

AVEO Reports Third Quarter 2010 Financial Results and Recent Developments

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Current Financial Position Supports Expanding and Accelerating Clinical Development Plans for Tivozanib

CAMBRIDGE, Mass., Nov 04, 2010 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced updated financial guidance and third quarter financial results, as well as recent developments.

"During the third quarter, we achieved two significant developments - completing enrollment of TIVO-1, our Phase 3 clinical trial of tivozanib in patients with advanced kidney cancer, which advances the expected timeline for top-line data for TIVO-1 by six months to mid-2011, and regaining worldwide rights to AV-299, our internally-discovered anti-HGF antibody," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "We now have two late-stage, unencumbered assets with potential to advance toward commercialization. We believe that these events, coupled with the proceeds from our recently-completed private placement, position AVEO well for achieving our vision of becoming a fully integrated cancer therapeutics company and making a meaningful contribution to the treatment of patients with cancer."

Financing and Financial Guidance

- On October 29, 2010, the company announced that it had entered into a definitive agreement with respect to the private placement of 4.5 million shares of its unregistered common stock at \$13.50 per share to a group of institutional and accredited investors. AVEO completed the private placement on November 3, 2010, resulting in approximately \$57 million in net proceeds to AVEO.
- With the net proceeds from the private placement financing, AVEO expects to end 2010 with at least \$100 million in cash and marketable securities.

Third Quarter 2010 Financial Results

- AVEO ended the third quarter of 2010 with cash and marketable securities of \$87.0 million.
- Total collaboration revenues for the third quarter of 2010 were \$6.2 million compared with \$5.9 million for the third quarter of 2009.
- Research and development (R&D) expense for the third quarter of 2010 was \$20.3 million compared with \$16.5 million for the same period of 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 expense was \$3.6 million for the third quarter of 2010 compared with \$2.5 million for the third quarter of 2009. The primary driver of the increase in spending was personnel-related expenses.
- Net loss for the third quarter of 2010 was \$18.6 million, or \$0.60 per common share (based on 30.9 million weighted average shares outstanding), compared with \$13.8 million, or \$8.56 per common share, for the third quarter of 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.

Recent Developments

- **Completed Enrollment of TIVO-1:** In August, AVEO announced that it achieved its enrollment target for TIVO-1 in patients with advanced renal cell carcinoma (RCC). AVEO initiated patient enrollment in TIVO-1 in February of this year and successfully reached the target enrollment of 500 patients six months ahead of schedule. The company expects top-line data from this trial in mid-2011.
- **Presented Previously Announced Phase 2 Tivozanib Data at IKCS and ESMO:** AVEO presented previously announced data from the Phase 2 randomized discontinuation trial with tivozanib showing that the median progression-free survival (PFS) achieved by patients with advanced clear cell RCC who had undergone a prior nephrectomy was 14.8 months. This is the same patient population being studied in the TIVO-1 Phase 3 trial. Median PFS among all 272 patients in the Phase 2 trial was 11.8 months. Off-target toxicities commonly associated with other VEGF-directed targeted

therapies, such as mucositis, fatigue and hand-foot syndrome, were notably low during treatment with tivozanib in the Phase 2 trial.

- **Regained Worldwide Rights to AV-299:** In September, AVEO announced that it regained worldwide rights from Merck (through its subsidiary, Schering Corporation) to develop and commercialize AV-299, AVEO's anti-hepatocyte growth factor (HGF) antibody candidate, effective as of December 27, 2010. AV-299 is a potent, anti-HGF antibody that was discovered by AVEO through its Human Response Platform(TM). Data from Phase 1 clinical trials of AV-299 indicate the potential for a favorable tolerability profile and good combinability with EGFR inhibitors, erlotinib (Tarceva^(R)) and gefitinib (Iressa^(R)). In June 2010, AVEO initiated a Phase 2 clinical trial evaluating AV-299 in combination with gefitinib versus gefitinib monotherapy in patients with non-small cell lung cancer (NSCLC). In conjunction with the Phase 2 trial initiation, AVEO received an \$8.5 million milestone payment from Merck under the terms of the collaboration agreement. As of the effective date of the return of right from Merck, the company will be responsible for future development, manufacturing and commercialization funding for the AV-299 program. Top-line efficacy data from the AV-299 Phase 2 trial are expected in 2012.
- **Awarded approximately \$733,000 in Grants under Patient Protection and Affordable Care Act:** In November, AVEO was informed that it has been awarded three separate grants totaling approximately \$733,000 under the Patient Protection and Affordable Care Act of 2010. These grants support both clinical and pre-clinical development activities related to tivozanib, AV-299, as well as AVEO's discovery stage programs and proprietary Human Response Platform (TM).

Upcoming Activities

AVEO expects to present at the following investor conferences:

- 22nd Annual Piper Jaffray Health Care Conference, New York City, November 30-December 1, 2010
- J.P. Morgan SMid Cap Conference, New York City, December 2-3, 2010
- Deutsche Bank's 2010 BioFEST, Boston, December 14-15, 2010

AVEO expects to have a presence at the following oncology meetings:

- 28th Annual Chemotherapy Foundation Symposium (CFS), New York City, November 9-13, 2010
- 22nd Annual Symposium of the European Organization for Research and Treatment of Cancer-National Cancer Institute-American Association for Cancer Research (EORTC-NCI-AACR), Berlin, Germany, November 16-19, 2010
- 33rd Annual San Antonio Breast Cancer Symposium (SABCS), San Antonio, Texas, December 8-12, 2010

Today's Conference Call and Webcast Reminder

The AVEO management team will host a conference call discussing the company's third quarter financial results, recent developments and 2010 financial guidance today at 10:00 a.m. (EDT). The call can be accessed by dialing 1-866-713-8563 (domestic) or 1-617-597-5311 (international) five minutes prior to the start of the call and providing the passcode 21275874. 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 75499695. 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. 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) integrates a proprietary cancer biology platform with drug development and commercial expertise in its efforts to discover and develop targeted cancer therapeutics. The company's lead product, tivozanib, is an oral, triple VEGF receptor inhibitor with a highly differentiated profile. Tivozanib is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in advanced kidney cancer, as well as additional clinical studies in other solid tumor types. AVEO's second product candidate, AV-299, is a potent, functional anti-HGF antibody that is currently in Phase 2 development. AVEO's proprietary, integrated cancer biology platform offers the company a unique advantage in oncology drug development and has provided a discovery engine for high-value 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.

Forward-Looking Statements

Statements in this press release about AVEO's future expectations, plans and prospects, including statements about AVEO becoming a fully integrated cancer therapeutics company and making a meaningful contribution to the treatment of patients living with cancer, AVEO's estimates for its 2010 financial performance (including its expected year-end cash balance), the expected timing of TIVO-1 trial results, the expected timing of data from the AV-299 Phase 2 trial, AVEO's proprietary, integrated cancer biology platform offering AVEO a unique advantage in oncology drug development, and other statements containing the words "believes," "anticipates," "plans," "expects," "will," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: AVEO's ability to successfully research, develop, obtain and maintain regulatory approvals for tivozanib, AV-299 and its other product candidates; AVEO's inability to obtain and maintain adequate protection for intellectual property rights relating to AVEO's product candidates and technologies; AVEO's ability to maintain its strategic partnerships and risks related to the failure of AVEO's strategic partners to meet their obligations under their agreements with AVEO; AVEO's ability to consummate additional strategic partnerships on favorable terms; unplanned operating expenses; AVEO's inability to raise substantial additional funds to achieve its goals; general economic and industry conditions; and other factors discussed in the "Risk Factors" section of AVEO's most recent Form 10-Q filed with the Securities and Exchange Commission, and in other filings that AVEO periodically makes with the SEC. In addition, the forward-looking statements included 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 AVEO's views to change. However, while AVEO may elect to update these forward-looking statements at some point in the future, AVEO specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing AVEO's views as of any date subsequent to the date of this press release.

AVEO Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	For the Three Months		For the Nine Months	
	Ended September 30,		Ended September 30,	
	2010	2009	2010	2009
Collaboration revenue	\$ 6,222	\$ 5,917	\$ 32,725	\$ 14,683
Operating expenses:				
Research and development	20,252	16,526	68,867	38,326
General and administrative	3,611	2,509	10,199	7,504
	23,863	19,035	79,066	45,830
Loss from operations	(17,641)	(13,118)	(46,341)	(31,147)
Other income and expense:				
Other income (expense), net	10	(56)	140	(273)
Interest expense	(1,029)	(678)	(2,361)	(2,141)
Interest income	52	54	87	121
Other income (expense), net	(967)	(680)	(2,134)	(2,293)
Net loss before taxes	(18,608)	(13,798)	(48,475)	(33,440)
Tax benefit				63
Net loss	\$(18,608)	\$(13,798)	\$(48,475)	\$(33,377)
Net loss per share--basic and diluted	\$ (0.60)	\$ (8.56)	\$ (2.13)	\$ (20.87)
Weighted-average number of common shares used in net loss per share--basic and diluted	30,889	1,611	22,773	1,599

AVEO Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,046	\$ 45,290
Marketable securities	46,976	6,011
Accounts receivable	220	487
Prepaid expenses and other current assets	3,598	1,306
Total current assets	90,840	53,094
Property and equipment, net	4,488	4,197
Other assets	577	1,946
Restricted cash	607	607
Total assets	\$ 96,512	\$ 59,844
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 8,797	\$ 7,491
Accrued expenses	9,111	7,389
Loans payable, net of discount	3,398	7,467
Deferred revenue	11,945	11,782
Deferred rent	264	176
Total current liabilities	33,515	34,305
Loans payable, net of current portion and discount	19,742	12,278
Deferred revenue, net of current portion	16,736	23,320
Deferred rent, net of current portion	621	819
Other liabilities	2,487	1,249
Warrants to purchase convertible preferred stock	-	1,459
Convertible preferred stock, \$.001 par value: 80,624 and no shares authorized at December 31, 2009 and September 30, 2010, respectively; 75,917 shares issued and outstanding at December 31, 2009 and no shares outstanding at September 30, 2010	-	156,705
Stockholders' equity (deficit):		
Preferred Stock, \$.001 par value: no shares and 5,000 shares authorized at December 31, 2009 and September 30, 2010, respectively; no shares issued and outstanding at December 31, 2009 and September 30, 2010, respectively	-	-
Common stock, \$.001 par value: 25,500 and 100,000 shares authorized at December 31, 2009 and September 30, 2010, respectively; 1,641 and 30,935 shares issued and outstanding at December 31, 2009 and September 30, 2010, respectively	-	2
Additional paid-in capital	249,580	7,432
Accumulated other comprehensive income	-	-
Accumulated deficit	(226,200)	(177,725)
Total stockholders' equity (deficit)	23,411	(170,291)
Total liabilities and stockholders' equity (deficit)	\$ 96,512	\$ 59,844

SOURCE: AVEO Pharmaceuticals, Inc.

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