Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2009 Financial Results

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SOUTH SAN FRANCISCO, CA, Mar 30, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported financial results for the fourth quarter and fiscal year ended December 31, 2009.

Net loss was $4.0 million for the fourth quarter of 2009 and $40.2 million for the year ended December 31, 2009. Net loss for the year included non-cash charges of $21.0 million related to the accounting for a tranched private placement, for which the initial $10.0 million was closed in April 2009 and the second $5.0 million was closed in October 2009. Loss from operations for 2009, which does not include these charges, was $19.1 million. As of December 31, 2009, cash, cash equivalents and marketable securities totaled $4.3 million, with no debt outstanding.

"The Sunesis team realized a number of important goals for our lead development program in 2009, culminating in voreloxin's advancement to Phase 3. This first-in-class anticancer compound is among the most promising product candidates for acute myeloid leukemia," said Daniel Swisher, Chief Executive Officer of Sunesis. "Voreloxin has a clear path to registration in AML. This randomized, placebo-controlled Phase 3 trial of voreloxin in combination with cytarabine, anticipating launch in the second half of 2010, is designed to demonstrate a meaningful improvement in overall survival in patients with relapsed or refractory AML. These patients represent a significant segment of the AML population with no appreciable advance in therapy in over thirty years."

About the Pivotal Phase 3 Trial

Following formal End-of-Phase 2 meetings with the U.S. Food and Drug Administration in January 2010, Sunesis announced plans to conduct a randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or primary refractory AML. 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. Sunesis anticipates initiating this trial in the second half of 2010. As part of the preparation for this pivotal study, the Company is obtaining the European Medicines Agency's scientific advice. Management is currently in the process of evaluating alternatives for funding the voreloxin development program.

Recent Highlights

-- Outlicensed 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.

-- Completed enrollment in 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.

-- Increased financial flexibility with controlled equity sales offering. 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 today, Sunesis has utilized the full facility with approximately 15.9 million shares of common stock sold raising gross proceeds of approximately $15.0 million. Net proceeds after expenses and commissions are approximately $14.2 million.

-- Presented positive data from two Phase 2 studies at ASH. Sunesis presented interim clinical data from its two Phase 2 trials of

voreloxin in AML at the 51st Annual Meeting of the American Society of Hematology (ASH) in December 2009. Among evaluable first relapse (n=36) and primary refractory patients (n=28) in the Phase 1b/2 combination trial, preliminary median overall survival is 7.8 months and the overall complete remission rate is 31%, most of which are complete remissions, or CRs. Historical median overall survival data in primary refractory and first relapse patients on currently available chemotherapies typically range from 3.4 to 5.9 months (Giles et al, Litzow et al.). All-cause mortality among these patients was 2% at 30 days and 8% at 60 days. This study forms the basis for the Company's planned pivotal Phase 3 trial.

Also at ASH, the Company presented interim clinical data from the Phase 2 trial of single-agent voreloxin in newly diagnosed elderly AML patients unlikely to benefit from standard induction chemotherapy (the REVEAL-1 trial). Based on trial results, Schedule C (72 mg/m2 on days one and four) has been determined to be the recommended dose regimen for future studies with single agent voreloxin in frontline elderly AML. For Schedule C, response rates (CR and complete remissions without full platelet recovery, or CRp) are 38%, most of which are CRs; 30- and 60-day all-cause mortality are 7% and 17%, respectively; and preliminary median overall survival is 7.3 months.

-- Presented nonclinical data demonstrating voreloxin's synergistic and additive effects in combination with current AML and MDS treatments. Sunesis reported data from two nonclinical studies of voreloxin in combination with cytarabine, azacitidine, decitabine and clofarabine at the AACR-EORTC-NCI Molecular Targets and Cancer Therapeutics Conference in November 2009.

-- Received orphan drug designation for voreloxin in AML. In November 2009, Sunesis announced that the U.S. Food and Drug Administration granted voreloxin orphan drug designation in AML. The designation provides eligibility for a seven-year period of market exclusivity in the United States after product approval and an exemption from user fees.

Financial Highlights

-- Revenues for the three months and year ended December 31, 2009 were $12,500 and $3.8 million, as compared to $12,500 and $5.4 million for the same periods in 2008. The decrease of $1.6 million between the annual periods was primarily due to the completion of research funding and technology access fee amortization under the Biogen Idec collaboration in June 2008, partially offset by the recognition in 2009 of $1.5 million for the Biogen Idec Raf kinase inhibitor milestone and $2.0 million for the sale to SARcode of Sunesis' interest in the lymphocyte function-associated antigen-1, or LFA-1, patents and related know-how that Sunesis had previously licensed to SARcode.

-- Research and development expenses decreased to $2.2 million and $13.2 million for the three months and year ended December 31, 2009, as compared to $4.6 million and $26.3 million for the same periods in 2008. The decrease of $2.4 million between the three month periods was primarily due to decreases in clinical expenses, outside services and facility costs. The decrease of $13.1 million between the annual periods was primarily due to savings from the termination of substantially all discovery research activities in June 2008.

-- General and administrative expenses for the three months and year ended December 31, 2009 were $1.9 million and $7.7 million, as compared to $2.2 million and $11.5 million for the same periods in 2008. The decreases were primarily due to reduced administrative headcount and facility costs from the restructurings in June 2008 and

March 2009.

-- Restructuring charges of $1.9 million were recorded in 2009, including $1.3 million for lease termination costs and $0.6 million for employee termination costs related to the March 2009 restructuring. For the three months and year ended December 31, 2008, restructuring charges were $0.4 million and $5.8 million, relating primarily to the June 2008 restructuring.

-- Other expense of $21.1 million was recorded in 2009, primarily resulting from non-cash charges of $21.0 million related to the accounting for the private placement.

-- Sunesis reported net losses of $4.0 million and $40.2 million for the three months and year ended December 31, 2009, as compared to net losses of $6.9 million and $37.2 million for the same periods in 2008.

-- Cash used in operations was $4.3 million and $20.2 million for the three months and year ended December 31, 2009, as compared to $7.0 million and $35.5 million for the same periods in 2008.

-- Financial statements for the fiscal year ended December 31, 2009, which will be included in the Company's Annual Report on Form 10-K to be filed with the Securities and Exchange Commission on March 31, 2010, contain a going concern qualification from the Company's independent registered public accounting firm. This disclosure is being made in compliance with Nasdaq Rule 5250(b)(2), which requires that a recent audit opinion containing a going concern qualification be announced in a press release. This announcement does not represent any change or amendment to the Company's 2009 financial statements or to its Annual Report on Form 10-K. Sunesis believes that it has sufficient resources to fund its operations through at least September 30, 2010, although the Company will need to raise substantial additional funding in the near term in order to sustain operations beyond that date and before undertaking the planned pivotal trial of voreloxin.

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 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 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 timing and our ability to arrange sufficient funding to finance the voreloxin pivotal trial and continue as a going concern, the sufficiency of our capital, the planned commencement of a pivotal trial of voreloxin and its timing, the financial benefits provided by the Cantor facility and the benefits of voreloxin in combination with cytarabine, azacitidine, decitabine and clofarabine. Words such as "planning," "planned," "may," "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' Quarterly Report on Form 10-Q for the quarter ended September 30, 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.
CONSOLIDATED BALANCE SHEETS

	December 31, 2009	December 31, 2008
ASSETS		(Note 1)
Current assets:		
Cash and cash equivalents	$ 4,258,715	$ 6,296,942
Marketable securities	-	4,321,844
Prepaids and other current assets	583,030	934,429
Total current assets	4,841,745	11,553,215
Property and equipment, net	263,111	612,241
Assets held-for-sale	-	470,547
Deposits and other assets	64,425	147,826
Total assets	$ 5,169,281	$ 12,783,829
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 360,300	$ 790,546
Accrued clinical expense	1,129,226	1,865,773
Accrued compensation	728,744	537,215
Accrued restructuring charges	11,982	191,170
Other accrued liabilities	749,494	1,360,434
Current portion of deferred rent	27,943	1,409,513
Deferred revenue	27,083	27,083
Total current liabilities	3,034,772	6,181,734
Non-current portion of deferred rent	74,105	110,919
Commitments		
Stockholders' equity:		
Convertible preferred stock	60,004,986	-
Common stock	3,590	3,441
Additional paid-in capital	298,469,584	322,671,604
Accumulated other comprehensive income	-	7,841
Accumulated deficit	(356,417,756)	(316,191,710)

Total stockholders' equity	2,060,404	6,491,176
Total liabilities and stockholders' equity	$ 5,169,281	$ 12,783,829

Note 1: The consolidated balance sheet as of December 31, 2008 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, 2008.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended December 31,		Year ended December 31,	
	2009	2008	2009	2008
Revenue:				
Collaboration revenue - related party	$ -	$ -	$ 1,500,000	$ 4,310,551
Collaboration revenue - other	12,500	12,500	50,000	606,789
License and other revenue	-	-	2,211,547	500,000
Total revenues	12,500	12,500	3,761,547	5,417,340
Operating expenses:				
Research and development	2,178,045	4,617,239	13,246,859	26,285,294
General and administrative	1,864,960	2,195,211	7,748,243	11,524,198
Restructuring charges	(18,451)	393,158	1,915,316	5,782,903
Total operating expenses	4,024,554	7,205,608	22,910,418	43,592,395
Loss from operations	(4,012,054)	(7,193,108)	(19,148,871)	(38,175,055)
Interest income	772	60,649	21,630	929,114
Interest expense	(139)	(17,224)	(1,188)	(171,308)
Other income (expense), net	(23,651)	222,551	(21,097,617)	231,622
Net loss	(4,035,072)	(6,927,132)	(40,226,046)	(37,185,627)
Deemed distribution to preferred stockholders	(1,188,400)	-	(27,563,400)	-
Loss attributable to common stockholders	$ (5,223,472)	$ (6,927,132)	$ (67,789,446)	$ (37,185,627)
Basic and diluted loss attributable to common				

stockholders per common share	$ (0.15)	$ (0.20)	$ (1.97)	$ (1.08)
Shares used in computing basic and diluted loss attributable to common stockholders per common share	34,678,757	34,404,578	34,480,716	34,387,177

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