AVEO PHARMACEUTICALS INC
Form 8-K
February 16, 2011

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): February 16, 2011

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.)**

75 Sidney Street

Cambridge, Massachusetts **02139**
(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 February 16, 2011, AVEO Pharmaceuticals, Inc., a Delaware corporation, together with its wholly owned subsidiary AVEO Pharma Limited, a corporation established under the laws of England (collectively, AVEO), entered into a Collaboration and License Agreement (the Agreement) with Astellas Pharma Inc., a Japanese corporation, and its indirect wholly owned subsidiaries Astellas US LLC, a Delaware limited liability company, and Astellas Pharma Europe Limited, a corporation established under the law of England and Wales (collectively, Astellas), to develop and commercialize tivozanib, AVEO s product candidate currently in phase 3 clinical development, for the treatment of a broad range of cancers, including renal cell carcinoma and breast and colorectal cancers. The terms of the Agreement are subject to AVEO s obligations to Kyowa Hakko Kirin (KHK) under a license agreement entered into with KHK in 2006 pursuant to which AVEO acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia (the KHK License Agreement).

Under the terms of the Agreement, AVEO and Astellas will share responsibility for continued development and commercialization of tivozanib in the United States, Mexico and Canada (collectively, North America) and in Europe under the joint development plan and joint commercialization plan, respectively. Throughout the rest of the world (the Royalty Territory), excluding Asia, where KHK has retained all development and commercialization rights, Astellas will have an exclusive, royalty-bearing license to develop and commercialize tivozanib.

Pending successful approval of tivozanib by applicable regulatory agencies, AVEO will hold all marketing authorizations in North America, including any new drug application (NDA) in the United States, and Astellas will hold all marketing authorizations in Europe and the Royalty Territory.

AVEO, as the lead commercialization party in North America, will have lead responsibility for formulating the commercialization strategy for North America under the joint commercialization plan, with each of AVEO and Astellas responsible for conducting fifty percent (50%) of the detailing and medical affairs activities in North America. Astellas will have lead responsibility for commercialization activities in Europe under the joint commercialization plan, with AVEO responsible for conducting fifty percent (50%) of the medical affairs activities in the major European countries. AVEO will book all sales of tivozanib in North America, if any, and Astellas will book all sales of tivozanib in Europe, if any. All costs associated with each party s conduct of development and commercialization activities in North America (including any regulatory milestones and royalties associated with tivozanib in North America which may become payable by AVEO to KHK under the KHK License Agreement), and any resulting profits or losses, will be split equally between the parties. All costs associated with each party s conduct of development and commercialization activities in Europe, and any resulting profits or losses, will be split equally between the parties. As between the parties, AVEO will remain responsible for complying with its sublicense revenue sharing obligations to KHK under the KHK License Agreement in connection with the development and commercialization of tivozanib outside of North America.

The collaboration activities in North America and Europe will be governed by a joint steering committee and specified development, manufacturing and commercialization subcommittees, each comprised of an equal number of representatives from each party. The joint steering committee will be

responsible for approving, by unanimous consent, the joint development plan and various aspects of the joint commercialization plan for North America and Europe, including commercialization strategy.

AVEO will be responsible for manufacturing, through its third party manufacturer, all of Astellas s requirements for tivozanib for North America, Europe and the Royalty Territory, pursuant to clinical supply and commercial supply agreements with Astellas. However, Astellas will be solely responsible for packaging and labeling with respect to commercial supply of tivozanib for Europe and the Royalty Territory. The parties will share equally AVEO s manufacturing costs for supply of tivozanib for North America and Europe, and Astellas s manufacturing costs for packaging and labeling with respect to commercial supply of tivozanib for Europe, and Astellas is obligated to pay AVEO for supply of tivozanib for the Royalty Territory.

Each party is obligated to use commercially reasonable efforts to develop and commercialize tivozanib in each of the United States, Mexico and Canada, including the filing of an NDA in the United States to treat renal cell carcinoma, and to develop and commercialize tivozanib in each European country specified in the Agreement. Astellas is also obligated to use commercially reasonable efforts to develop and commercialize tivozanib in each country in the Royalty Territory.

During the term of the Agreement, neither party nor its controlled affiliates may commercialize anywhere in North America, Europe or the Royalty Territory any product that has a specified mechanism of action for any oncology indication, except that Astellas may commercialize specified compounds for hematological cancer. Astellas may also commercialize products (other than tivozanib) in the Royalty Territory, on a country-by-country basis, upon expiration of the applicable royalty term, and in North America and Europe upon expiration of all valid claims under the licensed patents.

The Agreement contains standstill provisions pursuant to which Astellas agrees not to acquire more than five percent (5%) of AVEO s equity until the first anniversary of the date that is the later of (a) grant of marketing approval in the United States, and (b) grant of marketing approval in Europe, subject to exceptions specified in the Agreement.

Under the Agreement, AVEO will receive an initial cash payments of $125 million, composed of a $75 million license fee and $50 million in research and development funding, both of which are nonrefundable and non-creditable against any other amount due under the Agreement. AVEO expects to retain net proceeds of approximately $96 million of the initial cash pay from Astellas, after payments to KHK and strategic, legal and financial advisors. AVEO is also eligible to receive an aggregate of approximately $1.3 billion in potential milestone payments, comprised of (i) up to $575 million in milestone payments upon achievement of specified clinical development and regulatory milestone events, including up to $90 million in milestone payments in connection with specified regulatory filings, and receipt of marketing approvals, for tivozanib to treat renal cell carcinoma in the United States and Europe, and (ii) approximately $780 million in milestone payments upon the achievement of specified sales levels. In addition, if tivozanib is successfully developed and launched in the Royalty Territory, Astellas will be required to pay to AVEO tiered, double digit royalties on net sales of tivozanib in the Royalty Territory, if any, subject to offsets under certain circumstances.

Unless terminated earlier in accordance with the Agreement, the Agreement expires (a) with respect to the Royalty Territory, on a country-by-country basis, upon the latest to occur of: (i) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the composition of tivozanib, (ii) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the use of tivozanib, but only for so long as no generic competition exists in such country, and (iii) twelve years from first commercial sale of tivozanib in such country, and (b) with respect to North America and Europe as a whole, upon the expiration of all payment obligations between the parties related to development and commercialization of tivozanib in North America and Europe. After the second anniversary of the effective date of the Agreement, Astellas has the right to terminate the Agreement, in its entirety or solely with respect to the Royalty Territory, at any time upon 180 days prior written notice to AVEO. Either party may terminate the Agreement with respect to a specified territory or country as set

forth in the Agreement, if the other party fails to cure a material breach related to such territory or country, as applicable. AVEO may also terminate the Agreement in its entirety upon a patent-related challenge by Astellas, its affiliates or sublicensees, if such patent-related challenge is not withdrawn within 30 days following AVEO s notice to Astellas of such termination.

The Agreement may not be assigned by either party without the consent of the other party, except that either party may assign the Agreement without the other party s consent (i) to any of its affiliates, or (ii) if such party merges with, or all or substantially all of its business or assets are acquired by, another entity (whether by merger, sale of assets, sale of stock or otherwise), to such party s merger partner or acquirer.

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 2.02 Results of Operations and Financial Condition

On February 16, 2011, we issued a press release announcing our results for the fourth quarter and fiscal year ended December 31, 2011. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 2.02 of Form 8-K and Exhibit 99.2 attached hereto shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On February 16, 2011, AVEO and Astellas issued a press release announcing their entry into the 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 8-K contains forward-looking statements of AVEO Pharmaceuticals, Inc. (AVEO or the Company) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, sho negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the Company s plans under its Collaboration and License Agreement and expectations regarding the continued development, commercialization and manufacturing of tivozanib, as well as tivozanib s therapeutic and commercial potential; the regulatory approval of tivozanib in the treatment of specified types of cancer, including breast, colorectal and renal cell; the Company s potential achievement of clinical, regulatory and commercial milestones; and the Company s potential to receive

royalties on net sales of tivozanib in specified territories. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including any failure to receive regulatory or marketing approvals for tivozanib, any breach or early termination of the Collaboration and License Agreement and those factors discussed in the Risk Factors and elsewhere in the Company s most recent Form 10-Q and its other filings with the Securities and Exchange Commission. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond the Company s control and that could materially affect actual results, performance or achievements. The forward-looking statements in this Form 8-K represent the Company s views as of the date of this Form 8-K. The Company anticipates that subsequent events and development will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it has no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the Company s views as of any date subsequent to the date of this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

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

Exhibit No.	Description
99.1	Press Release dated February 16, 2011
99.2	Earnings Press Release dated February 16, 2011

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: February 16, 2011

By: /s/ Tuan Ha-Ngoc
Tuan Ha-Ngoc

Chief Executive Officer