

AVEO PHARMACEUTICALS INC
Form 8-K
August 17, 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 13, 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

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.

Novartis License Agreement

On August 13, 2015 (the Effective Date), AVEO Pharmaceuticals, Inc. (AVEO), entered into a License Agreement (the License Agreement) with Novartis International Pharmaceutical Ltd., a Bermuda corporation (Novartis). Under the License Agreement, AVEO has granted to Novartis the exclusive right to develop and commercialize worldwide AVEO's proprietary antibody AV-380 and related AVEO antibodies that bind to Growth Differentiation Factor 15 (GDF15) for the treatment and prevention of diseases and other conditions in all indications in humans.

Under the License Agreement, Novartis is required to make an upfront payment to AVEO of \$15 million within fifteen days of the Effective Date. Novartis also has the right for 90 days after the Effective Date to acquire AVEO's inventory of clinical quality, AV-380 biological drug substance. If Novartis exercises such right, it will reimburse AVEO up to \$3.45 million for such existing inventory. AVEO will also be eligible to receive (a) up to \$53 million in potential clinical milestone payments and up to \$105 million in potential regulatory milestone payments tied to the commencement of clinical trials and to regulatory approvals of products developed under the License Agreement in the United States, the European Union and Japan; and (b) up to \$150 million in potential sales based milestone payments based on annual net sales of such products. Upon commercialization, AVEO is eligible to receive tiered royalties on net sales of approved products ranging from the high single digits to the low double digits. Novartis has responsibility under the License Agreement for the development, manufacture and commercialization of the AVEO antibodies and any resulting approved therapeutic products.

The term of the License Agreement commenced on the Effective Date and will continue on a country-by-country basis until the later to occur of the 10th anniversary of the first commercial sale of a product in such country or the expiration of the last valid patent claim for a product in that country. Either party may terminate the License Agreement in the event of a material breach of the License Agreement by the other party that remains uncured for a period of sixty (60) days, which period may be extended an additional thirty (30) days under certain circumstances. Novartis may terminate the License Agreement, either in its entirety or with respect to any individual products or countries, at any time upon sixty (60) days' prior written notice. In addition, AVEO may terminate the License Agreement upon thirty (30) days' prior written notice if Novartis challenges certain patents controlled by AVEO related to the AVEO antibodies.

AVEO has agreed that it will not directly or indirectly develop, manufacture or commercialize any GDF15 modulator as a human therapeutic during the term of the License Agreement.

Amended and Restated St. Vincent's License Agreement

In order to sublicense certain necessary intellectual property rights to Novartis under the License Agreement, AVEO has entered into an Amended and Restated License Agreement with St. Vincent's Hospital Sydney Limited (St. Vincent's) on the Effective Date (the Amended St. Vincent's Agreement), which amends and restates the original license agreement, dated July 2, 2012, between AVEO and St. Vincent's. AVEO is required to make an upfront payment to St. Vincent's of \$1.5 million within 21 days of the Effective Date. St. Vincent's is also eligible to receive up to approximately \$18.9 million in connection with development and regulatory milestones under the Amended St. Vincent's Agreement. Royalties for approved products resulting from the License Agreement will also be payable to St. Vincent's, and AVEO and Novartis will share that obligation equally. Under the License Agreement with Novartis, AVEO is required to maintain the Amended St. Vincent's Agreement in effect, and not enter into any amendment that would adversely affect Novartis' rights during the term of the License Agreement.

The foregoing summary of the License Agreement and the Amended SVH Agreement does not purport to be complete and is qualified in its entirety by the full text of the License Agreement and the Amended SVH Agreement, each of

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 17, 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 17, 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 17, 2015

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

EXHIBIT INDEX

Exhibit

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