

AVEO PHARMACEUTICALS INC  
Form 424B3  
February 17, 2011

Filed Pursuant to Rule 424(b)(3)

File No. 333-170535

## **AVEO PHARMACEUTICALS, INC.**

**PROSPECTUS SUPPLEMENT NO. 3 DATED FEBRUARY 17, 2011**

**TO THE PROSPECTUS DATED NOVEMBER 10, 2010**

**4,500,000 SHARES**

**COMMON STOCK**

We are supplementing the prospectus included in the Registration Statement on Form S-1 dated November 10, 2010, which was declared effective by the Commission on November 23, 2010. The information contained herein supplements information set forth in the prospectus to include information contained in a Current Report on Form 8-K (except for the information furnished under Item 2.02 and the exhibits furnished thereto), which we filed with the Commission on February 16, 2011. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any amendments and supplements thereto.

**Investing in our common stock involves risks. See Risk Factors beginning on page 7 of the prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.**

The prospectus is supplemented as follows:

**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**  
**(State or Other Jurisdiction**  
  
**of Incorporation)**

**001-34655**  
**(Commission**  
  
**File Number)**

**04-3581650**  
**(IRS Employer**  
  
**Identification No.)**

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75 Sidney Street

Cambridge, Massachusetts  
(Address of Principal Executive Offices)

02139  
(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' 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' 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, show, and other similar expressions, and the 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:

<b>Exhibit No.</b>	<b>Description</b>
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



**FOR IMMEDIATE RELEASE**

**Astellas Pharma Inc.**

Corporate Communications

Astellas Pharma Inc.

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**AVEO Pharmaceuticals**

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**Astellas and AVEO Pharmaceuticals Enter into Worldwide Agreement to Develop and**

**Commercialize Tivozanib Outside of Asia**

*AVEO to Receive \$125 Million Upfront and \$1.3 Billion in Potential Milestones*

*Global 50/50 Profit Share with AVEO to Lead Commercialization in North America*

*and Astellas to Lead Commercialization in Europe*

*Agreement Accelerates Development of Tivozanib in Multiple Additional Cancer Indications*

**TOKYO, JAPAN and CAMBRIDGE, MASS., February 16, 2011** Astellas Pharma Inc. (TSE: 4503, Astellas ), a global pharmaceutical company, and AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO, AVEO ) today announced that they have entered into a worldwide agreement outside of Asia to develop and commercialize tivozanib, AVEO's lead product candidate designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors, for the treatment of a broad range of cancers. Tivozanib is currently being investigated in a pivotal, global Phase 3 clinical trial called TIVO-1 comparing the efficacy and safety of tivozanib to sorafenib (Nexavar®) in patients with advanced renal cell carcinoma (RCC), as well as in

additional clinical studies in other solid tumor types as a single agent and in combination with other anti-cancer agents.

Under the terms of the agreement, AVEO will receive an initial cash payment of \$125 million, composed of a \$75 million license fee and \$50 million in research and development funding. AVEO is also eligible to receive approximately \$1.3 billion in potential milestones comprised of \$575 million in clinical and regulatory milestones, including \$90 million in connection with the regulatory filings and market approval of tivozanib in RCC, as well as more than \$780 million in commercial milestones. Subject to regulatory approval, AVEO will lead commercialization of tivozanib in North America and Astellas will lead commercialization of tivozanib in the European Union (EU). The companies will share equally all North American and EU development and commercialization costs and profits for tivozanib. Outside of North America and EU, Astellas will be responsible for the development and commercialization costs of tivozanib and will be obligated to pay AVEO a tiered, double-digit royalty on sales in those territories. Pursuant to the terms of a licensing agreement between Kyowa Hakko Kirin and AVEO, Kyowa Hakko Kirin retains the rights to develop and commercialize tivozanib in Asia. AVEO will be responsible for the manufacturing of tivozanib. The upfront cash payment of \$125 million is not included in Astellas' current fiscal year (from April 1, 2010 to March 31, 2011) financial forecast.

We are very pleased to initiate this collaboration to co-develop and commercialize tivozanib with AVEO as it further supports our stated growth strategy of becoming a Global Category Leader in Oncology," said Masafumi Nogimori, president and chief executive officer of Astellas.

Oncology is a high-priority therapeutic area for Astellas. We share AVEO's vision for oncology drug development and confidence that the TIVO-1 trial is positioned for success. We also strongly believe tivozanib has significant potential in multiple cancers beyond RCC and we look forward to working together to maximize the market opportunities for tivozanib and improving the treatment of cancer patients.

This collaboration accomplishes the key strategic objectives we were seeking from a partnership for tivozanib which we believe positions us well to realize the full potential value of tivozanib in North America and Europe," stated Tuan Ha-Ngoc, president and chief executive officer of AVEO. In particular, the agreement enables us to build out our North American commercial infrastructure to not only launch tivozanib, but also to support future products emerging from our growing oncology pipeline. We are excited to work with Astellas in our efforts to bring tivozanib to market and, based upon our mutual expectation of a favorable outcome in the TIVO-1 trial, we will be moving forward to accelerate and expand the clinical development of tivozanib beyond RCC prior to top-line TIVO-1 data.

In 2010, AVEO both initiated and completed patient enrollment in TIVO-1, a global, randomized Phase 3 superiority trial evaluating the efficacy and safety of tivozanib compared to sorafenib in patients with clear cell RCC who had a prior nephrectomy. The primary endpoint of the trial is to compare the PFS of patients treated with tivozanib vs. sorafenib. AVEO expects to announce top-line data from TIVO-1 in mid-2011. In addition, tivozanib has demonstrated the ability to be combined with targeted therapies and chemotherapies in multiple indications in Phase 1b clinical trials. In conjunction with the ongoing TIVO-1 trial and combination studies, AVEO and Astellas

will jointly conduct and fund the expansion of tivozanib clinical development into additional solid tumor types.

RCC, or kidney cancer, is the eighth most commonly diagnosed cancer in men and women in the U.S<sup>1</sup>. Worldwide during 2010, it was estimated that more than 200,000 people would be diagnosed and more than 100,000 people would die from the disease<sup>2</sup>. RCC, which accounts for 90 percent of all malignant kidney tumors, is highly resistant to chemotherapy<sup>3</sup>. Despite advances in RCC therapies, significant unmet need persists. Currently available therapies provide patients less than one year of survival without disease progression and are associated with significant toxicities<sup>4</sup>.

#### **Conference Call Information**

AVEO will discuss this corporate development during its fourth quarter 2010 financial results conference call which is scheduled for today at 5:00 p.m. (EST). The call can be accessed by dialing 1-866-356-4441 (domestic) or 1-617-597-5396 (international) five minutes prior to the start of the call and providing the passcode 88594394. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-888-286-8010 (domestic) or 1-617-801-6888 (international), providing the passcode 36100132. The replay of the call will be available for two weeks from the date of the live call.

A live, listen-only webcast of the conference call can also be accessed by visiting the investors section of the AVEO website at [investor.aveopharma.com](http://investor.aveopharma.com). A replay of the webcast will be archived on the company's website for two weeks following the call.

#### **About Tivozanib**

Tivozanib, an investigational new drug, is designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors. Each of the three receptors of the VEGF pathway play an important role in angiogenesis (the formation of new blood vessels), which is critical in cancer cell growth. Tivozanib's high level of potency across VEGF receptors 1, 2 and 3 is designed to potently block the VEGF pathway. Tivozanib's high level of selectivity for VEGF receptors 1, 2 and 3 is designed to minimize off-target toxicities, and its oral, one capsule, once-daily administration may enhance convenience for patients.

In a large, multi-center, randomized Phase 2 clinical trial, the subset of patients with clear cell renal cell carcinoma (RCC) who had a prior nephrectomy receiving tivozanib therapy achieved 14.8 months progression free survival (PFS), the longest PFS reported for a single-agent therapy in this population<sup>5</sup>. The safety profile of tivozanib observed in the Phase 2 trial was notable for the minimal off-target toxicities often associated with VEGF, multi-targeted therapies. There was a low incidence of diarrhea, fatigue, stomatitis and hand-foot syndrome. Hypertension and dysphonia (hoarseness of voice), which are mechanism-related side effects associated with angiogenesis inhibitors, were the most commonly reported drug-related side effects, and both were manageable and reversible<sup>5</sup>. AVEO has completed patient enrollment in TIVO-1, a global, randomized, controlled Phase 3 clinical trial evaluating the efficacy of tivozanib compared to sorafenib (Nexavar<sup>®</sup>) in this same patient population. The primary endpoint of the trial is to

compare the PFS of patients treated with tivozanib vs. sorafenib. AVEO expects to announce top-line data from TIVO-1 in mid-2011.

Tivozanib has also demonstrated the ability to be combined with both targeted therapies and chemotherapies at the full dose and schedule<sup>6-8</sup>. In Phase 1b clinical trials to date, tivozanib has demonstrated safety in combination with temsirolimus (Torisel<sup>®</sup>) in patients with RCC<sup>6</sup>, FOLFOX6 chemotherapy regimen in patients with colorectal cancer<sup>7</sup>, and paclitaxel (Taxol<sup>®</sup>) in patients with metastatic breast cancer<sup>8</sup>. Tivozanib is also being evaluated in a Phase 1b trial in combination with oral capecitabine (Xeloda<sup>®</sup>) in patients with metastatic breast and colorectal cancers.

#### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 16,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas acquired OSI Pharmaceuticals, Inc. in June 2010 to add oncology infrastructure; OSI and AVEO have been collaborating on drug discovery and translational research related to OSI's novel epithelial-mesenchymal transition (EMT) agents and proprietary patient selection biomarkers since 2007. For more information on Astellas Pharma Inc., please visit our website at <http://www.astellas.com/en>.

#### **About AVEO**

AVEO Pharmaceuticals (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. The company's lead product candidate, tivozanib, is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in patients with advanced renal cell carcinoma, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, ficlatuzumab (AV-299), is a potent, functional anti-HGF/c-MET pathway antibody that is currently in Phase 2 clinical development. AVEO's proprietary Human Response Platform is designed to offer the company a unique advantage in cancer drug development and has provided a discovery engine for multiple therapeutic targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at [www.aveopharma.com](http://www.aveopharma.com).

#### **Cautionary Note Regarding Forward-Looking Statements**

*This press release contains forward-looking statements of AVEO that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, should, continue, contemplate, or the 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 expected strategic, operational and financial benefits of AVEO's collaboration with Astellas; AVEO's expectations about the receipt of license fees, milestones and other payments under the agreement with Astellas; tivozanib's therapeutic and commercial potential; AVEO's expectation regarding a favorable outcome in the TIVO-1 trial; AVEO's plans to accelerate the development of tivozanib in other indications and combinations; the potential therapeutic advantages and benefits of ficlatuzumab; plans and timelines for AVEO's ongoing and planned preclinical studies and clinical trials and the development of our commercial infrastructure; and AVEO's plans to leverage its Human Response Platform. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: the potential inability of Astellas and AVEO to fully realize the benefits contemplated by their collaboration agreement; difficulties, delays and failures in AVEO's ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and AVEO's other product candidates; the possibility that AVEO will not obtain positive results in its Phase 3 clinical trial of tivozanib and/or that tivozanib will not achieve the regulatory approvals required for its successful commercialization either in the U.S. or abroad; potential delays in data availability from TIVO-1; AVEO's inability to obtain and maintain adequate protection for intellectual property rights relating to AVEO's product candidates and technologies; unplanned operating expenses; AVEO's inability to raise substantial additional funds to achieve AVEO's goals; adverse general economic and industry conditions; and those risks discussed in Risk Factors and elsewhere in AVEO's Quarterly Report on Form 10-Q for the period ended September 30, 2010 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent AVEO's views as of the date of this press release. 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 AVEO's views as of any date subsequent to the date of this press release.*

1. [www.cancer.org/cancer/kidneycancer](http://www.cancer.org/cancer/kidneycancer); <http://seer.cancer.gov/statfacts/html/kidrp.html>
2. Jemal A, Murray T, Ward E, et al. Cancer statistics, 2005. CA Cancer J Clin. 2005;55(1):10-30.  
Parkin DM, Bray F, Ferlay J, et al. Global cancer statistics, 2002. CA Cancer J Clin. 2005;55(2):74-108.

Franklin JR, Figlin R, Belldegrun A. Renal cell carcinoma: basic biology and clinical behavior. Semin Urol Oncol. 1996; 14:208.

3. Decision Resources December 2010 All Rights Reserved
4. Package inserts  
Rini B, et al. J Clin Oncol. 2009;27(27):4462-4468

Motzer RJ, et al. 2009

Esclier B, et al. 2009

5. Bhargava P, et al. Poster presented at the ASCO Annual Meeting; June 4-8, 2010; Chicago, IL. Abstract 4599. In the tivozanib Phase 2 trial, the intent to treat patient population (n=272) achieved 11.8 months median PFS.
6. Kabbinavar FF, et al. Presented at the International Kidney Cancer Symposium; October 1-2, 2010; Chicago, IL.
7. Eskens FALM, et al. Poster presented at the EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics; November 16-19, 2010; Berlin, Germany
8. Mayer EL, et al. Poster presented at the SABCS Annual Meeting; December 8-12, 2010; San Antonio, TX.

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## NEWS RELEASE

For Immediate Release

**Investor Contact:**

Monique Allaire,

AVEO Pharmaceuticals, Inc.

(617) 299-5810

**Media Contact:**

Caton Lovett,

Pure Communications

(910) 232-7166

### AVEO Reports 2010 Financial Results and Highlights Progress with Tivozanib and Ficlatusumab

**CAMBRIDGE, Mass., February 16, 2011** AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today reported consolidated 2010 financial results and reviewed key 2010 accomplishments.

Last year was a transformational year for AVEO with our initial public offering, rapid enrollment of our pivotal Phase 3 trial for tivozanib, TIVO-1, and regaining full rights to ficlatuzumab, said Tuan Ha-Ngoc, president and chief executive officer of AVEO. As we begin 2011, we expect to continue the momentum of 2010 by focusing on the successful execution of our clinical-stage programs while simultaneously building a fully integrated oncology therapeutics company. These efforts are off to a solid start with the announcement today of our development and commercialization agreement for tivozanib with Astellas.

#### Full Year 2010 Financial Results

AVEO ended 2010 with cash, cash equivalents and marketable securities of \$140.2 million.

Total collaboration revenues for 2010 were \$44.7 million compared with \$20.7 million for 2009. The primary driver for the increase was revenues related to AVEO's strategic alliances in 2010, including an \$8.5 million milestone payment from Merck for the start of the Phase 2 trial of ficlatuzumab and a \$5 million milestone payment from Biogen Idec for the selection of AV-203 as the clinical candidate in AVEO's anti-ErbB3 program.

Research and development (R&D) expense for 2010 was \$86.3 million compared with \$51.8 million for 2009. The increase in R&D spending was primarily driven by clinical costs associated with TIVO-1, AVEO's global Phase 3 clinical trial of tivozanib in patients with advanced RCC, which commenced enrollment in February 2010.

General and administrative (G&A) expense for 2010 was \$14.8 million compared with \$10.1 million for 2009. The primary driver of the increase in G&A spending were increases in personnel-related expenses and in costs associated with being a publicly traded company.

Net loss for 2010 was \$58.8 million, or \$2.30 per common share (based on 25.6 million weighted average shares outstanding), compared with \$44.1 million, or \$27.43 per common share, for 2009 (based on 1.6 million weighted average shares outstanding).

The difference in the number of weighted average shares outstanding primarily resulted from AVEO's initial public offering in March 2010, as well as the conversion of all preferred stock to common stock in connection with the initial public offering.

**Astellas Collaboration** AVEO announced today that it has entered into an agreement with Astellas Pharma Inc. to jointly develop and commercialize tivozanib worldwide outside of Asia. As part of this agreement, AVEO will receive \$125 million in up-front payments from Astellas. For additional information regarding AVEO's collaboration agreement with Astellas, please refer to the press release that was issued on February 16, 2011.

## Financial Guidance

AVEO expects to end 2011 with at least \$125 million in cash, cash equivalents and marketable securities, including approximately \$96 million in net proceeds (after payments to Kyowa Hakko Kirin and strategic, legal and financial advisors) from the initial up-front cash payment of \$125 million in connection with the Astellas Collaboration. AVEO anticipates that this capital should allow it to fund its operations through 2012 based on its updated operating plans, which includes an accelerated and expanded clinical development plan for tivozanib in breast and colorectal cancers.

## 2010 Key Accomplishments

**Achieved notable results in Phase 2 clinical trial of tivozanib:** At ASCO in June 2010, AVEO announced the results from its Phase 2 placebo-controlled, randomized discontinuation trial assessing the efficacy and safety of once-daily, oral tivozanib in 272 patients with locally advanced or metastatic renal cell carcinoma (RCC). Median progression-free survival (PFS) among all 272 patients (as assessed by independent radiological review) was 11.8 months, and median PFS of patients with clear cell RCC who had undergone a prior nephrectomy was 14.8 months. The safety profile of tivozanib observed in the Phase 2 trial was notable for the minimal off-target toxicities often associated with VEGF, multi-targeted therapies. There was a low incidence of diarrhea, fatigue, stomatitis and hand-foot syndrome. Hypertension and dysphonia (hoarseness of voice), which are mechanism-related side effects associated with angiogenesis inhibitors, were the most commonly reported drug-related side effects, and both were manageable and reversible.

**Completed enrollment of pivotal tivozanib Phase 3 trial, TIVO-1:** In August 2010, AVEO achieved its target enrollment for its global Phase 3 pivotal trial called TIVO-1 comparing the efficacy and safety of tivozanib to sorafenib (Nexavar<sup>®</sup>) in patients with clear cell RCC who have undergone a prior nephrectomy. The primary endpoint of the trial is to compare the PFS of patients treated with tivozanib vs. sorafenib. AVEO initiated patient enrollment in TIVO-1 in February of 2010 and successfully reached the target enrollment of 500 patients six months ahead of schedule. The company expects to announce top-line data from this trial in mid-2011.

**Reported early clinical data demonstrating combinability of tivozanib at full dose and schedule:** In Phase 1b clinical trials to date, tivozanib has demonstrated safety in combination with temsirolimus (Torisel<sup>®</sup>) in patients with RCC, FOLFOX6 chemotherapy regimen in patients with colorectal cancer, and paclitaxel (Taxol<sup>®</sup>) in patients with metastatic breast cancer. In November 2010, AVEO also initiated a Phase 1b trial evaluating tivozanib in combination with oral capecitabine (Xeloda<sup>®</sup>) in patients with metastatic breast and colorectal cancers.

**Regained worldwide rights to ficlatuzumab (AV-299):** In September 2010, AVEO announced that it regained worldwide rights from Merck (through its subsidiary, Schering Corporation) to develop and commercialize ficlatuzumab, AVEO's potent, anti-hepatocyte growth factor (HGF) antibody candidate. Ficlatuzumab was discovered by AVEO through its Human Response Platform. Data from Phase 1 clinical trials of ficlatuzumab indicate the potential for a favorable tolerability profile and good combinability with EGFR inhibitors, erlotinib (Tarceva<sup>®</sup>) and gefitinib (Iressa<sup>®</sup>). In June 2010, AVEO initiated a Phase 2 clinical trial evaluating ficlatuzumab in combination with gefitinib versus gefitinib monotherapy in the first-line setting in patients with non-small cell lung cancer (NSCLC). Top-line data from the ficlatuzumab Phase 2 trial are expected in early 2012.

**Completed an initial public offering and private placement raising a net total of approximately \$137 million:** In March 2010, AVEO completed its initial public offering of 9,000,000 shares of its common stock at a price of \$9.00 per share. In addition, the underwriters of the offering exercised their option to purchase an additional 968,539 shares of common stock to cover over-allotments. Net proceeds to AVEO from the initial public offering were approximately \$80.3 million. In November 2010, AVEO completed a private placement of 4.5 million shares of its common stock with a select group of institutional and accredited investors at a price of \$13.50 per share. Net proceeds to AVEO from the private placement were approximately \$56.6 million.

### Upcoming Activities

AVEO expects to present at the following investor conferences:

- RBC Capital Markets 2011 Healthcare Conference, March 2-3, in New York City.
- Citi 2011 Global Health Care Conference, March 1-3, in New York City.
- Cowen and Company 31<sup>st</sup> Annual Health Care Conference, March 7-9, in Boston, Mass.
- Barclays Capital 2011 Global Healthcare Conference, March 15-17, in Miami, Fla.

AVEO expects to present at the following oncology and pharmacology meetings:

- American Society of Clinical Oncology (ASCO) 2011 Genitourinary Cancers Symposium, February 17-19, at the Orlando World Center Marriott.
- 112<sup>th</sup> Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASPCT), March 2-5, at the Hyatt Regency Dallas at Reunion.
- 7<sup>th</sup> Annual Conference of the Hematology/Oncology Pharmacy Association (HOPA), March 23-26, at the Grand America Hotel in Salt Lake City, Utah.
- 36<sup>th</sup> Annual Conference of the Oncology Nursing Society (ONS), April 28-May 1, at the Boston Convention and Exhibit Center.

### Today's Conference Call and Webcast Reminder

The AVEO management team will host a conference call at 5:00 p.m. (EST) today. The call can be accessed by dialing 1-866-356-4441 (domestic) or 1-617-597-5396 (international) five minutes prior to the start of the call and providing the passcode 88594394. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-888-286-8010 (domestic) or 1-617-801-6888 (international), providing the passcode 36100132. The replay of the call will be available for two weeks from the date of the live call.

A live, listen-only webcast of the conference call can also be accessed by visiting the investors section of the AVEO website at [investor.aveopharma.com](http://investor.aveopharma.com). A replay of the webcast will be archived on the company's website for two weeks following the call.

### About AVEO

AVEO Pharmaceuticals (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. The company's lead product candidate, tivozanib, is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in patients with advanced renal cell carcinoma, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, ficlatuzumab (AV-299), is a potent, functional anti-HGF/c-MET pathway antibody that is currently in Phase 2 clinical development. AVEO's proprietary Human Response Platform is designed to offer the company a unique advantage in cancer drug development and has provided a discovery engine for multiple therapeutic targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at [www.aveopharma.com](http://www.aveopharma.com).

### Cautionary Note Regarding Forward-Looking Statements

*This press release contains forward-looking statements of AVEO that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words anticipate, believe, estimate, expect, intend, may, plan, target, potential, will, could, should,*



*seek, or the 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 successful design and execution of AVEO's clinical-stage programs; AVEO's plans to expand and accelerate its clinical development plan for tivozanib in breast and colorectal cancer; AVEO's plans to continue to build a fully integrated oncology company; tivozanib's therapeutic and commercial potential; AVEO's estimates for its 2011 financial performance (including its expected year-end cash balance), AVEO's estimates regarding its ability to fund its operations through 2012; the expected timing of TIVO-1 trial results; the expected timing of data from the ficlatuzumab Phase 2 clinical trial; the potential therapeutic advantages and benefits of ficlatuzumab; and AVEO's plans to leverage its Human Response Platform. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: difficulties, delays and failures in AVEO's ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib, ficlatuzumab and AVEO's other product candidates; the possibility that AVEO will not obtain positive results in its Phase 3 clinical trial of tivozanib and/or that tivozanib will not achieve the regulatory approvals required for its successful commercialization either in the U.S. or abroad; potential delays in data availability from TIVO-1 and/or the ficlatuzumab Phase 2 clinical trial; AVEO's inability to obtain and maintain adequate protection for intellectual property rights relating to AVEO's product candidates and technologies; unplanned operating expenses; AVEO's inability to raise substantial additional funds to achieve AVEO's goals; adverse general economic and industry conditions; and those risks discussed in Risk Factors and elsewhere in AVEO's Quarterly Report on Form 10-Q for the period ended September 30, 2010 and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent AVEO's views as of the date of this press release. AVEO anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date subsequent to the date of this press release.*

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## AVEO Pharmaceuticals, Inc.

## Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	December 31, 2010	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 45,791	\$ 45,290
Marketable securities	94,407	6,011
Accounts receivable	391	487
Prepaid expenses and other current assets	4,864	1,306
<b>Total current assets</b>	<b>145,453</b>	<b>53,094</b>
Property and equipment, net	4,532	4,197
Other assets	456	1,946
Restricted cash	607	607
<b>Total assets</b>	<b>\$ 151,048</b>	<b>\$ 59,844</b>
<b>Liabilities and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 9,247	\$ 7,491
Accrued expenses	10,121	7,389
Loans payable, net of discount	5,766	7,467
Deferred revenue	16,693	11,782
Deferred rent	266	176
<b>Total current liabilities</b>	<b>42,093</b>	<b>34,305</b>
Loans payable, net of current portion and discount	17,636	12,278
Deferred revenue, net of current portion	16,509	23,320
Deferred rent, net of current portion	553	819
Other liabilities	2,487	1,249
Warrants to purchase convertible preferred stock		1,459
Convertible preferred stock, \$.001 par value: 0 and 80,624 shares authorized at December 31, 2010 and 2009, respectively; 0 and 75,917 shares issued and outstanding at December 31, 2010 and 2009, respectively		156,705
<b>Total liabilities</b>		<b>156,705</b>
Stockholders equity (deficit):		
Preferred Stock, \$.001 par value: 5,000 and 0 shares authorized at December 31, 2010 and 2009, respectively; no shares issued and outstanding at December 31, 2010 and 2009, respectively		
Common stock, \$.001 par value: 100,000 and 25,500 shares authorized at December 31, 2010 and 2009, respectively; 35,604 and 1,641 shares issued and outstanding at December 31, 2010 and 2009, respectively	36	2
Additional paid-in capital	308,268	7,432
Accumulated other comprehensive income	(20)	
Accumulated deficit	(236,514)	(177,725)
<b>Total stockholders equity (deficit)</b>	<b>71,770</b>	<b>(170,291)</b>
<b>Total liabilities and stockholders equity (deficit)</b>	<b>\$ 151,048</b>	<b>\$ 59,844</b>

## AVEO Pharmaceuticals, Inc.

## Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2010	2009	2010	2009
Collaboration revenue	\$ 11,957	\$ 6,036	\$ 44,682	\$ 20,719
Operating expenses:				
Research and development	17,478	13,466	86,345	51,792
General and administrative	4,564	2,616	14,763	10,120
	22,042	16,082	101,108	61,912
Loss from operations	(10,085)	(10,046)	(56,426)	(41,193)
Other income and expense:				
Other income (expense), net	760	(60)	900	(333)
Interest expense	(1,028)	(670)	(3,389)	(2,811)
Interest income	39	23	126	144
Other income (expense), net	(229)	(707)	(2,363)	(3,000)
Net loss before taxes	(10,314)	(10,753)	(58,789)	(44,193)
Tax benefit		37		100
Net loss	\$ (10,314)	\$ (10,716)	\$ (58,789)	\$ (44,093)
Net loss per share basic and diluted	\$ (0.30)	\$ (6.57)	\$ (2.30)	\$ (27.43)
Weighted-average number of common shares used in net loss per share basic and diluted	33,914	1,630	25,582	1,607