Sunesis Pharmaceuticals Reports First Quarter Financial Results and Recent Highlights

May 9, 2013 7:00 AM ET

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

SOUTH SAN FRANCISCO, Calif., May 9, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended March 31, 2013. Loss from operations for the three months ended March 31, 2013 was $7.8 million. As of March 31, 2013, cash, cash equivalents and marketable securities totaled $61.0 million.

"We continue to make great progress with the VALOR trial, which has now enrolled 611 patients, keeping us on track to complete full enrollment in 2013," said Daniel Swisher, Chief Executive Officer of Sunesis. "We expect a planned periodic safety analysis of VALOR by the trial's independent Data and Safety Monitoring Board to occur in June, with unblinding expected in the first half of 2014 after reaching 562 events and locking the final study database."

Mr. Swisher added: "We are also pleased to report that the mono-therapy vosaroxin arm of the LI-1 trial in front-line elderly AML completed enrollment of the first 50 patients in April. We now look forward to the first planned interim evaluation later this year. Enrollment of the combination arm continues and an interim evaluation of the first 50 patients on this arm is also expected before year end."

First Quarter 2013 and Recent Highlights

- ***Continued strong execution of VALOR trial.*** Enrollment and execution of the VALOR trial remains on track, with 611 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 approximately 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 82 vosaroxin-treated patients, including 53 patients in the fully enrolled mono-therapy vosaroxin arm and 29 patients on the combination of vosaroxin with LoDAC arm as of April 29, 2013. Sunesis anticipates the first planned interim evaluations of the LI-1 trial following enrollment of 50 patients per vosaroxin treatment arm to occur in 2013. The LI-1 trial 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.

- ***MLN2480 pan-Raf inhibitor.*** A poster on the pan-Raf inhibitor MLN2480 titled "MLN2480, an investigational oral pan-Raf kinase inhibitor in patients with relapsed or refractory solid tumors: Phase I study" will be presented at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

Financial Highlights

- Cash and investments totaled $61.0 million as of March 31, 2013, as compared to $71.2 million as of December 31, 2012. The decrease of $10.2 million was due to $9.5 million used in operating activities and $0.7 million of principal payments against notes payable, which had a balance of $24.3 million before debt discounts as of March 31, 2013.

- Total revenue was $2.0 million for the three months ended March 31, 2013, as compared to nil for the same period in 2012. Revenue in the 2013 period was due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.

- Research and development expense increased to $7.4 million for the three months ended March 31, 2013 from $6.6 million during the same period in 2012, primarily due to an increase of $1.0 million in clinical trial expenses, partially offset by a reduction of $0.2 million in outside services and consulting costs.

- General and administrative expense for the three months ended March 31, 2013 was $2.4 million, as compared to $2.2 million for the same period in 2012. The increase in 2013 was primarily due to an increase in personnel-related costs.

- Interest expense was $0.8 million for the three months ended March 31, 2013, as compared to $0.3 million for the same period in 2012. The increase in 2013 was due to the draw-down of the second tranche of $15.0 million from the 2011 venture loan facility in September 2012.

- Other expense, net, was $3.0 million for the three months ended March 31, 2013, as compared to $4.8 million for the same period in 2012. The amounts for each period were primarily comprised of non-cash charges pertaining to the revaluation of warrants issued in the underwritten offering completed in October 2010.

- Cash used in operations was $9.5 million for the three months ended March 31, 2013, as compared to $9.3 million for the same period in 2012. Net cash used in the 2013 period resulted primarily from the net loss of $11.6 million and changes in operating assets and liabilities of $1.7 million, partially offset by net adjustments for non-cash items of $3.8 million.

- Sunesis reported a loss from operations of $7.8 million for the three months ended March 31, 2013, as compared to $8.8 million for the same period in 2012. Net loss was $11.6 million and $13.9 million for the same respective periods.

Conference Call Information

Sunesis will host an update conference call today, May 9th at 11:00 a.m. Eastern Time. The call can be accessed by dialing (877) 280-4958 (U.S. and Canada) or (857) 244-7315 (international), and entering passcode 39516372. 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 Sunesis 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 approximately 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.

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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 and (iv) the progress of the kinase collaboration programs. Words such as "anticipates," "continue," "currently," "expected," "on track," "planned," "potential," "supports," 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, European Commission 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' Annual Report on Form 10-K for the year ended December 31, 2012 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, when available. 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 Sunesis' 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)

	March 31, 2013	**December 31, 2012**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 12,555	$ 14,940
Marketable securities	48,482	56,287
Prepaids and other current assets	1,188	1,705
Total current assets	62,225	72,932
Property and equipment, net	36	43
Deposits and other assets	32	42
Total assets	$ 62,293	$ 73,017
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,527	$ 78
Accrued clinical expense	4,340	5,449

Accrued compensation	678	1,465
Other accrued liabilities	2,246	2,113
Current portion of deferred revenue	7,956	7,956
Current portion of notes payable	8,232	6,610
Warrant liability	10,922	8,070
Total current liabilities	35,901	31,741
Non-current portion of deferred revenue	9,679	11,668
Non-current portion of notes payable	15,609	17,651
Commitments		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	457,803	457,011
Accumulated other comprehensive income	17	38
Accumulated deficit	(456,721)	(445,097)
Total stockholders' equity	1,104	11,957
Total liabilities and stockholders' equity	$ 62,293	$ 73,017

Note 1: The condensed consolidated balance sheet as of December 31, 2012 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, 2012.

SUNESIS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except per share amounts)

	Three months ended March 31,	
	2013	**2012**
	(Unaudited)	
Revenue:		
License and other revenue	$ 1,989	$ --
Total revenues	1,989	--
Operating expenses:		
Research and development	7,377	6,646
General and administrative	2,444	2,189
Total operating expenses	9,821	8,835
Loss from operations	(7,832)	(8,835)

Interest expense	(831)	(315)
Other income (expense), net	(2,961)	(4,774)
Net loss	(11,624)	(13,924)
Unrealized loss on available-for-sale securities	(21)	(11)
Comprehensive loss	$ (11,645)	$ (13,935)
Basic and diluted loss per common share:		
Net loss	$ (11,624)	$ (13,924)
Shares used in computing basic and diluted loss per common share	51,587	46,793
Basic and diluted loss per common share	$ (0.23)	$ (0.30)

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