Sunesis Pharmaceuticals Reports Second Quarter 2010 Financial Results

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SOUTH SAN FRANCISCO, CA, Aug 12, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported financial results for the second quarter ended June 30, 2010. Net loss was $4.8 million for the second quarter of 2010. For the first half of 2010, net loss was $9.4 million. As of June 30, 2010, Sunesis had cash and cash equivalents of $49.3 million.

"The second quarter was an important period for Sunesis, as we reached key clinical, regulatory and financial milestones leading up to the launch of our planned Phase 3 pivotal trial of vosaroxin in acute myeloid leukemia in the second half of this year," said Daniel Swisher, Chief Executive Officer of Sunesis. "During the period, important Phase 2 data on vosaroxin's activity and safety in AML and ovarian cancer were presented at the ASCO annual meeting, we received scientific advice from the EMA on our proposed development plans for vosaroxin, and we strengthened our balance sheet. We continue to make progress toward the initiation of our pivotal Phase 3 trial, known as the VALOR trial, and are working toward ensuring its successful launch and execution."

Recent Highlights

-- Announced the membership of the Steering Committee for the VALOR trial. Last week the Company named Eric Feldman, MD (Chair) from Weill Cornell Medical College, Harry Erba, MD, PhD from the University of Michigan, Gary Schiller, MD from the University of California, Los Angeles, Robert Stuart, MD from the University of South Carolina and Norbert Vey, MD from the Institut Paoli-Calmettes, Marseille, France as the members of the Steering Committee for the VALOR trial. The Steering Committee will provide scientific oversight for the VALOR trial as well as communicate its recommendations regarding study conduct with the trial's Data Safety Monitoring Board and Sunesis.
-- Announced new nonproprietary name, vosaroxin. Last week the Company 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 acute myeloid leukemia (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, through 2025.
-- Completed consultative review process with EMA for vosaroxin in AML. In June, Sunesis received scientific advice from the European Medicines Agency (EMA) on the Company's proposed plans for further development of vosaroxin in AML, including the Company's plans for a pivotal trial in patients with first relapsed or primary refractory AML. Based on feedback and guidance received from the FDA and EMA, the Company expects that future results demonstrating a convincing magnitude of improvement in overall survival, the trial's primary endpoint, along with a favorable benefit-risk ratio in the planned Phase 3 VALOR trial, would be sufficient as the primary basis for registration of vosaroxin in both the U.S. and Europe.
-- Presented updated, positive Phase 2 data for vosaroxin at ASCO. In June, Sunesis presented positive data from its Phase 2 trials of vosaroxin in AML and ovarian cancer at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting. The ASCO presentations are available on the Sunesis website at http://www.sunesis.com.

Data from the fully-enrolled Phase 2 trial of vosaraxin in combination with cytabarine in relapsed/refractory AML demonstrated a meaningful improvement in overall survival relative to

literature-based values reported for current treatment standards of care, including cytarabine-based regimens. Among evaluable first relapse (n=36) and primary refractory patients (n=33) treated at doses of 80 to 90 mg/m2 of vosaroxin on days one and four, in addition to cytarabine on days one through five, median overall survival is 7.1 months. Of these patients, over 80% were either primary refractory or had an initial first remission (CR1) of less than 12 months; 20 patients remain in survival follow-up and are beyond the median. The overall remission rate was 29% with the vast majority being complete remissions (17 of 20). All-cause mortality among these patients was 3% at 30 days and 9% at 60 days. This study forms the basis for the planned pivotal Phase 3 VALOR trial.

The Company also presented promising data from its fully-enrolled Phase 2 trial (REVEAL-1) of single-agent vosaroxin in previously untreated, elderly AML patients. The REVEAL-1 trial includes three dosing schedules. As previously reported, Schedule C (72 mg/m2 of vosaroxin on days one and four) is the recommended dose regimen for further study. For Schedule C (n=29), median overall survival is 7.7 months and one year survival is 38%, with 33% of patients remaining in follow-up. Response rate (CR and CRp) was 38%; 30- and 60-day all-cause mortality were 7% and 17%, respectively.

Final data from the Company's Phase 2 trial of vosaroxin in platinum-resistant ovarian cancer demonstrated encouraging, durable anti-tumor activity across all three dose cohorts. Cohort B (60 mg/m2 of vosaroxin given every four weeks) is the recommended dose regimen for further study. For Cohort B (n=37), 54% of patients achieved disease control including 11% objective response rate (ORR, 1 CR and 3 PRs), low incidence of grade 3 or higher febrile neutropenia (5%) and a long progression-free survival (PFS). Median PFS was 85 days.

Financial Highlights

- In June, Sunesis received gross proceeds of $28.5 million from the sale of common stock in the third and final tranche of its private placement pursuant to the March 2009 securities purchase agreement with a group of accredited investors. In conjunction with this common stock closing, all outstanding shares of Series A convertible preferred stock issued in the April and October 2009 closings of the private placement were converted into common stock. Net proceeds from the closing will be approximately $26.7 million, with associated fees to the placement agents to be paid in the third quarter.
- In April, Sunesis entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co. pursuant to which the Company may issue and sell shares of common stock from time to time with aggregate proceeds of up to $20.0 million. As of June 30, 2010, Sunesis had sold 11.7 million shares of common stock, raising gross proceeds of $10.7 million. Net proceeds after expenses and commissions were $10.3 million.
- Revenues for the three and six months ended June 30, 2010 were $15,000 and $27,000, compared to $3.5 million and $3.7 million for the same periods in 2009. Revenue in the 2009 periods was primarily comprised of a $1.5 million milestone earned from Biogen Idec's selection of a Raf kinase inhibitor development candidate for the treatment of cancer and $2.0 million from the sale to SARcode of the Company's interest in all patents and related know-how that had previously been the subject of a license agreement with them.
- Research and development expenses decreased to $3.0 million and $6.1 million for the three and six months ended June 30, 2010, compared to $3.4 million and $7.7 million for the same periods in 2009. The decrease of $0.4 million between the three month periods was primarily due to a decrease in clinical expenses. The decrease of $1.6 million

between the six month periods was primarily due to decreases in clinical expenses, outside services and facility costs.

-- General and administrative expenses for the three and six months ended June 30, 2010 were $1.9 million and $3.4 million, compared to $2.0 million and $4.3 million for the same periods in 2009. The decrease of $0.9 million between the six month periods was primarily due to reduced administrative headcount from the March 2009 restructuring and reduced facility costs.

-- Sunesis reported net loss of $4.8 million and $9.4 million for the three and six months ended June 30, 2010, compared to net loss of $22.9 million and $31.2 million for the same periods in 2009.

-- Cash used in operations was $4.2 million and $8.0 million for the three and six months ended June 30, 2010, compared to $5.8 million and $12.4 million for the same periods in 2009.

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 second half of this year.

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, vosaroxin, 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 Sunesis' plans to initiate a pivotal Phase 3 clinical trial of vosaroxin in the second half of this year, the safety and efficacy of vosaroxin and the completion of the patent validation process. Words such as "evaluate," "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 fully finance the planned vosaroxin pivotal trial, the risk that Sunesis' development activities for vosaroxin could be 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 March 31, 2010 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

	June 30, 2010	December 31, 2009
ASSETS	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 49,297,623	$ 4,258,715
Prepaids and other current assets	318,397	583,030
Total current assets	49,616,020	4,841,745
Property and equipment, net	127,246	263,111
Deposits and other assets	98,846	64,425
Total assets	$ 49,842,112	$ 5,169,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 766,824	$ 360,300
Accrued clinical expense	976,540	1,129,226
Accrued compensation	1,162,198	728,744
Other accrued liabilities	2,597,470	761,476
Current portion of deferred rent	26,015	27,943
Deferred revenue	-	27,083
Total current liabilities	5,529,047	3,034,772
Non-current portion of deferred rent	61,741	74,105
Commitments		
Stockholders' equity:		
Convertible preferred stock	-	60,004,986
Common stock	22,118	3,590
Additional paid-in capital	410,078,591	298,469,584
Accumulated deficit	(365,849,385)	(356,417,756)
Total stockholders' equity	44,251,324	2,060,404
Total liabilities and stockholders' equity	$ 49,842,112	$ 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 June 30,		Six months ended June 30,	
	2010	2009	2010	2009
	(Unaudited)		(Unaudited)	
Revenue:				
Collaboration revenue	$ 14,583	$ 1,512,500	$ 27,083	$ 1,525,000
License and other revenue	-	2,000,000	-	2,211,547
Total revenues	14,583	3,512,500	27,083	3,736,547
Operating expenses:				
Research and development	2,971,273	3,448,685	6,081,114	7,712,836
General and administrative	1,861,623	1,994,903	3,415,535	4,349,916
Restructuring charges	-	532	-	1,863,393
Total operating expenses	4,832,896	5,444,120	9,496,649	13,926,145

Loss from operations	(4,818,313)	(1,931,620)	(9,469,566)	(10,189,598)
Other income (expense), net	34,366	(20,946,844)	37,937	(21,052,301)
Net loss	(4,783,947)	(22,878,464)	(9,431,629)	(31,241,899)
Deemed distribution to preferred stockholders	-	(26,375,000)	-	(26,375,000)
Loss attributable to common stockholders	$(4,783,947)	$(49,253,464)	$(9,431,629)	$(57,616,899)
Basic and diluted loss attributable to common stockholders per common share	$ (0.07)	$ (1.43)	$ (0.17)	$ (1.67)
Shares used in computing basic and diluted loss attributable to common stockholders per common share	65,473,222	34,412,870	54,226,396	34,411,327

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