Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2012 Financial Results and Recent Highlights

March 13, 2013 7:01 AM ET

Sunesis to Host Conference Call Today at 11:00AM Eastern Time

SOUTH SAN FRANCISCO, Calif., March 13, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the fourth quarter and year ended December 31, 2012. Loss from operations for the three months and year ended December 31, 2012 was $8.1 million and $34.6 million, respectively. As of December 31, 2012, cash, cash equivalents and marketable securities totaled $71.2 million.

"Last year was a transformational year for Sunesis, one which brought us several steps closer to realizing vosaroxin's potential as a new treatment standard in AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "We continue to make progress with the VALOR trial, which has now enrolled 563 patients, and remain on track to both complete the target enrollment of approximately 675 patients in 2013 and unblind the study and announce top-line results in the first half of 2014. With a strong balance sheet, Sunesis is well funded to conduct VALOR through to data read-out and to prepare for the corresponding regulatory and pre-launch activities for vosaroxin."

Mr. Swisher added: "While VALOR moves towards completion, we continue to support the important progress in the NCRI-sponsored LI-1 Phase 2/3 trial and in our kinase inhibitor collaborations with Biogen Idec and Millennium Pharmaceuticals."

Fourth Quarter 2012 and Recent Highlights

- ***Continued strong execution of VALOR trial.*** Enrollment and execution of the VALOR trial remains on track, with 563 patients enrolled as of yesterday. Enrollment is currently ongoing at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. Target enrollment of 675 patients is expected to be complete by the end of 2013, with unblinding expected in the first half of 2014 after reaching 562 events and locking the final study database.

- ***Continued progress of LI-1 trial***. Enrollment in the Less Intensive 1 (LI-1) trial, a Phase 2/3 randomized, controlled trial evaluating novel treatment regimens, including two treatment arms containing vosaroxin, in newly diagnosed elderly acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) patients, has reached 62 vosaroxin-treated patients as of March 5, 2013. LI-1 is being conducted by the United Kingdom's National Cancer Research Institute under the direction of Professor Alan K. Burnett, Head of Haematology at Cardiff University.

- ***Received new U.S. patent in collaboration with Takeda/Millennium.*** In October 2012, Sunesis and Millennium were granted a composition of matter patent in the U.S. covering the MLN2480 pan-Raf inhibitor currently in clinical development. This patent is expected to expire in 2031.

2013 Key Milestones

VALOR

- **Completion of enrollment.** Sunesis remains on track to complete full enrollment of the VALOR trial in 2013.

- **Interim safety analysis.** Sunesis expects a planned interim safety analysis of VALOR by the trial's independent Data and Safety Monitoring Board to occur in June 2013.

LI-1

- **First interim analyses.** Sunesis anticipates the first two planned interim assessments of the LI-1 trial in 2013 following enrollment of 50 evaluable patients in the respective treatment arms containing vosaroxin. Various treatment options will be evaluated in a randomized Phase 2/3 design with primary endpoints of overall survival, complete remission rate and duration of response. Treatment arms that exhibit promising results are expected to continue enrolling up to a total of 200

patients per arm.

Other Vosaroxin

- **Initiation of investigator sponsored trials.** Sunesis is evaluating additional indications and trials for vosaroxin, and expects to support the initiation of additional investigator sponsored trials in MDS and AML at leading centers in 2013.

- **Expansion of the intellectual property estate**. Sunesis expects to secure additional patents in 2013, with the goal of supporting its global vosaroxin patent estate and intellectual property strategy. The company's multi-layered patent portfolio currently supports market exclusivity for vosaroxin to 2030 in the U.S., and beyond 2025 in multiple geographies internationally.

Kinase Inhibitor Program

- **Continued progress with partnered kinase inhibitor programs.** Sunesis currently has partnered kinase inhibitor programs in oncology with Millennium Pharmaceuticals and immunology with Biogen Idec.

Financial Highlights

- Cash and investments totaled $71.2 million as of December 31, 2012, as compared to $44.1 million as of December 31, 2011. The increase of $27.1 million was primarily due to the receipt of $25.0 million under a royalty agreement with Royalty Pharma; the draw-down of the second tranche of $15.0 million from the 2011 venture loan facility; net proceeds from sales of common stock under controlled equity offering agreements of $17.6 million; and proceeds from the exercise of warrants, stock options and stock purchase rights of $1.9 million, partially offset by other net operating cash outflows. As of September 30, 2012, outstanding debt totaled $25.0 million.

- Revenues for the three months and year ended December 31, 2012 were $2.0 million and $3.8 million, as compared to nil and $5.0 million for the same periods in 2011. Revenue in 2012 was comprised of $1.5 million received from Biogen Idec in June 2012 for the advancement of pre-clinical work and $2.3 million of deferred revenue recognized related to the royalty agreement.

- Research and development expenses increased to $7.6 million and $29.2 million for the three months and year ended December 31, 2012, as compared to $6.3 million and $22.6 million for the same periods in 2011. The increases in 2012 were primarily due to an increase in clinical and other expenses related to the VALOR trial.

- General and administrative expenses for the three months and year ended December 31, 2012 were $2.5 million and $9.2 million, as compared to $2.2 million and $8.3 million for the same periods in 2011. The increases in 2012 were primarily due to higher non-cash stock-based compensation expenses and other personnel-related costs.

- Interest expense was $0.8 million and $1.9 million for the three months and year ended December 31, 2012 as compared to $0.3 million and $0.3 million for the same periods in 2011. The increases in 2012 were due to the timing of the first and second tranche draw-downs under the 2011 venture loan facility.

- Other income, net was $4.9 million for the three months ended December 31, 2012 as compared to $4,000 for the same period in 2011. Other expense, net was $7.5 million for the year ended December 31, 2012, as compared to other income, net of $6.0 million for the same period in 2011. The amounts for each period were primarily comprised of non-cash charges and credits pertaining to the revaluation of warrants issued in the underwritten offering completed in October 2010.

- Cash used in operations was $9.3 million and $10.6 million for the three months and year ended December 31, 2012, as compared to $7.3 million and $22.8 million for the same periods in 2011. Net cash used in 2012 resulted primarily from the net loss of $44.0 million, partially offset by net adjustments for non-cash items of $7.5 million for the revaluation of warrants issued in the 2010 Offering and $2.7 million for stock-based compensation, and changes in operating assets and liabilities of $22.7 million, including a net increase in deferred revenue of $19.6 million related to the receipt of the $25.0 million payment from Royalty Pharma, and an increase of $3.1 million in accrued clinical expenses related to the VALOR trial.

- Sunesis reported loss from operations of $8.1 million and $34.6 million for the three months and year ended December 31, 2012, as compared to $8.5 million and $25.9 million for the same periods in 2011. Net loss was $4.1 million and $44.0 million for the three months and year ended December 31, 2012, as compared to $8.7 million and $20.1 million for the same periods in 2011.

Conference Call Information

Sunesis will host an update conference call today, March 13th at 11:00 a.m. Eastern Time. The call can be accessed by dialing (866) 383-8108 (U.S. and Canada) or (617) 597-5343 (international), and entering passcode 36968092. 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 the company's website for two weeks.

About VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial's target enrollment is 675 patients at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are randomized in a ratio of 1:1 to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

About Vosaroxin

Vosaroxin is a first-in-class anti-cancer 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. Both the U.S. Food and Drug Administration (FDA) and European Commission have granted orphan drug designation to vosaroxin for the treatment of AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory acute myeloid leukemia in combination with cytarabine.

About AML

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 there will be approximately 14,590 new cases of AML and approximately 10,370 deaths from AML in the U.S. in 2013. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom, and Japan) is over 50,000. 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.

The Sunesis Pharmaceuticals, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=8773

This press release contains forward-looking statements, including statements related to: (i) Sunesis' overall strategy, (ii) the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical programs discussed in this release, (iii) the sufficiency of Sunesis' financial resources, (iv) the progress of the kinase collaboration programs and (v) the sufficiency of Sunesis' intellectual property estate and the patent exclusivity period for vosaroxin and the MLN2480 pan-Raf inhibitor in the United States and other jurisdictions. Words such as "anticipates," "continue," "currently," "move toward," "promising," "expected" "on

track," "currently," "planned," "anticipates," "supports," "continue," "potential," 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 substantial additional funding to complete the development and commercialization of vosaroxin, risks related to Sunesis' ability to raise the capital that it believes to be accessible and is required to fully finance the development and commercialization of vosaroxin, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk 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 supply of the active pharmaceutical ingredients required for the conduct of the VALOR trial, the risk of third party opposition to granted patents related to 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 September 30, 2012, Sunesis' Annual Report on Form 10-K for the year ended December 31, 2012, when available, and Sunesis' 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

(In thousands)

	December 31, 2012	**December 31, 2011**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 14,940	$ 9,311
Marketable securities	56,287	34,804
Prepaids and other current assets	1,705	1,550
Total current assets	72,932	45,665
Property and equipment, net	43	74
Deposits and other assets	42	130
Total assets	$ 73,017	$ 45,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 78	$ 658
Accrued clinical expense	5,449	2,370
Accrued compensation	1,465	1,274
Other accrued liabilities	2,113	1,805
Current portion of deferred revenue	7,956	--
Current portion of notes payable	6,610	--
Warrant liability	8,070	2,276
Total current liabilities	31,741	8,383

Non-current portion of deferred revenue	11,668	--
Non-current portion of notes payable	17,651	9,453
Non-current portion of deferred rent	--	13
Commitments		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	457,011	429,142
Accumulated other comprehensive income (loss)	38	19
Accumulated deficit	(445,097)	(401,146)
Total stockholders' equity	11,957	28,020
Total liabilities and stockholders' equity	$ 73,017	$ 45,869

Note 1: The condensed consolidated balance sheet as of December 31, 2011 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, 2011.

SUNESIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share amounts)

	Three months ended December 31,		**Year ended December 31,**	
	2012	**2011**	**2012**	**2011**
	(Unaudited)		**(Unaudited)**	**(Note 2)**
Revenue:				
License and other revenue	$ 1,989	$ --	$ 3,754	$ 5,000
Total revenues	1,989	--	3,754	5,000
Operating expenses:				
Research and development	7,589	6,326	29,185	22,563
General and administrative	2,473	2,159	9,175	8,303
Total operating expenses	10,062	8,485	38,360	30,866
Loss from operations	(8,073)	(8,485)	(34,606)	(25,866)
Interest expense	(839)	(259)	(1,855)	(259)
Other income (expense), net	4,860	4	(7,490)	5,984
Net loss	(4,052)	(8,740)	(43,951)	(20,141)
Unrealized gain (loss) on available-for-sale securities	41	(1)	19	34
Comprehensive loss	$ (4,011)	$ (8,741)	$ (43,932)	$ (20,107)

Basic and diluted loss per common share:				
Net loss:				
Basic	(4,052)	(8,740)	(43,951)	(20,141)
Diluted	(10,352)	(8,740)	(43,951)	(20,141)
Shares used in computing net loss per common share:				
Basic	51,412	46,733	48,146	46,412
Diluted	52,848	46,733	48,146	46,412
Net loss per common share:				
Basic	$ (0.08)	$ (0.19)	$ (0.91)	$ (0.43)
Diluted	$ (0.20)	$ (0.19)	$ (0.91)	$ (0.43)

Note 2: The consolidated statement of operations and comprehensive income (loss) for the year ended December 31, 2011 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, 2011.

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