Sunesis Pharmaceuticals Reports Third Quarter Financial Results and Recent Highlights

November 12, 2013 7:00 AM ET

Sunesis to Host Conference Call Today at 11AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended September 30, 2013. Loss from operations for the three and nine months ended September 30, 2013 was $7.8 million and $24.2 million, respectively. As of September 30, 2013, cash, cash equivalents and marketable securities totaled $45.5 million.

"The VALOR trial, which completed enrollment this past quarter, is the largest company-sponsored trial ever undertaken in relapsed/refractory AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "Based on current available information, we expect to unblind VALOR in the second quarter of 2014, once 562 events are reached and the final database is locked. With a strong balance sheet, we remain well funded to prosecute VALOR beyond data read-out and to prepare for the corresponding regulatory and pre-launch activities for vosaroxin."

Mr. Swisher added: "Importantly, as VALOR nears completion, we continue to explore the potential of vosaroxin in additional patient settings and in novel combinations with leading treatment standards, through a variety of ongoing investigator sponsored trials."

Third Quarter 2013 and Recent Highlights

Continued strong execution of VALOR trial. In September, enrollment in the Sunesis Phase 3 VALOR trial was completed on schedule. VALOR is a pivotal, randomized, double-blind, placebo-controlled trial of vosaroxin plus cytarabine in first relapsed or refractory acute myeloid leukemia (AML). Unblinding of the VALOR trial is currently expected in the second quarter of 2014, after reaching 562 events and locking the final study database.

Announced successful completion of Phase 1b stage and initiation of Phase 2 cohort of MD Anderson Cancer Center-sponsored trial of vosaroxin in AML and high-risk MDS. In October, Sunesis announced the initiation of the Phase 2 cohort of a Phase 1b/2, MD Anderson Cancer Center-sponsored study of vosaroxin in combination with decitabine in older patients with previously untreated AML and high-risk myelodysplastic syndrome (MDS). The trial is being conducted under the direction of Naval Daver, M.D., Assistant Professor, Department of Leukemia, and Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, both of the MD Anderson Cancer Center at the University of Texas. Dr. Ravandi is also a principal investigator of the Phase 3 VALOR trial.

Announced initiation of U.S. investigator sponsored trial in MDS. In October, Sunesis announced the initiation of an investigator-sponsored trial of vosaroxin in patients with MDS who have previously failed treatment with hypomethylating agent-based therapy. This Phase 1/2 trial is designed to evaluate vosaroxin alone in adult patients with previously treated, intermediate-2 or high-risk MDS, and is being conducted at Weill Cornell Medical College and New York-Presbyterian Hospital under the direction of Gail J. Roboz, M.D., Associate Professor Medicine and Director of the Leukemia Program.

LI-1 trial update. Enrollment of the first 50 patients in the combination arm of vosaroxin and low-dose cytarbine (LoDAC) in the Less Intensive 1 (LI-1) trial, a Phase 2/3 randomized, controlled trial evaluating novel treatment regimens in newly diagnosed elderly AML and high-risk MDS patients, is complete and the first interim evaluation of this treatment arm is expected to take place before year end. The LI-1 trial is being conducted under the direction of Professor Alan K. Burnett, Head of Haematology at Cardiff University.

Financial Highlights

- Cash and investments totaled $45.5 million as of September 30, 2013, as compared to $71.2 million as of December 31, 2012. The decrease of $25.7 million was primarily due to $27.7 million of cash used in operating activities and $5.0 million of principal payments against notes payable, partially offset by $6.6 million of net proceeds from sales of common stock through the at-the-market facility with Cantor Fitzgerald & Co. The notes payable had an outstanding balance of $20.0 million as of September 30, 2013. Subsequent to quarter end, Sunesis raised an additional $4.5 million, net, through sales

under the at-the-market facility, bringing pro-forma cash at quarter end to $50.0 million.

- Total revenue was $2.0 million and $6.0 million for the three and nine months ended September 30, 2013, as compared to $0.3 million and $1.8 million for the same periods in 2012. Revenue in the 2013 periods was due to deferred revenue recognized related to the royalty agreement with Royalty Pharma. Revenue in the nine-month period in 2012 was primarily due to the receipt of a payment of $1.5 million from Biogen Idec in June 2012 for the advancement of pre-clinical work under the current agreement with Biogen Idec.

- Research and development expense totaled $7.0 million and $22.0 million for the three and nine months ended September 30, 2013, as compared to $6.9 million and $21.6 million during the same periods in 2012. The increase between the comparable three month periods was primarily due to increased personnel costs offset by a decrease in drug manufacturing costs. The increase between the comparable nine month periods was primarily due to increased clinical trial expenses.

- General and administrative expenses for the three and nine months ended September 30, 2013 were $2.8 million and $8.1 million, as compared to $2.3 million and $6.7 million for the same periods in 2012. The increases between the comparable periods were primarily due to higher professional service costs.

- Interest expense was $0.7 million and $2.3 million for the three and nine months ended September 30, 2013, as compared to $0.4 million and $1.0 million for the same periods 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.

- Net other income was $0.9 million for the three months ended September 30, 2013, as compared to net other expense of $8.1 million for the same period in 2012. Net other expense was $0.9 million for the nine months ended September 30, 2013, as compared to $12.4 million for the same period in 2012. The amounts for each period were primarily comprised of non-cash charges or credits for the revaluation of warrants issued in the underwritten offering completed in October 2010.

- Cash used in operations was $27.7 million for the nine months ended September 30, 2013, as compared to $1.4 million for the same period in 2012, which included $25.0 million received from Royalty Pharma. Net cash used in the 2013 period resulted primarily from the net loss of $27.4 million and changes in operating assets and liabilities of $4.5 million, partially offset by net adjustments for non-cash items of $4.2 million.

- Sunesis reported a loss from operations of $7.8 million and $24.2 million for the three and nine months ended September 30, 2013, as compared to $8.9 million and $26.5 million for the same periods in 2012. Net loss was $7.6 million and $27.4 million for the three and nine months ended September 30, 2013 as compared to $17.4 million and $39.9 million for the same periods in 2012.

Conference Call Information

Sunesis will host an update conference call today, November 12 at 11:00 a.m. Eastern Time. The call can be accessed by dialing 800-901-5213 (U.S. and Canada) or 617-786-2962 (international), and entering passcode 49842581 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 is being conducted at more than 100 leading sites in the U.S., Canada, Europe, Australia, New Zealand and South Korea. Patients 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 acute myeloid leukemia (AML). Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML 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.

This press release contains forward-looking statements, including statements related to the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical programs discussed in this release. Words such as "believe," "continue," "estimate," "expect," "improve," "positive," "potential," "remain," 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 and potential commercialization of vosaroxin, 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, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 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)

	September 30, 2013	**December 31, 2012**
ASSETS	**(Unaudited)**	**(Note 1)**

Current assets:		
Cash and cash equivalents	$ 21,732	$ 14,940
Marketable securities	23,766	56,287
Prepaids and other current assets	1,014	1,705
Total current assets	46,512	72,932
Property and equipment, net	27	43
Deposits and other assets	16	42
Total assets	$ 46,555	$ 73,017
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,459	$ 78
Accrued clinical expense	4,838	5,449
Accrued compensation	1,302	1,465
Other accrued liabilities	1,973	2,113
Current portion of deferred revenue	7,956	7,956
Current portion of notes payable	8,750	6,610
Warrant liability	9,054	8,070
Total current liabilities	35,332	31,741
Non-current portion of deferred revenue	5,701	11,668
Non-current portion of notes payable	11,299	17,651
Commitments		
Stockholders' equity (deficit):		
Common stock	5	5
Additional paid-in capital	466,727	457,011
Accumulated other comprehensive income	9	38
Accumulated deficit	(472,518)	(445,097)
Total stockholders' equity (deficit)	(5,777)	11,957
Total liabilities and stockholders' equity (deficit)	$ 46,555	$ 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 September 30,	**Nine months ended September 30,**

	2013	2012	2013	2012
	(Unaudited)		(Unaudited)	
Revenue:				
License and other revenue	$ 1,989	$ 265	$ 5,967	$ 1,765
Total revenues	1,989	265	5,967	1,765
Operating expenses:				
Research and development	6,957	6,878	22,008	21,596
General and administrative	2,807	2,331	8,140	6,702
Total operating expenses	9,764	9,209	30,148	28,298
Loss from operations	(7,775)	(8,944)	(24,181)	(26,533)
Interest expense	(695)	(385)	(2,294)	(1,016)
Other income (expense), net	863	(8,067)	(946)	(12,350)
Net loss	(7,607)	(17,396)	(27,421)	(39,899)
Unrealized gain (loss) on available-for-sale securities	9	2	(29)	(22)
Comprehensive loss	$ (7,598)	$ (17,394)	$ (27,450)	$ (39,921)
Basic and diluted loss per common share:				
Net loss:				
Basic	$ (7,607)	$ (17,396)	$ (27,421)	$ (39,899)
Diluted	(8,329)	(17,396)	(27,421)	(39,899)
Shares used in computing net loss per common share:				
Basic	51,698	47,398	51,639	47,049
Diluted	53,271	47,398	51,639	47,049
Net loss per common share:				
Basic	$ (0.15)	$ (0.37)	$ (0.53)	$ (0.85)
Diluted	$ (0.16)	$ (0.37)	$ (0.53)	$ (0.85)

CONTACT: Investor and Media Inquiries:
David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals, Inc.