

AVEO PHARMACEUTICALS INC
Form 8-K
August 05, 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): August 4, 2015

AVEO Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-34655
(Commission

File Number)

04-3581650
(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

650 East Kendall Street

Cambridge, Massachusetts 02142

(Former Name or Former Address, if Changed Since Last Report)

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.

On August 4, 2015 (the Effective Date), AVEO Pharmaceuticals, Inc., a Delaware corporation (AVEO), entered into a License Agreement (the License Agreement) with JSC Pharmstandard- Ufimskiy Vitamin Plant, a company registered under the laws of the Russian Federation (Pharmstandard). Pharmstandard is a subsidiary of Pharmstandard OJSC. Under the License Agreement, AVEO has granted to Pharmstandard the exclusive, sublicensable right to develop, manufacture and commercialize tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States (the Licensed Territories) for all diseases and conditions in humans, excluding non-oncologic ocular conditions.

Under the License Agreement, Pharmstandard is required to make an upfront payment to AVEO of \$1.5 million, of which \$1.0 million is payable within ten (10) business days of the Effective Date of the License Agreement (or, if later, upon AVEO's delivery to Pharmstandard of a Certification of U.S. Tax Residency), and \$500,000 is payable within fifteen (15) business days of the date the License Agreement is registered with the Federal Service for Intellectual Property of the Russian Federation. AVEO is also eligible to receive \$7.5 million in connection with the first marketing authorization of tivozanib in Russia. If Russian regulatory authorities require additional studies to be conducted by Pharmstandard prior to approval, this amount would be reduced to \$3.0 million. In addition, AVEO is eligible to receive \$3.0 million for each additional approved indication of tivozanib, if Pharmstandard elects to seek any such approvals, as well as a high single-digit royalty on net sales in the Licensed Territories.

Pharmstandard is obligated to use commercially reasonable efforts to develop and commercialize tivozanib throughout the Licensed Territories, and Pharmstandard has responsibility for all activities and costs associated with the further development, manufacture, regulatory filings and commercialization of tivozanib in the Licensed Territories. Pharmstandard is obligated to file an application for marketing authorization in Russia for tivozanib for the treatment of renal cell carcinoma no later than the first anniversary of the Effective Date, unless Russian regulatory authorities require Pharmstandard to conduct an additional clinical trial prior to approval and Pharmstandard is actively performing such trial.

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 the last marketing authorization for such product in such country or (c) the 10th anniversary of the first commercial sale of such product in such country. Either party may terminate the License Agreement in the event of 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. After the first anniversary of the Effective Date, Pharmstandard may terminate the License Agreement at any time upon ninety (90) days' prior written notice. In addition, AVEO may terminate the License Agreement upon thirty (30) days' prior written notice if Pharmstandard challenges certain patents controlled by AVEO or AVEO's licensor, Kyowa HAKKO Kirin (KHK), related to tivozanib.

A percentage of all upfront, milestone and royalty payments received by AVEO are due to KHK as a sublicensing fee under the License Agreement between AVEO and KHK (formerly Kirin Brewery Co. Ltd.) 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 August 5, 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 August 5, 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: August 5, 2015

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

EXHIBIT INDEX

Exhibit

| No. | Description |
|------------|--------------------|
| 99.1 | Press Release |