Sunesis Pharmaceuticals Reports Third Quarter 2010 Financial Results

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SOUTH SAN FRANCISCO, CA, Oct 28, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported financial results for the third quarter ended September 30, 2010. Net loss was $5.1 million for the third quarter of 2010 and $14.5 million for the nine months ended September 30, 2010. As of September 30, 2010, cash, cash equivalents and marketable securities totaled $40.8 million, with no debt outstanding. On October 6, 2010, Sunesis closed an underwritten offering for gross proceeds of $15.5 million.

"Sunesis has recently achieved several corporate milestones," said Daniel Swisher, Chief Executive Officer of Sunesis. "We are on track to enroll the first patient in the VALOR trial in the fourth quarter of this year. With over $55 million in cash following our October offering, Sunesis believes that it now has the resources available and accessible to fund the VALOR trial until its planned unblinding in mid-2013."

Third Quarter and Recent Highlights

-- Announced the membership of the Steering Committee for the VALOR trial. In August, Sunesis announced the formation of a Steering Committee for the VALOR trial, comprised of leading experts in the field of hematology and oncology. The committee, led by Dr. Eric Feldman, Professor of Medicine and Director of the Leukemia Program and Hematological Malignancies at Weill Cornell Medical College, will provide scientific oversight for the trial as well as communicate its recommendations regarding trial conduct with the trial's Data Safety Monitoring Board and Sunesis.

-- Appointed clinical trial partners for VALOR trial. In August, Sunesis announced the appointment of clinical trial partners for the VALOR trial, including (i) ICON, a contract research organization with global capabilities, hematology expertise and extensive Phase 3 clinical trial experience; (ii) Catalent Pharma Solutions, a leading global provider of advanced technologies, and development, clinical, manufacturing and packaging services, including global comparator procurement, secondary packaging and logistics; and (iii) Cytel, a highly regarded statistical services provider. Sunesis has also retained the Clinical Development Group, LLC to augment Sunesis' Phase 3 operational and strategic support for the VALOR trial, including clinical site management and patient recruitment. Key individuals from the Clinical Development Group have recent, multinational Phase 3 AML trial experience, including Ann Cahill, formerly the Vice President of Clinical Development at Vion Pharmaceuticals.

-- Announced new nonproprietary name, vosaroxin. In August, Sunesis announced that the United States Adopted Names (USAN) Council has accepted the new nonproprietary name "vosaroxin" for its lead drug candidate (formerly known as voreloxin).

-- Granted European patent for vosaroxin. In July, Sunesis announced that the European Patent Office (EPO) has granted Sunesis a patent covering combinations of vosaroxin with cytarabine, the standard-of-care treatment for AML. Following completion of the patent validation process, the patent will provide coverage for such combination products in 30 member states of the European Patent Convention, including the major European markets, to 2025.

Financial Highlights

-- In October, Sunesis completed a $15.5 million underwritten offering of approximately 44.1 million units at $0.35 per unit, with each unit consisting of one share of the company's common stock and a warrant to purchase 0.5 of a share of the company's common stock. Net proceeds from the offering were approximately $14.3 million. The warrants are exercisable six months after issuance at an exercise price of $0.42 per share, and will expire five years from the date of issuance.

-- Revenues for the three and nine months ended September 30, 2010 were nil and $27,000, compared to $12,500 and $3.7 million for the same periods in 2009. Revenue in 2009 was primarily comprised of a $1.5 million milestone earned from Biogen Idec Inc.'s selection of a Raf kinase inhibitor development candidate for the treatment of cancer and $2.0 million from the sale to SARcode Corporation of Sunesis' interest in the lymphocyte function-associated antigen-1, or LFA-1, patents and related know-how that had previously been the subject of a license agreement with SARcode.

-- Research and development expenses for the three and nine months ended September 30, 2010 were $3.5 million and $9.6 million, compared to $3.4 million and $11.1 million for the same periods in 2009. The decrease of $1.5 million between the nine month periods was primarily due to lower clinical site payments, data management costs, facility costs and headcount-related expenses.

-- General and administrative expenses for the three and nine months ended September 30, 2010 were $1.8 million and $5.2 million, compared to $1.5 million and $5.9 million for the same periods in 2009. The increase of $0.3 million between the three month periods was primarily due to higher professional services costs. The decrease of $0.7 million between the nine month periods was primarily due to lower headcount-related expenses.

-- Sunesis reported net loss of $5.1 million and $14.5 million for the three and nine months ended September 30, 2010, compared to a net loss of $4.9 million and $36.2 million for the same periods in 2009. Net loss for the nine month period in 2009 included non-cash charges of $21.0 million related to the accounting for the private placement of Sunesis' securities in 2009.

-- Cash used in operations for the three and nine months ended September 30, 2010 was $7.2 million and $15.2 million, compared to $3.5 million and $15.9 million for the same periods in 2009. Cash used in the three months ended September 30, 2010 included $2.2 million of non-recurring items, primarily comprised of prepayments related to the VALOR trial.

About VALOR

Sunesis anticipates initiating VALOR, a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML, in the fourth quarter of 2010. The trial is designed to evaluate approximately 450 patients, multi-nationally, including leading sites in the U.S. and Europe. Patients will be randomized one to one to receive either voreloxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. Additionally, the VALOR trial employs an innovative, adaptive trial design that allows for a one-time sample size adjustment by the Data Safety Monitoring Board at the interim analysis to ensure adequate power across a broader range of clinically meaningful and statistically

significant survival outcomes. The study's primary endpoint is overall survival.

About Vosaroxin (formerly voreloxin)

Vosaroxin, formerly known as voreloxin, is a first-in-class anticancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Vosaroxin both intercalates DNA and inhibits topoisomerase II, resulting in replication dependent, site-selective DNA damage, G2 arrest and apoptosis. Sunesis plans to initiate the VALOR trial, a multinational, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial of vosaroxin in combination with cytarabine in a relapsed/refractory AML patient population, in the fourth quarter 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 American Cancer Society estimates that 12,330 new cases of AML will be diagnosed and approximately 9,000 deaths from AML will occur in the U.S. in 2010. 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, vosaroxin, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including without limitation statements related to Sunesis' plans to initiate a pivotal Phase 3 clinical trial of vosaroxin in the fourth quarter of this year, Sunesis' belief as to the sufficiency of its available and accessible cash resources to fund the VALOR trial until its planned unblinding in mid-2013 and the completion of the European patent validation process for vosaroxin. Words such as "believe," "accessible," "on track," "could," "plan," "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' ability to raise the capital that it believes to be accessible and is required to fund the VALOR trial until its planned unblinding in mid-2013, risks that the costs of the Phase 3 VALOR trial could exceed Sunesis' current estimates and that Sunesis may be required to expand the number of patients included in the trial based on the pre-specified interim analysis of data from the trial, each of which would require Sunesis to raise more capital prior to the unblinding of the VALOR trial than the amount currently anticipated to be required, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin, the risk that unfavorable economic and market conditions may make it more difficult and costly to raise additional capital, the risk that the VALOR trial may not be initiated on the anticipated timeline and that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin may not demonstrate safety or efficacy or lead to regulatory approval, the risk that data to date and trends may not be predictive of future data or results, the risk that Sunesis' nonclinical studies and clinical studies 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 vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, Sunesis' final prospectus supplement filed with the Securities and Exchange Commission pursuant to Rule 424(b)(5) under the Securities Act of 1933, as amended, on October 1, 2010 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, when available. 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

	September 30, 2010	December 31, 2009
ASSETS	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 14,140,109	$ 4,258,715
Marketable securities	26,653,325	-
Prepaids and other current assets	2,025,721	583,030
Total current assets	42,819,155	4,841,745
Property and equipment, net	98,480	263,111
Deposits and other assets	59,974	64,425
Total assets	$ 42,977,609	$ 5,169,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 308,163	$ 360,300
Accrued clinical expense	1,430,072	1,129,226
Accrued compensation	599,375	728,744
Other accrued liabilities	1,154,847	761,476
Current portion of deferred rent	25,051	27,943
Deferred revenue	-	27,083
Total current liabilities	3,517,508	3,034,772
Non-current portion of deferred rent	54,789	74,105
Commitments		
Stockholders' equity:		
Convertible preferred stock	-	60,004,986
Common stock	22,192	3,590
Additional paid-in capital	410,308,771	298,469,584
Accumulated other comprehensive income	7,768	-
Accumulated deficit	(370,933,419)	(356,417,756)
Total stockholders' equity	39,405,312	2,060,404
Total liabilities and stockholders' equity	$ 42,977,609	$ 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 September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue	$ -	$ 12,500	$ 27,083	$ 1,537,500
License and other				

revenue	-	-	-	2,211,547
Total revenues	-	12,500	27,083	3,749,047
Operating expenses:				
Research and development	3,478,656	3,355,977	9,559,770	11,068,814
General and administrative	1,804,173	1,533,367	5,219,708	5,883,283
Restructuring charges	-	70,375	-	1,933,767
Total operating expenses	5,282,829	4,959,719	14,779,478	18,885,864
Loss from operations	(5,282,829)	(4,947,219)	(14,752,395)	(15,136,817)
Other income (expense), net	198,795	(1,855)	236,732	(21,054,157)
Net loss	(5,084,034)	(4,949,074)	(14,515,663)	(36,190,974)
Deemed distribution to preferred stockholders	-	-	-	(26,375,000)
Loss attributable to common stockholders	$ (5,084,034)	$(4,949,074)	$(14,515,663)	$(62,565,974)
Basic and diluted loss attributable to common stockholders per common share	$ (0.02)	$ (0.14)	$ (0.13)	$ (1.82)
Shares used in computing basic and diluted loss attributable to common stockholders per common share	221,819,920	34,419,185	110,704,800	34,413,977

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SOURCE: Sunesis Pharmaceuticals