Sunesis Pharmaceuticals Reports First Quarter 2010 Financial Results

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SOUTH SAN FRANCISCO, CA, Apr 29, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported financial results for the first quarter ended March 31, 2010. Net loss was $4.6 million for the first quarter of 2010. As of March 31, 2010, Sunesis had cash and cash equivalents of $14.7 million.

"Since the beginning of the year, we have made significant progress with our regulatory and clinical efforts for voreloxin, paving the way for the launch of our Phase 3 pivotal trial in patients with relapsed or refractory acute myeloid leukemia (AML) in the second half of 2010," said Daniel Swisher, Chief Executive Officer of Sunesis. "We believe voreloxin represents one of the most promising anticancer compounds in development for the treatment of AML, and the outcomes of our productive meetings with the FDA have provided a clear registration path for voreloxin in this indication. We are now focused on finalizing preparations for the Phase 3 trial and look forward to sharing updated data from our fully enrolled Phase 2 AML and ovarian cancer trials at ASCO in June."

Recent Highlights

-- Upcoming presentations at ASCO. In April, Sunesis announced that three abstracts have been accepted for presentation on June 7 at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, which runs from June 4-8. The presentations include an oral presentation of final data from the Company's Phase 2 trial of voreloxin in ovarian cancer, as well as poster presentations and discussion sessions of maturing data from its two Phase 2 studies of voreloxin in AML.

-- Milestone meetings with the FDA and EMA. In February, Sunesis announced that it completed formal End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA) related to voreloxin in AML. Based on the development clarity achieved as a result of these meetings, the Company intends to proceed with its plan to conduct a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial evaluating voreloxin in combination with cytarabine, a widely used chemotherapy, in patients with first relapsed or primary refractory AML. Sunesis also reported that, as part of its global development strategy, a pre-submission meeting has been held with the European Medicines Agency (EMA) to obtain the EMA's scientific advice on the development program for voreloxin, including the proposed Phase 3 trial, later this quarter.

-- Completion of enrollment in Phase 2 voreloxin combination trial. In January, the Company reported the completion of enrollment in its Phase 1b/2 clinical trial evaluating voreloxin in combination with cytarabine in patients with relapsed or refractory AML. This study serves as the basis for the Company's planned Phase 3 trial.

-- Outlicensing of proprietary drug discovery technology. In February, Sunesis granted Carmot Therapeutics, Inc. an exclusive license to its proprietary Fragment-Based Lead Discovery technology, "Chemotype Evolution," for use in identifying promising drug candidates in a broad range of therapeutic areas, including inflammatory, metabolic and neurodegenerative diseases. Sunesis retains full rights to the technology for use in its future internal discovery efforts.

Financial Highlights

-- In January, Sunesis entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co. pursuant to which the Company could issue and sell shares of common stock from time to time with aggregate proceeds of up to $15.0 million. As of March 31, 2010, Sunesis had utilized the full facility with 15.9 million shares of common stock sold raising gross proceeds of $15.0 million. Net proceeds after expenses and commissions were $14.2 million.

-- Revenues for the three months ended March 31, 2010 were $12,500 compared to $0.2 million for the same period in 2009. Revenue in the 2009 period was primarily related to the sale of compound libraries that were not core to the Company's ongoing development efforts.

-- Research and development expenses decreased to $3.1 million for the three months ended March 31, 2010, as compared to $4.3 million for the same period in 2009. The decrease of $1.2 million between the three month periods was primarily due to decreases in clinical expenses, outside services and facility costs.

-- General and administrative expenses for the three months ended March 31, 2010 were $1.6 million as compared to $2.4 million for the same period in 2009. The decrease was primarily due to reduced administrative headcount from the March 2009 restructuring and reduced facility costs.

-- Sunesis reported net losses of $4.6 million for the three months ended March 31, 2010, as compared to net losses of $8.4 million for the same period in 2009.

-- Cash used in operations was $3.7 million for the three months ended March 31, 2010, as compared to $6.6 million for the same period in 2009.

About Voreloxin

Voreloxin is a first-in-class anticancer quinolone derivative, or AQD, a class of compounds that has not been used previously for the treatment of cancer. Voreloxin both intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis. Voreloxin is currently being evaluated in a fully enrolled single agent Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients and in a fully enrolled Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML. A Phase 2 single agent trial in platinum-resistant ovarian cancer has also completed enrollment. Sunesis anticipates initiating a Phase 3 trial of voreloxin in AML in the second half of 2010.

About the Pivotal Phase 3 Trial

Sunesis anticipates initiating a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or primary refractory AML in the second half of 2010. The trial is designed to evaluate approximately 450 patients, multi-nationally, including leading sites in the U.S. and Europe. Patients are expected to be randomized one to one to receive either voreloxin (90 mg/m2) on days one and four in combination with cytarabine (1 g/m2) daily for five days, or placebo in combination with cytarabine. The study's primary endpoint is overall survival.

About Acute Myeloid Leukemia

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The National Cancer Institute estimated that nearly 13,000 new cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. in 2009. Additionally, it is estimated that prevalence of AML is approximately 25,000 in the U.S. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors typically die within one year, resulting in an acute need for new treatment options for these patients.

About Ovarian Cancer

In the United States, ovarian cancer remains the leading cause of death from gynecologic malignancies and is the fifth leading cause of cancer death overall in women behind lung, breast, colorectal and pancreatic cancers. According to the American Cancer Society, in 2009 there were an estimated 21,550 new cases and more than 14,000 deaths from ovarian cancer in the U.S. alone. Following frontline treatment, recurrence rates among ovarian cancer patients are high. Treatment options remain limited following relapse, and overall long-term survival has not changed significantly over the past 40 years in women with recurrent disease, with less than 30 percent of patients surviving for more than five years.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. Sunesis has built a highly experienced cancer drug development organization committed to advancing its lead product candidate, voreloxin, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis, please visit http://www.sunesis.com.

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This press release contains forward-looking statements, including without limitation statements related to the benefits and efficacy of voreloxin, timing and the Company's ability to arrange sufficient funding to finance the voreloxin pivotal trial and continue as a going concern, the sufficiency of the Company's capital, the planned commencement of a pivotal trial of voreloxin and its timing, the timing of the Company's pre-submission meeting with the EMA, the benefits of voreloxin in combination with cytarabine, and the timing of the results of the Company's Phase 2 AML and ovarian cancer trials. Words such as "believe," "may," "look forward," "planning," "planned," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Sunesis' current expectations. Forward-looking statements involve risks and uncertainties. Sunesis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to Sunesis' need for additional funding to finance the voreloxin pivotal trial and to continue as a going concern, the risk that Sunesis' drug development activities for voreloxin could be halted or significantly delayed for various reasons, the risk that Sunesis' clinical trials for voreloxin may not demonstrate safety or efficacy or lead to regulatory approval, the risk that preliminary data and trends may not be predictive of future data or results, the risk that Sunesis' nonclinical studies and clinical trials may not satisfy the requirements of the FDA or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of voreloxin, and the risk that Sunesis' proprietary rights may not adequately protect voreloxin. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Annual Report on Form 10-K for the year ended December 31, 2009 and other filings with the Securities and Exchange Commission. Sunesis expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

SUNESIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2010	December 31, 2009
	(Unaudited)	(Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,669,251	$ 4,258,715
Prepaids and other current assets	372,109	583,030
Total current assets	15,041,360	4,841,745
Property and equipment, net	223,726	263,111
Deposits and other assets	64,425	64,425

Total assets	$ 15,329,511	$ 5,169,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 673,333	$ 360,300
Accrued clinical expense	1,073,122	1,129,226
Accrued compensation	921,338	728,744
Other accrued liabilities	763,198	761,476
Current portion of deferred rent	26,979	27,943
Deferred revenue	14,583	27,083
Total current liabilities	3,472,553	3,034,772
Non-current portion of deferred rent	68,692	74,105
Commitments		
Stockholders' equity:		
Convertible preferred stock	60,004,986	60,004,986
Common stock	5,798	3,590
Additional paid-in capital	312,842,920	298,469,584
Accumulated deficit	(361,065,438)	(356,417,756)
Total stockholders' equity	11,788,266	2,060,404
Total liabilities and stockholders' equity	$ 15,329,511	$ 5,169,281

Note 1: The condensed consolidated balance sheet as of December 31, 2009 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

SUNESIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended March 31,	
	2010	2009
	(Unaudited)	
Revenue:		
Collaboration revenue	$ 12,500	$ 12,500
License and other revenue	-	211,547
Total revenues	12,500	224,047
Operating expenses:		
Research and development	3,109,841	4,264,152
General and administrative	1,553,912	2,355,012
Restructuring charges	-	1,862,861
Total operating expenses	4,663,753	8,482,025
Loss from operations	(4,651,253)	(8,257,978)
Other income (expense), net	3,571	(105,458)
Net loss	$ (4,647,682)	$ (8,363,436)
Basic and diluted net loss per common share	$ (0.11)	$ (0.24)
Shares used in computing basic and diluted net loss per common share	42,854,606	34,409,768

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SOURCE: Sunesis Pharmaceuticals