Sunesis Pharmaceuticals Reports First Quarter 2016 Financial Results and Recent Highlights

May 5, 2016 7:01 AM ET

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

SOUTH SAN FRANCISCO, Calif., May 05, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the first quarter ended March 31, 2016. Loss from operations for the three months ended March 31, 2016 was $10.1 million. As of March 31, 2016, cash, cash equivalents and marketable securities totaled $40.0 million.

"The first quarter of 2016 saw several important milestones, including, notably, the advancement of our unique BTK-inhibitor SNS-062 into the clinic in a Phase 1A study," said Daniel Swisher, Chief Executive Officer of Sunesis. "Resistance to available BTK-inhibitors is a growing concern, and SNS-062's characteristics as a non-covalently binding inhibitor position it to address this emerging unmet need. Ongoing dose escalation in our Healthy Volunteer Study is proceeding well. We are actively planning for our Phase 1B/2 study in patients with B-cell malignancies to start later this year."

Mr. Swisher added: "We also continue to progress our efforts to bring vosaroxin to market in Europe as an important new treatment option for patients with relapsed/refractory AML. Our Marketing Authorization Application has now reached the 120-day comment and question time point. With continued regulatory advancement and strong outreach efforts underway, we aim to enter into a European collaboration later this year to support a market launch in 2017."

First Quarter 2016 and Recent Highlights

- ***First Subject Dosed in Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK-inhibitor SNS-062.*** In March 2016, the first patient was dosed in a Phase 1A, randomized, double-blind, placebo-controlled dose-ranging study to investigate the safety, pharmacokinetics and pharmacodynamics of its oral, next-generation, non-covalently binding BTK-inhibitor, SNS-062, in healthy subjects. If a successful outcome is achieved in Phase 1A SNS-062 is expected to proceed to a Phase 1B/2 study in patients with B-cell malignancies later this year.

- ***Secured $15 Million Venture Loan.*** In March 2016, Sunesis entered into a $15 million loan agreement with Bridge Bank, a division of Western Alliance Bank, and Solar Capital Ltd. The loan was used for the repayment of existing indebtedness and will be used for general corporate purposes.

- ***First Patient Treated in Vanderbilt University-Sponsored Phase 2 VITAL Study of Vosaroxin in Combination with Infusional Cytarabine in Patients with Previously Untreated AML.*** In March 2016, the first patient was treated in an investigator-sponsored study of vosaroxin and cytarabine in adult patients with previously untreated acute myeloid leukemia (AML). The trial is being conducted at the Vanderbilt-Ingram Cancer Center at Vanderbilt University under the direction of Michael R. Savona, M.D., FACP, Associate Professor of Medicine and Director of Hematology Early Therapeutics Program, and Stephen A. Strickland, M.D., MSCI, Assistant Professor of Medicine.

- ***Strengthened Executive Management Team and Board of Directors.*** In March 2016, Sunesis announced the appointment of Geoffrey Parker to the Sunesis Board of Directors. In February 2016, Sunesis announced the promotion of Deborah A. Thomas, Ph.D., to the role of Senior Vice President, Regulatory Affairs, Quality Assurance, and Non-Clinical Development.

- ***Validation of Marketing Authorization Application by the European Medicines Agency for Vosaroxin in AML.*** At year-end 2015, the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for vosaroxin as a treatment for relapsed refractory acute myeloid leukemia (AML) in patients aged 60

years and older. Validation confirms that the submission is complete and initiates the Centralized Review process by the EMA's Committee for Medicinal Products for Human Use (CHMP). The MAA, if authorized, provides a marketing license valid in all 28 EU member states.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $40.0 million as of March 31, 2016, as compared to $46.4 million as of December 31, 2015. The decrease of $6.4 million was primarily due to $10.7 million of net cash used in operating activities and $8.0 million of principal and final payments against notes payable, partially offset by $12.3 million raised from debt financing. An additional $2.5 million in net loan proceeds was received on April 1, 2016. This capital is expected to be sufficient to fund operations through the second quarter of 2017.

- Revenue for the three months ended March 31, 2016 was $0.6 million, as compared to $0.9 million for the same period in 2015. The decrease between the periods was primarily due to the increase in estimated performance period through which the remaining balance of deferred revenue will be amortized.

- Research and development expense was $6.2 million for the three months ended March 31, 2016 as compared to $4.5 million for the same period in 2015. The increase between the periods was primarily due to the increase of $1.3 million in consulting and other outside services costs and $0.4 million in clinical trials and medical affairs expenses.

- General and administrative expense was $4.3 million for the three months ended March 31, 2016 as compared to $5.1 million for the same period in 2015. The decrease between the periods was primarily due to a $0.8 million decrease in personnel costs and professional services and commercial costs.

- Interest expense was $0.3 million for the three months ended March 31, 2016, compared to $0.2 million for the same period in 2015.

- Net other income was nil for the three months ended March 31, 2016 as compared to net other expense of $0.1 million for the same period in 2015. The amount for the period in 2015 was primarily comprised of non-cash credits or charges for the revaluation of warrants issued in the October 2010 underwritten offering.

- Cash used in operating activities was $10.7 million for the three months ended March 31, 2016, including a $0.5 million milestone payment relating to the MAA filing, as compared to $11.6 million for the same period in 2015.

- Sunesis reported loss from operations of $9.9 million for the three months ended March 31, 2016 as compared to $8.8 million for the same period in 2015. Net loss was $10.1 million for the three months ended March 31, 2016, as compared to $9.1 million for the same period in 2015.

Conference Call Information

Sunesis will host an update conference call today, May 5th at 11:00 a.m. Eastern Time. The call can be accessed by dialing (877) 771-6242 (U.S. and Canada) or (440) 996-5676 (international) and entering passcode 96476414. 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 QINPREZO™ (vosaroxin)

QINPREZO™ (vosaroxin) is an anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that 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 AML in combination with cytarabine. Vosaroxin is an investigational drug that has not been approved for use in any jurisdiction.

The trademark name QINPREZO is conditionally accepted by the FDA and the EMA as the proprietary name for the vosaroxin drug product candidate.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the potential treatment of solid and hematologic cancers. Sunesis has built a highly experienced cancer drug development organization committed to improving the lives of people with cancer and is currently pursuing regulatory approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older. In addition, the company is advancing its kinase-inhibitor pipeline of novel targeted therapies into the clinic.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, including the anticipated progress and potential approval of vosaroxin by the EMA, clinical development of SNS 062, potential ex-US partnership, the expected progress in its kinase inhibitor pipeline, and the sufficiency of Sunesis' cash resources. Words such as "expect," "look forward," "potential," "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, the risk that Sunesis may not be able to receive regulatory approval of vosaroxin in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including its pipeline of kinase inhibitors, 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, risks related to the conduct of Sunesis' clinical trials, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, and 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 and other product candidates. 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, 2015, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,858	$ 26,886
Marketable securities	16,158	19,544
Prepaids and other current assets	701	558
Total current assets	40,717	46,988
Property and equipment, net	11	14
Total assets	$ 40,728	$ 47,002
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,581	$ 2,453
Accrued clinical expense	2,185	1,954
Accrued compensation	929	1,606
Other accrued liabilities	1,639	2,711
Current portion of deferred revenue	2,441	2,441
Current portion of notes payable	-	7,834
Warrant liability	-	-
Total current liabilities	9,775	18,999
Non-current portion of deferred revenue	-	610
Non-current portion of notes payable	11,685	-
Commitments		
Stockholders' equity:		
Preferred stock	16,459	16,459
Common stock	9	9
Additional paid-in capital	572,257	570,309
Accumulated other comprehensive loss	2	(11)
Accumulated deficit	(569,459)	(559,373)
Total stockholders' equity	19,268	27,393
Total liabilities and stockholders' equity	$ 40,728	$ 47,002

Note 1: The consolidated balance sheet as of December 31, 2015 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, 2015.

SUNESIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three months ended March 31,	
	2016	**2015**
	(Unaudited)	**(Unaudited)**
Revenue:		
License and other revenue	$ 640	$ 854
Total revenues	640	854
Operating expenses:		
Research and development	6,209	4,512
General and administrative	4,295	5,111
Total operating expenses	10,504	9,623
Loss from operations	(9,864)	(8,769)
Interest expense	(298)	(239)
Other income (expense), net	76	(120)
Net loss	(10,086)	(9,128)
Unrealized gain (loss) on available-for-sale securities	13	2
Comprehensive loss	$ (10,073)	$ (9,126)
Basic and diluted loss per common share:		
Net loss	$ (10,086)	$ (9,128)
Shares used in computing basic and diluted loss per common share	86,660	67,641
Basic and diluted loss per common share	$ (0.12)	$ (0.13)

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