Sunesis Reports Financial Results for the Second Quarter 2009

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SOUTH SAN FRANCISCO, Calif., July 29, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today reported financial results for the second quarter ended June 30, 2009.

Total revenue for the second quarter of 2009 was $3.5 million, with a net loss of $22.9 million, including non-cash charges of $21.0 million related to the financing completed in April. Loss from operations was $1.9 million for the second quarter and $10.2 million for the first half of 2009. As of June 30, 2009, cash, cash equivalents and marketable securities totaled $7.3 million, with no debt outstanding.

"In the second quarter, we completed the initial closing of a tranched financing of up to $43.5 million with a syndicate of experienced life science investors. We also presented positive new data on all three of our Phase 2 voreloxin studies at ASCO," said Daniel Swisher, Chief Executive Officer of Sunesis. "As we finish enrollment of both of our Phase 2 studies in AML, we are actively planning for an End-of-Phase 2 meeting later this year with the FDA to gain concurrence on our AML registration strategy."

Recent Highlights

- In April, Sunesis completed a $10.0 million initial closing of a tranched private placement of up to $43.5 million. The private placement contemplates the sale of up to $15.0 million of units of convertible preferred stock and common stock warrants and up to $28.5 million in common stock to accredited investors, including certain members of management. In the initial closing, $10.0 million of units were sold, resulting in net proceeds of $8.8 million. The remaining units may be issued by Sunesis upon the satisfaction of a clinical milestone and Sunesis' common stock trading above a specified floor price or upon approval by a majority of the investors in the private placement, among other conditions, and the common stock of the private placement may be sold upon approval by the company and a majority of the investors in the private placement, among other conditions.
- At the American Society of Clinical Oncology (ASCO) 2009 Annual Meeting in June, the company presented new data from three ongoing clinical trials demonstrating that voreloxin shows promising safety and efficacy in AML and in platinum-resistant ovarian cancer. These presentations can be found on the Sunesis website at http://www.sunesis.com/products-in-development/presentations.php
  - REVEAL-1 (Response Evaluation of VorEloxin in AmL) is a Phase 2 dose regimen optimization study of single agent voreloxin in newly diagnosed elderly AML patients who are unlikely to benefit from standard induction chemotherapy. Interim clinical data from this study continue to show that voreloxin can induce durable complete remissions across several dosing schedules.
  - The Phase 1b/2 trial is designed to evaluate the safety, pharmacokinetics and anti-leukemic activity of escalating doses of voreloxin when administered on days one and four with cytarabine given either as a continuous infusion of 400 mg/m2 daily for five days (CIV Schedule) or as a two hour IV bolus of 1 g/m2 daily for five days (Bolus Schedule). Across both the CIV and Bolus Schedules, a total of 14 patients with primary refractory AML were enrolled and treated with a voreloxin dose of 80 mg/m2 or higher. Five of 14 of these patients achieved a CR or CRp for an overall CR or CRp rate of 36 percent, which compares favorably relative to expected remission rates in this AML population of approximately 10 to 15 percent. In the Bolus Schedule, both first relapse and primary refractory patients are currently being enrolled in Phase 2.
  - Updated clinical data from the Phase 2 study of single agent voreloxin in women with platinum-resistant ovarian cancer were also presented at the ASCO 2009 Annual Meeting. Approximately a third of the study patients have also failed prior treatment with Doxil(R).

Three dose cohorts of voreloxin have been studied, 48 mg/m2 given every three weeks, 60 mg/m2 given every four weeks and 75 mg/m2 given every four weeks. Across all three dosing cohorts, 74 patients (52%) experienced disease control, defined as an objective response or stable disease for 12 weeks or more. The preliminary median progression free survival (PFS) for each of the three cohorts by increasing dose is 82 days, 84 days, and 109 days, respectively. The preliminary median PFS for the 44 women who were both platinum resistant and also had failed treatment with Doxil(R) is 90 days.

-- In July, Sunesis received a $1.5 million milestone payment from Biogen Idec (Nasdaq: BIIB) for the selection of a Raf kinase inhibitor development candidate for the treatment of cancer. Biogen Idec is currently conducting IND-enabling GLP preclinical work. Sunesis retains an option to participate in the co-development and co-promotion of the Raf kinase inhibitor resulting from this collaboration.

-- On July 24, 2009, Sunesis applied to transfer the listing of its common stock from The NASDAQ Global Market to The NASDAQ Capital Market. The NASDAQ Capital Market is a continuous trading market that operates in the same manner as The NASDAQ Global Market. All companies listed on The NASDAQ Capital Market must meet certain financial requirements and adhere to NASDAQ's corporate governance standards. Sunesis believes it is in compliance with the minimum stockholders' equity requirement and all other applicable criteria for continued listing on The NASDAQ Capital Market, but for the $1.00 bid price requirement, which has been suspended by NASDAQ through August 2, 2009. If the application is approved, the company will no longer be subject to delisting from NASDAQ as a result of the previously disclosed stockholders' equity deficiency as of December 31, 2008, but it will need to comply with The NASDAQ Capital Markets' continued listing requirements on an ongoing basis.

Financial Highlights

-- Revenues for the three and six months ended June 30, 2009 were $3.5 million and $3.7 million compared to $2.6 million and $4.9 million for the same periods in 2008. Sunesis recognized $2.0 million in the second quarter of 2009 for the sale to SARcode of its 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 them, and $1.5 million for the Biogen Idec Raf kinase inhibitor milestone referred to above. Revenues in the 2008 periods were primarily related to research funding under the Biogen Idec collaboration.
-- Research and development expenses decreased to $3.4 million and $7.7 million for the three and six months ended June 30, 2009 from $8.3 million and $17.0 million for the same periods in 2008. The decreases were 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 six months of 2009 were $2.0 million and $4.3 million compared to $3.2 million and $6.5 million for the same periods in 2008. The decreases were primarily due to reduced administrative headcount and facility costs as a result of the company's June 2008 and March 2009 restructurings.
-- Restructuring charges of $1.9 million were recorded in the first half of 2009, including $1.3 million for lease termination activities and $0.6 million for employee termination costs related to the March 2009 restructuring. For the three and six months ended June 30, 2008, restructuring charges were $4.9 million and $5.2 million, relating primarily to the June 2008 restructuring.
-- Other expense of $21.0 million and $21.1 million was recorded in the three and six months ended June 30, 2009, primarily resulting from non-cash charges of $21.0 million related to the accounting for the private placement.
-- Sunesis reported net losses of $22.9 million and $31.2 million for the three and six months ended June 30, 2009, compared to reported net

losses of $13.6 million and $23.2 million for the same periods in 2008.

-- Cash used in operations was $5.8 million and $12.4 million for the three and six month periods ending June 30, 2009, compared to $8.2 million and $18.7 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 a Phase 2 clinical trial (known as 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 over 13,000 new cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. during 2007. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. A majority of elderly patients are not considered candidates for standard induction therapy or decline therapy, resulting in an acute need for new treatment options.

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 Pharmaceuticals, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including without limitation statements related to the potential safety and efficacy and commercial potential of voreloxin, the completion of the tranched financing, the activity of voreloxin in nonclinical studies, planned additional enrollment, clinical testing and development efforts, the timing of the End-of-Phase 2 meeting with FDA and the company's ability to transfer to The NASDAQ Capital Market. Words such as "demonstrating," "planning," "promising," "shows" 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 could be halted significantly or 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, including the pace of enrollment, risks related to the manufacturing of voreloxin, the risk that Sunesis' proprietary rights may not adequately protect voreloxin and the risk that NASDAQ does not permit Sunesis to transfer to The NASDAQ Capital Market and that Sunesis may be subject to delisting

proceedings. 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, 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.

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SUNESIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2009	December 31, 2008
	(Unaudited)	(Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$6,842,425	$6,296,942
Marketable securities	506,619	4,321,844
Accounts receivable	1,500,000	-
Prepaids and other current assets	404,106	934,429
Total current assets	9,253,150	11,553,215
Property and equipment, net	407,725	612,241
Assets held-for-sale	23,653	470,547
Deposits and other assets	101,275	147,826
Total assets	$9,785,803	$12,783,829
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$2,049,936	$2,150,980
Accrued clinical expense	1,321,786	1,865,773
Accrued compensation	415,007	537,215
Accrued restructuring charges	59,993	191,170
Current portion of deferred rent	23,308	1,409,513
Current portion of deferred revenue	2,083	27,083
Total current liabilities	3,872,113	6,181,734
Non-current portion of deferred rent	87,755	110,919
Commitments		
Stockholders' equity:		
Convertible preferred stock	56,163,436	-
Common stock	3,442	3,441
Additional paid-in capital	297,092,539	322,671,604
Accumulated other comprehensive income	127	7,841
Accumulated deficit	(347,433,609)	(316,191,710)
Total stockholders' equity	5,825,935	6,491,176
Total liabilities and stockholders' equity	$9,785,803	$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 June 30,		Six months ended June 30,	
	2009	2008	2009	2008
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue-related party	$1,500,000	$2,544,868	$1,500,000	$4,310,551
Collaboration revenue-other	12,500	46,372	25,000	583,872
License and other revenue	2,000,000	-	2,211,547	-
Total revenues	3,512,500	2,591,240	3,736,547	4,894,423
Operating expenses:				
Research and development	3,448,685	8,262,604	7,712,836	17,005,499
General and administrative	1,994,903	3,235,061	4,349,916	6,501,190
Restructuring charges	532	4,876,746	1,863,393	5,197,520
Total operating expenses	5,444,120	16,374,411	13,926,145	28,704,209
Loss from operations	(1,931,620)	(13,783,171)	(10,189,598)	(23,809,786)
Interest income	6,000	269,385	18,812	729,797
Interest expense	(375)	(54,433)	(987)	(113,806)
Other income (expense), net	(20,952,469)	(199)	(21,070,126)	472
Net loss	(22,878,464)	(13,568,418)	(31,241,899)	(23,193,323)
Deemed distribution to preferred stockholders	(26,375,000)	-	(26,375,000)	-
Loss attributable to common stockholders	$(49,253,464)	$(13,568,418)	$(57,616,899)	$(23,193,323)
Basic and diluted loss attributable to common stockholders per common				

share	$(1.43)	$(0.39)	$(1.67)	$(0.67)
Shares used in computing basic and diluted loss attributable to common stockholders per common share	34,412,870	34,377,367	34,411,327	34,371,132

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com