AVEO PHARMACEUTICALS INC
Form 8-K
November 12, 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): November 10, 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))

1.01 Entry into Definitive Material Agreement

On November 10, 2014 (the Effective Date), AVEO Pharmaceuticals, Inc., a Delaware corporation (AVEO), entered into a Research and Exclusive Option Agreement (the Option Agreement) with Ophthotech Corporation, a Delaware corporation (Ophthotech), pursuant to which AVEO has provided Ophthotech an exclusive option to enter into a definitive license agreement (the Option) under which AVEO would grant Ophthotech the right to develop and commercialize AVEO s small molecule vascular endothelial growth factor tyrosine kinase inhibitor, tivozanib, outside of Asia for the potential diagnosis, prevention and treatment of non-oncologic diseases or conditions of the eye in humans.

AVEO has granted to Ophthotech an exclusive, royalty free license or sublicense, as applicable, under intellectual property rights controlled by AVEO solely to perform the research and development activities related to the use of tivozanib as set forth in the development plan during the Option Period (as defined below). These activities include formulation work for ocular administration, preclinical research and the conduct of a Phase 1/2a, proof of concept clinical trial of a product containing tivozanib in patients with wet age-related macular degeneration (the POC Study).

Ophthotech is required to pay AVEO a fee of $500,000 within ten days of the Effective Date in consideration for the grant of the Option. AVEO is obligated to make available to Ophthotech, at no cost to Ophthotech, certain quantities of tivozanib hydrochloride including manufacturing additional quantities of tivozanib in the event stability data indicates that the current supply will expire prior to the end of February 2017.

During the Option Period, if Ophthotech elects to continue the development of tivozanib for non-oncologic diseases of the eye, AVEO is entitled to receive $2 million upon acceptance of the first Investigational New Drug application for the purpose of conducting a human clinical study of tivozanib in ocular diseases (the IND Submission Milestone Payment). AVEO is also entitled to receive $6 million (the Clinical Efficacy Milestone Payment) on the earlier of (a) December 31, 2016 and (b) the later to occur of: (i) the achievement of a clinical milestone in the POC Study (the Clinical Efficacy Milestone) and (ii) the earlier of (A) the date twelve (12) months after the Parties agreement as to the form and substance of the KHK Amendment (as defined below) or (B) the date ninety (90) days after the entry into the KHK Amendment, subject to Ophthotech s right to terminate the Option Agreement on 90 days written notice (the date on which such payment is due, the Clinical Efficacy Milestone Payment Trigger Date).

Ophthotech may exercise the Option at any time until the latest to occur of: (i) twelve (12) months after the achievement of the Clinical Efficacy Milestone, (ii) ninety (90) days after the Clinical Efficacy Milestone Payment Trigger Date, and (iii) thirty (30) days after AVEO and Ophthotech agree as to the definitive form of license agreement (the Option Period).

During the Option Period, AVEO will not grant a license to any third party that would preclude AVEO from being able to grant to Ophthotech the rights and licenses that are contemplated by the definitive license agreement, and AVEO will not engage in any research, development or commercialization of tivozanib in the field covered by the contemplated definitive license agreement, except as specified in the Option Agreement.

The terms of the Option Agreement are subject to AVEO s obligations to Kyowa Hakko Kirin (KHK) under a license agreement entered into by AVEO with KHK in 2006, pursuant to which AVEO acquired exclusive rights to develop and commercialize tivozanib for all human diseases outside of Asia (the KHK License Agreement). A percentage of all payments received by AVEO under the Option Agreement and any definitive license agreement must be paid to KHK. AVEO is required to maintain the KHK Agreement in effect, and not enter into any amendment or termination thereof that would adversely affect Opthotech s rights, during the Option Period.

During the Option Period, AVEO and Ophthotech are obligated to negotiate in good faith the form and substance of a definitive license agreement, as well as the form and substance of an amendment to the KHK License Agreement (the KHK Amendment), to modify certain rights and obligations of the parties and sublicensees thereunder, particularly with respect to rights to improvements that are not specifically related to tivozanib, and regulatory affairs matters.

Upon exercise of the Option, Ophthotech is required to pay AVEO a fee of $2 million in addition to the IND Submission Milestone Payment if such payment has not then been previously paid. If upon exercise of the Option, the Clinical Efficacy Milestone Payment Trigger Date has not yet occurred, AVEO shall be entitled to the Clinical Efficacy Milestone Payment at such time that the Clinical Efficacy Milestone Payment Date does occur if the license agreement remains in effect as of such date. The license agreement, if entered into upon Ophthotech s exercise of the Option, will provide for AVEO to be entitled to receive (i) $10 million upon meeting certain efficacy and safety endpoints in phase 2 clinical trials that would enable the commencement of a phase 3 clinical trial, (ii) $20 million upon marketing approval in the United States, (iii) $20 million upon marketing approval in the UK, Germany, Spain, Italy and France and (iv) up to $45 million in sales-based milestone payments. Ophthotech would also be required to pay tiered, double digit royalties, up to the mid-teens, on net sales of tivozanib or products containing tivozanib.

Either party may terminate the Option Agreement in the event of an uncured material breach of the Option Agreement by the other party which remains uncured for a period of ninety (90) days (or thirty (30) days for a breach relating to non-payment), or upon bankruptcy or like proceedings relating to the other party. Ophthotech may terminate the Option Agreement at any time upon ninety (90) days prior written notice to AVEO. In addition, AVEO may terminate the Option Agreement upon thirty (30) days prior written notice to Ophthotech if Ophthotech challenges certain patents controlled by AVEO related to tivozanib. Unless terminated as provided above, the Option Agreement will expire upon the expiration of the Option Period or the entry into the definitive license agreement.

The foregoing summary of the Option Agreement does not purport to be complete and is qualified in its entirety by the full text of the Option 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 November 11, 2014, AVEO issued a press release announcing its entry into the Option 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) The following exhibits are included in this report:

Exhibit No.	Description
99.1	Press Release dated November 11, 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: November 11, 2014

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