Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2008 Financial Results

April 1, 2009 2:00 PM ET

-- Conference Call Scheduled for Today at 5:00 p.m. EDT -

SOUTH SAN FRANCISCO, Calif., April 1, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today reported financial results for the fourth quarter and fiscal year ended December 31, 2008.

Total revenue for the year ended December 31, 2008 was $5.4 million, with a net loss of $37.2 million. As of December 31, 2008, cash, cash equivalents and marketable securities totaled $10.6 million, with no outstanding debt. Sunesis Pharmaceuticals separately announced today the execution of a securities purchase agreement with accredited investors, including certain members of management, providing for a private placement, subject to the satisfaction of conditions, of up to $43.5 million in a tranched financing, including two tranches of units consisting of convertible preferred stock and common stock warrants, and a tranche of common stock.

Recent Highlights

- Presented interim clinical data of the Phase 2 voreloxin single-agent REVEAL-1 trial at the 50th Annual Meeting of the American Society of Hematology, with a year end update that coincided with the 27th Annual J.P. Morgan Healthcare Conference in San Francisco. The REVEAL-1 trial is enrolling newly diagnosed elderly AML patients unlikely to benefit from standard induction chemotherapy. Schedules A (72 mg/m2 of voreloxin weekly for three weeks) and B (72 mg/m2 of voreloxin weekly for two weeks) are fully enrolled, and patients are now being enrolled on Schedule C (72 mg/m2 of voreloxin on days one and four). In Schedule A, twelve of 29 patients achieved complete remission (CR) or complete remission without full platelet recovery (CRp) with a 30-day all-cause mortality of 17%. An update of the interim data suggests that Schedule B is better tolerated by patients than Schedule A, while maintaining anti-leukemic activity. Ten of 35 patients on Schedule B have achieved CR or CRp. In addition to improved tolerability, the 30-day all-cause mortality has been reduced to 9%. To date, 16 of the planned 30 patients have been enrolled in Schedule C.
- Presented interim clinical data of the Phase 1b/2 trial of voreloxin combined with cytarabine in relapsed/refractory AML at the 50th Annual Meeting of the American Society of Hematology, with a year end update that coincided with the 27th Annual J.P. Morgan Healthcare Conference in San Francisco. A maximum tolerated dose of 80 mg/m2 of voreloxin was established for Schedule A (continuous infusion of cytarabine), with 9 CRs or CRps reported in the Phase 1b dose escalation. Early data show that six of fourteen evaluable AML patients in first relapse enrolled in the Phase 2 portion of Schedule A of this trial have achieved CR, with a preliminary 30-day all-cause mortality of less than 10%. In addition, one patient who achieved a partial response proceeded to bone marrow transplant. Enrollment for Schedule A is complete. In Schedule B (a 2 hour intravenous infusion of cytarabine), the third dose escalation cohort, with a dose of 90 mg/m2 of voreloxin, is fully enrolled. Complete remissions have been observed in Schedule B in both relapsed and treatment refractory patients. Enrollment into the Phase 2 portion of Schedule B is expected to begin shortly.
- Presented updated interim data from an ongoing Phase 2 clinical trial of single-agent voreloxin in platinum-resistant ovarian cancer patients at the 12th Biennial Meeting International Gynecologic Cancer Society, with a year end update that coincided with the 27th Annual J.P. Morgan Healthcare Conference in San Francisco. Three schedules of voreloxin have been studied, 48 mg/m2 given every three weeks (N=65), and 60 mg/m2 (N=37) and 75 mg/m2 (N=35) given every four weeks. Enrollment of this trial completed late last year. Data from this trial show encouraging durable anti-tumor activity in the 48 mg/m2 cohort, as measured by GOG

RECIST criteria with partial and complete responses, and progression-free survival. Some of the patients dosed with 60 mg/m2 or 75 mg/m2 of voreloxin still remain on study and complete and partial responses have been observed. Voreloxin has generally been well tolerated at all three dose levels.

-- In March 2009, Sunesis sold to SARcode Corporation all of the company's interest in patents and know-how related to the LFA-1 inhibitors program previously licensed to SARcode for a total cash consideration of $2 million. Sunesis continues to hold a series of secured convertible notes issued by SARcode having a total principal value of $1 million.

-- In January 2009, Sunesis entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises for its prior company headquarters at 341 Oyster Point Boulevard in South San Francisco, CA. In consideration of the early termination of the existing lease agreement, Sunesis agreed to pay the lessor an aggregate fee of $2.2 million, thus substantially reducing its future financial liabilities, and the landlord retained the $0.3 million security deposit it received upon signing of the lease.

-- Sunesis filed today a Form 12b-25 with the Securities and Exchange Commission disclosing its inability to timely file its Annual Report on Form 10-K for the year ended December 31, 2008 due to the timing of the placement announced today. Sunesis intends to file its Annual Report on Form 10-K as soon as practicable, and in any event within the 15 day extension period afforded by Rule 12b-25 under the Securities Exchange Act of 1934, as amended. As disclosed in the Form 12b-25, Sunesis expects to receive a "going concern" opinion from its independent registered public accounting firm when the Annual Report on Form 10-K is filed, whether or not the private placement closes. The foregoing disclosure regarding the "going concern" opinion is required under NASDAQ rules and requires that a company receiving an audit opinion that expresses doubt about the ability of the company to continue as a going concern make a public announcement disclosing the receipt of such opinion. With the anticipated proceeds from the initial closing of the private placement announced today, Sunesis believes that it has sufficient resources to fund its operations at least through the end of 2009.

Financial Highlights

-- No material revenue was recorded in the fourth quarter of 2008, compared to $1.8 million in the fourth quarter of the prior year. Revenue totaled $5.4 million for the year ended December 31, 2008, compared to $9.7 million for the year ended December 31, 2007. The decrease in revenue year-over-year was primarily due to the conclusion of the research phase of the kinase inhibitor collaboration with Biogen Idec in June 2008 and lower amortization of license fees and milestone payments from our collaboration with Merck & Co., Inc.

-- Research and development (R&D) expense was $4.6 million for the fourth quarter of 2008, compared to $8.3 million for the same period in 2007. R&D expense for the year ended December 31, 2008 totaled $26.3 million, compared to $36.1 million in 2007. The quarter-over-quarter and year-over-year decrease in R&D expense was primarily due to the termination of discovery research activities in June 2008 and decrease in clinical trial activities related to SNS-032 and SNS-314, partially offset by increased clinical trial activities related to voreloxin.

-- General and administrative (G&A) expense for the fourth quarter of 2008 was $2.2 million, compared to $2.8 million for the fourth quarter of 2007. For the year ended December 31, 2008, G&A expense was $11.5 million, compared to $13.6 million in 2007. The quarter-over-quarter and year-over-year decrease primarily resulted from reduced headcount resulting from Sunesis' reorganization and reduction in force in June 2008.

-- In the fourth quarter ended December 31, 2008, Sunesis recorded a $0.4

million additional restructuring charge relating to the company's reorganization and reduction in force in June 2008. Cash restructuring costs accounted for approximately $3.8 million of the total $5.8 million restructuring charge recorded for the year.

-- Sunesis reported a net loss of $6.9 million for the fourth quarter of 2008 and $37.2 million for the twelve-month period ended December 31, 2008, compared to a reported net loss of $8.8 million and $38.8 million, respectively, for the three-month and twelve-month periods ended December 31, 2007.

Conference Call Information

Sunesis management will host a conference call today to review the fourth quarter and full-year 2008 financial results and the private placement transaction separately announced today and to provide a general business update at 5:00 p.m. EDT / 2:00 p.m. PDT. Individual and institutional investors can access the call via 1-877-874-1567 (U.S. and Canada) or +1- 719-325-4788 (international). To access the live audio webcast or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on Sunesis' website until April 15, 2009.

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 hematologic and solid 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, efficacy and commercial potential of voreloxin; planned additional clinical testing and development efforts for voreloxin; the timing of enrollment in the ongoing clinical trials of voreloxin; and the sufficiency of Sunesis' cash resources. Words such as "contributed," "positive," "potential," "believe," "achieved," "interim," "suggests," "improved," "show," "encouraging," "well tolerated" 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 the satisfaction of the conditions to the completion of the financing transaction announced today and Sunesis' need for additional funding; the risk that Sunesis' development activities for voreloxin, including enrollment and reporting of results, 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' preclinical studies and clinical trials may not satisfy the requirements of the FDA or other regulatory agencies; and risks related to the conduct of Sunesis' clinical trials and manufacturing. 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, 2008, Current Report on Form 8-K anticipated to be filed on the date of this press release 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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Investor Contact:
Sunesis Pharmaceuticals, Inc.
Eric Bjerkholt
650-266-3717

Media Contact:
Sunesis Pharmaceuticals, Inc.
Dan Weinseimer
650-266-3739

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31 2008	December 31 2007
ASSETS		(Note 1)
Current assets:		
Cash and cash equivalents	$6,296,942	$11,726,126
Marketable securities	4,321,844	35,957,933
Prepaids and other current assets	934,429	945,583
Total current assets	11,553,215	48,629,642
Property and equipment, net	612,241	4,238,498
Assets held-for-sale	470,547	-
Deposits and other assets	147,826	377,798
Total assets	$12,783,829	$53,245,938
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$4,207,923	$4,515,426
Accrued compensation	537,215	2,225,868
Current portion of deferred rent	1,409,513	-
Current portion of deferred revenue	27,083	1,227,031
Current portion of equipment financing	-	953,940
Total current liabilities	6,181,734	8,922,265

Non current portion of equipment financing	-	1,352,684
Non-current portion of deferred rent	110,919	1,576,734
Total liabilities	6,292,653	11,851,683
Commitments		
Stockholders' equity:		
Common stock	3,441	3,437
Additional paid-in capital	322,671,604	320,579,240
Deferred stock-based compensation	-	(251,601)
Accumulated other comprehensive income	7,841	69,262
Accumulated deficit	(316,191,710)	(279,006,083)
Total stockholders' equity	6,491,176	41,394,255
Total liabilities and stockholders' equity	$12,783,829	$53,245,938

Note 1: The consolidated balance sheet at December 31, 2007 has been derived from the audited financial statements at that date included in the Company's Form 10-K for the fiscal year ended December 31, 2007.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended December 31,		Twelve months ended December 31,	
	2008	2007	2008	2007
Revenue:				
Collaboration revenue	$12,500	$1,796,708	$4,917,340	$9,163,513
License revenue	-	250,000	500,000	500,000
Total revenues	12,500	2,046,708	5,417,340	9,663,513
Operating expenses:				
Research and development	4,617,239	8,268,413	26,285,294	36,060,470
General and administrative	2,195,211	2,820,543	11,524,198	13,569,578
Restructuring and impairment charges	393,158	345,426	5,782,903	1,563,274
Total operating expenses	7,205,608	11,434,382	43,592,395	51,193,322
Loss from operations	(7,193,108)	(9,387,674)	(38,175,055)	(41,529,809)
Interest income	60,649	661,381	929,114	2,971,666
Interest expense	(17,224)	(57,631)	(171,308)	(209,885)
Other income, net	222,551	5,949	231,622	7,108
Net loss	$(6,927,132)	$(8,777,975)	$(37,185,627)	$(38,760,920)
Basic and diluted				

loss per share	$(0.20)	$(0.26)	$(1.08)	$(1.20)
Shares used in computing basic and diluted loss per share	34,404,578	34,336,345	34,387,177	32,340,203

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com