AVEO Reports 2010 Financial Results and Highlights Progress with Tivozanib and Ficlatuzumab

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CAMBRIDGE, Mass., Feb 16, 2011 (BUSINESS WIRE) -- 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(R)) 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(R)) in patients with RCC, FOLFOX6 chemotherapy regimen in patients with colorectal cancer, and paclitaxel (Taxol(R)) in patients with metastatic breast cancer. In November 2010, AVEO also initiated a Phase 1b trial evaluating tivozanib in combination with oral capecitabine (Xeloda(R)) 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(TM). Data from Phase 1 clinical trials of ficlatuzumab 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 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 31st 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.
- 112th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASPCT), March 2-5, at the Hyatt Regency Dallas at Reunion.
- 7th Annual Conference of the Hematology/Oncology Pharmacy Association (HOPA), March 23-26, at the Grand America Hotel in Salt Lake City, Utah.
- 36th 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. 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(TM) 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.

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 andexecution 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' 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(TM).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.

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

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

	December 31, 2010	December 31, 2009
Assets		
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
Total current assets	145,453	53,094
Property and equipment, net	4,532	4,197
Other assets	456	1,946
Restricted cash	607	607
Total assets	$ 151,048	$ 59,844
Liabilities and stockholders' equity (deficit)		
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
Total current liabilities	42,093	34,305
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
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)
Total stockholders' equity (deficit)	71,770	(170,291)
Total liabilities and stockholders' equity (deficit)	$ 151,048	$ 59,844

SOURCE: AVEO Pharmaceuticals, Inc.

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