between AVEO and KHK dated as of December 21, 2006.

The foregoing summary of the License Agreement does not purport to be complete and is qualified in its entirety by the full text of the License Agreement, which AVEO intends to file as an exhibit to its future filings with the Securities and Exchange Commission.

Item 8.01. Other Events.

On December 21, 2015, AVEO issued a press release announcing its entry into the License Agreement described in Item 1.01 above. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by AVEO Pharmaceuticals, Inc. on December 21, 2015

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: December 21, 2015

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by AVEO Pharmaceuticals, Inc. on December 21, 2015