

Sunesis Reports Financial Results for the Third Quarter of 2009

November 16, 2009 2:17 PM ET

Voreloxin Abstracts Accepted for Presentation at ASH

SOUTH SAN FRANCISCO, CA, Nov 16, 2009 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported financial results for the third quarter ended September 30, 2009. Sunesis also announced that two abstracts related to the voreloxin clinical program in Acute Myeloid Leukemia (AML) have been accepted for presentation at the 51st Annual Meeting of the American Society of Hematology (ASH), scheduled for December 5 - 8, 2009 in New Orleans.

Net loss was \$4.9 million for the third quarter of 2009 and \$36.2 million for the nine months ended September 30, 2009. The year-to-date net loss included non-cash charges of \$21.0 million related to the accounting for the initial closing of a tranché private placement of Sunesis' securities completed in April. Loss from operations for this nine-month period, excluding these charges, was \$15.1 million. As of September 30, 2009, cash, cash equivalents and marketable securities totaled \$3.9 million, with no debt outstanding. On October 30, 2009, Sunesis closed the \$5.0 million second tranche of the April 2009 private placement.

"We are pleased with the ongoing support from our investor syndicate in recognizing the significant clinical and regulatory progress we have made with our voreloxin program. The additional funding provides us with the necessary capital to support ongoing clinical trials through this critical phase in our voreloxin development program," said Daniel Swisher, Chief Executive Officer of Sunesis. "We look forward to presenting new data from our AML studies at the ASH Annual Meeting and are planning for an important End-of-Phase 2 meeting with the FDA to gain concurrence on our registration strategy in AML, with a pivotal trial planned to commence in 2010."

ASH Presentations

At the upcoming ASH meeting, Sunesis will provide updates on its two ongoing clinical trials of voreloxin in AML: the REVEAL-1 trial of single-agent voreloxin in newly diagnosed elderly AML patients and the Phase 1b/2 trial of voreloxin in combination with cytarabine in relapsed/refractory AML. Below are details of the presentations:

Saturday December 5 (poster presentation)

Abstract # 1037

Title: "A Phase 2 Dose Regimen Optimization Study of Three Schedules of Voreloxin as Single Agent Therapy for Elderly Patients with Newly Diagnosed Acute Myeloid Leukemia"

Viewing: 9:00AM to 7:30PM

Presentation: 5:30PM to 7:30PM

Location: Ernest N. Morial Convention Center, Hall E

Poster Board # I-59

Monday December 7 (oral presentation)

Abstract # 635

Title: "Phase 1b/2 Pharmacokinetic/Pharmacodynamic (PK/PD) Study of Combination Voreloxin and Cytarabine in Relapsed or Refractory Acute Myeloid Leukemia Patients"

Session Time: 4:30PM to 6:00PM

Presentation Time: 5:30PM

Location: Ernest N. Morial Convention Center, Rooms 343-345

Recent Highlights

-- In October, Sunesis announced the completion of enrollment in the Phase 2 REVEAL-1 trial. REVEAL-1 (Response Evaluation of VorEloxin in AML) is a Phase 2 dose regimen optimization trial of single-agent voreloxin in newly diagnosed elderly AML patients who are unlikely to benefit from standard induction chemotherapy. A total of 113 patients were enrolled and dosed in one of three dosing schedules.

- In October, Sunesis closed the \$5.0 million second tranche of the April 2009 private placement, in which units consisting of convertible preferred stock and warrants to purchase common stock were sold on equivalent terms as those sold in the initial closing of \$10.0 million in April. The net proceeds were approximately \$4.7 million and will be used for working capital and other general corporate purposes. A remaining tranche of up to \$28.5 million of common stock may be invested pursuant to the private placement at the election of the holders of a majority of the convertible preferred stock, in their sole discretion, with the date of termination of the preferred stockholders' right to make such an election subject to Sunesis' future cash balance.
- Earlier in November, Sunesis announced that the U.S. Food and Drug Administration (FDA) had granted voreloxin orphan drug designation for the treatment of AML. Orphan drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. 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 and nine months ended September 30, 2009 were \$12,500 and \$3.7 million, as compared to \$0.5 million and \$5.4 million for the same periods in 2008. The decrease of \$0.5 million between the three month periods was due to SARcode license fee revenue recognized in the 2008 period. The decrease of \$1.7 million between the nine month 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 the 2009 period 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 \$3.4 million and \$11.1 million for the three and nine months ended September 30, 2009, as compared to \$4.7 million and \$21.7 million for the same periods in 2008. The decrease of \$1.3 million between the three month periods was primarily due to decreases in facility costs, outside services and clinical expenses. The decrease of \$10.6 million between the nine month periods was primarily due to savings from the termination of substantially all discovery research activities in June 2008.
- General and administrative expenses for the first three and nine months of 2009 were \$1.5 million and \$5.9 million, as compared to \$2.8 million and \$9.3 million for the same periods in 2008. The decreases were primarily due to reduced administrative headcount and facility costs as a result of Sunesis' June 2008 and March 2009 restructurings.
- Restructuring charges of \$1.9 million were recorded in the first nine months of 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 and nine months ended September 30, 2008, restructuring charges were \$0.2 million and \$5.4 million, relating primarily to the June 2008 restructuring.
- Other expense of \$21.1 million was recorded in the nine months ended September 30, 2009, primarily resulting from non-cash charges of \$21.0 million related to the accounting for the initial closing of the private placement in April 2009.

- Sunesis reported net losses of \$4.9 million and \$36.2 million for the three and nine months ended September 30, 2009, as compared to reported net losses of \$7.1 million and \$30.3 million for the same periods in 2008.
- Cash used in operations was \$3.5 million and \$15.9 million for the three and nine month periods ending September 30, 2009, as compared to \$9.8 million and \$28.5 million for the same periods in 2008.

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 the REVEAL-1 trial in previously untreated elderly AML patients and in a Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML, as well as in an ongoing Phase 2 single-agent trial in platinum-resistant ovarian cancer.

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 Leukemia and Lymphoma Society estimates that nearly 13,000 new cases of AML will be diagnosed and approximately 9,000 deaths from AML will occur in the U.S. during 2009. 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 2008 there were an estimated 21,650 new cases and more than 15,000 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, with five-year survival rates at less than 30 percent.

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>.

SUNESIS and the logo are trademarks of Sunesis Pharmaceuticals, Inc.

This press release contains forward-looking statements, including without limitation statements related to the sufficiency of our capital, the timing and outcome of the End-of-Phase 2 interaction with the FDA, the planned commencement of a pivotal trial of voreloxin and its timing and the remaining tranche of the April 2009 private placement transaction. 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, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2009	December 31, 2008
	----- (Unaudited)	----- (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,872,322	\$ 6,296,942
Marketable securities	-	4,321,844
Prepays and other current assets	429,765	934,429
	-----	-----
Total current assets	4,302,087	11,553,215
Property and equipment, net	321,402	612,241
Assets held-for-sale	23,653	470,547
Deposits and other assets	101,275	147,826
	-----	-----
Total assets	\$ 4,748,417	\$ 12,783,829
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 581,771	\$ 790,546
Accrued clinical expense	1,207,370	1,865,773
Accrued compensation	536,189	537,215
Accrued restructuring charges	45,173	191,170
Other accrued liabilities	1,026,388	1,360,434
Current portion of deferred rent	27,266	1,409,513
Current portion of deferred revenue	39,583	27,083
	-----	-----
Total current liabilities	3,463,740	6,181,734
Non-current portion of deferred rent	79,840	110,919
Commitments		
Stockholders' equity:		
Convertible preferred stock	56,144,950	--
Common stock	3,442	3,441
Additional paid-in capital	297,439,129	322,671,604
Accumulated other comprehensive income	-	7,841
Accumulated deficit	(352,382,684)	(316,191,710)
	-----	-----
Total stockholders' equity	1,204,837	6,491,176
	-----	-----
Total liabilities and stockholders' equity	\$ 4,748,417	\$ 12,783,829
	=====	=====

Note 1: The condensed 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
	-----	-----	-----	-----
Revenue:				
Collaboration				
	-----	-----	-----	-----
	(Unaudited)		(Unaudited)	

revenue					
- related party	\$	-	\$	-	\$ 1,500,000 \$ 4,310,551
Collaboration					
revenue					
- other		12,500		10,417	37,500 594,289
License and other					
revenue		-		500,000	2,211,547 500,000
		-----		-----	-----
Total revenues		12,500		510,417	3,749,047 5,404,840
Operating expenses:					
Research and					
development		3,355,977		4,662,556	11,068,814 21,668,055
General and					
administrative		1,533,367		2,827,797	5,883,283 9,328,987
Restructuring					
charges		70,375		192,225	1,933,767 5,389,745
		-----		-----	-----
Total operating					
expenses		4,959,719		7,682,578	18,885,864 36,386,787
		-----		-----	-----
Loss from operations		(4,947,219)		(7,172,161)	(15,136,817) (30,981,947)
Interest income		2,045		138,668	20,858 868,465
Interest expense		(62)		(40,278)	(1,049) (154,084)
Other income					
(expense), net		(3,838)		8,599	(21,073,966) 9,071
		-----		-----	-----
Net loss		(4,949,074)		(7,065,172)	(36,190,974) (30,258,495)
Deemed distribution					
to preferred					
stockholders		-		-	(26,375,000) -
		-----		-----	-----
Loss attributable to					
common stockholders		\$(4,949,074)		\$(7,065,172)	\$(62,565,974)\$(30,258,495)
		=====		=====	=====
Basic and diluted loss					
attributable to					
common stockholders					
per common share		\$ (0.14)		\$ (0.21)	\$ (1.82)\$ (0.88)
Shares used in					
computing basic and					
diluted loss					
attributable to					
common stockholders					
per common share		34,419,185		34,401,519	34,413,977 34,381,335

Investor and Media Inquiries:

Andrea Rabney
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

SOURCE: Sunesis

Copyright 2009 Marketwire, Inc., All rights reserved.

News Provided by COMTEX