Sunesis Pharmaceuticals Reports First Quarter 2017 Financial Results and Recent Highlights

May 8, 2017 7:00 AM ET

Sunesis to Host Conference Call Today at 2:00 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., May 08, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the first quarter ended March 31, 2017. Loss from operations for the three months ended March 31, 2017 was $9.4 million. As of March 31, 2017, cash, cash equivalents and marketable securities totaled $35.2 million.

"Following recent regulatory developments, our reversible non-covalent BTK inhibitor, SNS-062, is the central focus of our development efforts and resources," said Daniel Swisher, President and Chief Executive Officer of Sunesis. "Data from SNS-062's preclinical and healthy volunteer studies suggest a unique drug profile for this next-generation BTK inhibitor and the potential to overcome the key resistance mechanism of ibrutinib. SNS-062 has the potential to address this increasingly well-defined and prevalent unmet need in CLL and other B-cell malignancy patients with C481S mutations, and we look forward to dosing the first patient in our Phase 1B/2 study this quarter."

Mr. Swisher continued, "With regard to vosaroxin, we plan to continue to advance its development through investigator-sponsored group trials, and will carefully assess business development alternatives to support any future registration-directed studies. We expect that our current cash resources are sufficient to fund the company into June 2018."

First Quarter 2017 and Recent Highlights

- ***Announced Withdrawal of Marketing Authorization Application (MAA) for Vosaroxin in Europe and Shifted Primary Development Focus to Non-Covalent Reversible BTK Inhibitor SNS-062.*** On May 1st, Sunesis announced the withdrawal of its European Marketing Authorization Application (MAA) for vosaroxin as a treatment for relapsed/refractory acute myeloid leukemia (AML) in patients aged 60 years and older. The decision followed recent interactions with the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP), during which the Company made an assessment based on feedback from its rapporteurs and input from its regulatory consultants that the committee was likely to formally adopt a negative opinion and a withdrawal of its application was the best option at this time. The Company also announced its plans to reduce its investment in its AML program and shift an increasing portion of resources to the Company's kinase inhibitor pipeline, with an emphasis on timely prosecution of SNS-062.

- ***Progress Toward Initiation of a Phase 1b/2 Trial of Non-Covalent Reversible BTK Inhibitor SNS-062 in Patients with B-Cell Malignancies.*** Sunesis continues to make progress toward the initiation of treatment in a Phase 1b/2 Trial evaluating its unique, proprietary, non-covalent reversible BTK-inhibitor SNS-062 in patients with B-cell malignancies. The Company has activated multiple clinical sites across the U.S., including at U.C. Irvine Cancer Center and The Ohio State University Comprehensive Cancer Center. These sites are beginning to actively identify patients. An additional three top U.S. centers, Dana-Faber Cancer Institute, MD Anderson Cancer Center and Weill Cornell Cancer Center, expected to be initiated this quarter. Sunesis expects to announce the dosing of the first patient this quarter.

- ***Announced Poster Presentation on BTK Inhibitor SNS-062 at the AACR Annual Meeting.*** In March, Sunesis announced a poster presentation at the American Association for Cancer Research 2017 Annual Meeting. The poster, titled "SNS-062 demonstrates efficacy in chronic lymphocytic leukemia in vitro and inhibits C481S mutated Bruton tyrosine kinase" detailed results from The Ohio State University-sponsored preclinical study, conducted in collaboration with Sunesis, that examined the potency of SNS-062 versus ibrutinib and acalabrutinib, specifically relating to the C481S mutation.

- ***Announced Progress in Ongoing Investigator-Sponsored Studies Evaluating Vosaroxin in Patients with Acute Myeloid Leukemia (AML).*** Sunesis announced today that the Vanderbilt University sponsored VITAL (**V**osaroxin and **I**nfusional Cytarabine for Frontline **T**reatment of **A**cute Myeloid **L**eukemia) study of vosaroxin in combination with cytarabine in patients with previously untreated AML has progressed from Stage 1 to Stage 2. The single-arm, open-label trial enrolled 17 patients in Stage 1 and, following a one-time interim analysis by the Data Safety Monitoring Board of responses exceeding a pre-defined efficacy threshold, is now proceeding to enrollment in Stage 2. In this stage, the trial will enroll at least 24 additional patients. The study is being expanded to four additional sites including Yale University, UCLA, Medical University of South Carolina and University of Alabama.

  Sunesis also announced today that vosaroxin has been selected as a treatment arm in the Phase 2/3 BIG-1 (**B**ackbone **I**nter**G**roup-1) trial. BIG-1 is an open label, multicenter phase 2/3 study with multiple randomization phases at different stages of AML treatment that is designed to improve overall survival in younger patients (18 to 60 years). The vosaroxin portion of the trial, which is expected to begin dosing imminently, will enroll up to 200 patients with favorable or intermediate risk AML, who will receive consolidation therapy of intermediate dose cytarabine with vosaroxin. The study is being conducted at multiple French centers, led by the University Hospital of Angers under the direction of Professor Norbert Ifrah, and the University Institute of Hematology at the Hôpital Saint-Louis under the direction of Professor Hervé Dombret.

- ***Announced Organizational Updates.*** In March, Sunesis announced two management additions: Judy Fox Ph.D. to the position of Chief Scientific Officer and Pietro Taverna, Ph.D. to Executive Director, Translational Medicine. In April, Eric Bjerkholt resigned from his position of Chief Financial Officer. Dan Swisher, our Chief Executive Officer, has assumed the CFO responsibilities on an interim basis.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $35.2 million as of March 31, 2017, as compared to $42.6 million as of December 31, 2016. The decrease of $7.4 million was primarily due to $9.7 million of net cash used in operating activities offset by $2.2 million from sales of common stock through the company's at the market facility. The Company expects that its current cash resources are sufficient to fund the company into June 2018.

- Revenue for the three months ended March 31, 2017 was $0.7 million, as compared to $0.6 million for the same period on 2016. Revenue in each period was primarily due to deferred revenue recognized related to the Royalty Agreement with Royalty Pharma.

- Research and development expense was $6.2 million for the three months ended March 31, 2017 and for the same period in 2016, primarily relating to the vosaroxin development program in each period.

- General and administrative expense was $3.9 million for the three months ended March 31, 2017 as compared to $4.3 million for the same period in 2016. The decrease of $0.4 million in 2016 was primarily due to decrease in personnel expenses and commercial expenses.

- Interest expense was $0.5 million for the three months ended March 31, 2017 as compared to $0.3 million and for the same period in 2016. The increase in the 2017 period was primarily due to the increase in the notes payable.

- Net other income was $0.1 million for the three months ended March 31, 2017 and for the same period in 2016. The other income was primarily comprised of interest income from the short-term investments.

- Cash used in operating activities was $9.7 million for the three months ended March 31, 2017, as compared to $10.7 million for the same period in 2016. Net cash used in the 2017 period resulted primarily from the net loss of $9.8 million and changes in operating assets and liabilities of $0.9 million, partially offset by net adjustments for

non-cash items of $1.0 million.

- Sunesis reported loss from operations of $9.4 million for the three months ended March 31, 2017, as compared to $9.9 million for the same period in 2016. Net loss was $9.8 million for the three months ended March 31, 2017, as compared to $10.1 million for the same period in 2016.

Conference Call Information

Sunesis will host a conference today at 2:00 p.m. Eastern Time. The call can be accessed by dialing (844) 296-7720 (U.S. and Canada) or (574) 990-1148 (international) and entering passcode 13018661. 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 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. Currently, the company is focused on advancing its novel kinase-inhibitor pipeline, which includes its proprietary reversible non-covalent BTK-inhibitor, SNS-062.

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

This press release contains forward-looking statements, including statements related to the continued development and commercialization of vosaroxin, the timing of our Phase 1b/2 trial of SNS-062, and the sufficiency of Sunesis' cash and funding into June 2018. Words such as "advance," "continue," "expect," "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 SNS-062 or vosaroxin could be otherwise halted or significantly delayed for various reasons, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, including SNS-062, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including SNS-062 or 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 timing or conduct of Sunesis' clinical trials, 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 SNS-062, vosaroxin and other product candidates. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 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, 2017 (Unaudited)	December 31, 2016 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,470	$ 8,056
Marketable securities	23,706	34,532
Prepaids and other current assets	714	643
Total current assets	35,890	43,231
Property and equipment, net	1	3
Total assets	$ 35,891	$ 43,234
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,647	$ 1,871
Accrued clinical expense	1,351	1,434
Accrued compensation	1,055	2,000
Other accrued liabilities	1,782	1,691
Current portion of deferred revenue	-	610
Current portion of notes payable	4,583	3,333
Total current liabilities	11,418	10,939
Non-current portion of notes payable	9,930	11,102
Other accrued liabilities	226	169
Commitments		
Stockholders' equity:		
Preferred stock	18,808	18,808
Common stock	2	2
Additional paid-in capital	602,755	599,632
Accumulated other comprehensive income (loss)	(18)	(22)
Accumulated deficit	(607,230)	(597,396)
Total stockholders' equity	14,317	21,024
Total liabilities and stockholders' equity	35,891	43,234

Note 1: The consolidated balance sheet as of December 31, 2016 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, 2016.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three months ended March 31,	
	2017	2016
	(Unaudited)	(Unaudited)
Revenue:		
License and other revenue	$ 669	$ 640
Total revenues	669	640
Operating expenses:		
Research and development	6,162	6,209
General and administrative	3,942	4,295
Total operating expenses	10,104	10,504
Loss from operations	(9,435)	(9,864)
Interest expense	(484)	(298)
Other income (expense), net	85	76
Net loss	(9,834)	(10,086)
Unrealized gain (loss) on available-for-sale securities	4	13
Comprehensive loss	$ (9,830)	$ (10,073)
Basic and diluted loss per common share:		
Net loss	$ (9,834)	$ (10,086)
Shares used in computing basic and diluted loss per common share	21,029	14,443
Basic and diluted loss per common share	$ (0.47)	$ (0.70)

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