AVEO PHARMACEUTICALS INC
Form 8-K
April 10, 2014

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 9, 2014

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.)**

650 East Kendall Street

Cambridge, Massachusetts 02142
(Address of Principal Executive Offices) (Zip Code)
Registrant s telephone number, including area code: (617) 299-5000

(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 April 9, 2014, AVEO Pharmaceuticals, Inc. (AVEO) entered into a worldwide agreement (the Agreement) with Biodesix, Inc. (Biodesix) to develop and commercialize AVEO s hepatocyte growth factor (HGF) inhibitory antibody ficlatuzumab, with Biodesix s proprietary companion diagnostic test, VeriStrat®, a serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced non-small cell lung cancer (NSCLC). AVEO completed a phase 2 clinical study evaluating ficlatuzumab in combination with gefitinib in first line NSCLC, which trial failed to demonstrate a statistically significant benefit in the intent- to-treat population. However, an exploratory analysis using VeriStrat identified a patient sub-population that experienced a progression-free survival and overall survival benefit on the combination therapy in the phase 2 trial.

Under the Agreement, AVEO grants Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize VeriStrat and Biodesix granted AVEO perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, with respect to the development and commercialization of ficlatuzumab; each license includes the right to sublicense, subject to certain exceptions. Pursuant to a joint development plan to be agreed upon by a joint steering committee, AVEO retains primary responsibility for clinical development of ficlatuzumab in a proof of concept clinical study of ficlatuzumab for NSCLC, in which VeriStrat will be used to select clinical trial subjects (the NSCLC POC Trial). The NSCLC POC Trial will be fully funded by Biodesix up to a maximum of $15 million (the Cap). After the Cap is reached, AVEO and Biodesix will share equally in the costs of the NSCLC trial, and AVEO and Biodesix will each be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed-upon by Biodesix and AVEO, including all milestone payments and royalties payable to third parties, if any.

Pending marketing approval of ficlatuzumab and subject to a commercialization agreement to be entered into after receipt of results from the NSCLC POC Trial, AVEO and Biodesix will share equally in commercialization profits and losses, subject to AVEO s right to be the lead commercialization party and to book worldwide sales of ficlatuzumab.

Biodesix is solely responsible for the VeriStrat development costs, as well as VeriStrat sales and marketing costs. Following the approval of the VeriStrat test as a companion diagnostic for ficlatuzumab, Biodesix will make the VeriStrat test available and use commercially reasonable efforts to seek reimbursement in all geographies where ficlatuzumab is approved. AVEO will reimburse Biodesix a pre-specified amount, under certain circumstances for VeriStrat tests performed.

Prior to the first commercial sale of ficlatuzumab and after the earlier of (i) the Cap being reached or (ii) the completion of the NSCLC POC Trial, each party has the right to elect to discontinue participating in further development or commercialization efforts with respect to ficlatuzumab (an Opt-Out). If either AVEO or Biodesix elects to Opt-Out (the Opting Out Party), then the Opting-Out Party shall not be responsible for any future costs associated in developing and commercializing ficlatuzumab other than any ongoing clinical studies. After election of an Opt-Out, the non-opting out party shall have sole decision-making authority with respect to further development and commercialization of ficlatuzumab. Additionally, the Opting-Out Party shall be entitled to receive, if ficlatuzumab is successfully developed and commercialized, a royalty equal to 10% of net sales of ficlatuzumab throughout the world, if any, subject to offsets under certain circumstances.

If Biodesix elects to opt-out, it will continue to be responsible for its development and commercialization obligations with respect to VeriStrat. If AVEO elects to opt-out, it will continue to make the existing supply of ficlatuzumab available to Biodesix for the purposes of enabling Biodesix to complete the development of ficlatuzumab, and Biodesix will have the right to commercialize ficlatuzumab.

Prior to any Opt-Out, the parties shall share equally in any payments received from a third party licensee; provided, however, after any Opt-Out, the Opting Out Party shall be entitled to receive only a reduced portion of such third party payments.

The agreement will remain in effect until the expiration of all payment obligations between the parties related to development and commercialization of ficlatuzumab, unless earlier terminated.

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

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibits are included in this report:

Exhibit No.	Description
99.1	Press release issued by AVEO on April 10, 2014

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 10, 2014

By: /s/ Tuan Ha-Ngoc
Tuan Ha-Ngoc
President and Chief Executive Officer