

Sunesis Pharmaceuticals Reports First Quarter 2015 Financial Results and Recent Highlights

May 5, 2015 7:01 AM ET

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

SOUTH SAN FRANCISCO, Calif., May 5, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the first quarter ended March 31, 2015. Loss from operations for the three months ended March 31, 2015 was \$8.8 million. As of March 31, 2015, cash, cash equivalents and marketable securities totaled \$39.8 million.

"Sunesis is committed to improving treatment outcomes of acute myeloid leukemia patients," said Daniel Swisher, Chief Executive Officer of Sunesis. "Working toward this goal, we remain in an active dialogue with the FDA to determine a regulatory path forward in the United States and look forward to gaining further clarity around mid-2015 with the hope that we can proceed to a rolling NDA submission in the second half of the year. In Europe, we have been assigned a Rapporteur and a Co-Rapporteur who are two appointed members of the EMA's Committee of Human Medicinal Products, and we plan to meet with the Rapporteurs in mid-2015 to discuss our MAA filing. In addition, we continue to see progress with vosaroxin in our investigator sponsored trials and with our kinase-inhibitor programs, including the planned submission of an IND for our differentiated BTK inhibitor, SNS-062."

Additional First Quarter 2015 Highlights

- **Announced completion of Investigational New Drug (IND) application-enabling toxicology studies for SNS-062.** In March, Sunesis announced that it completed preclinical toxicology studies of SNS-062, a non-covalently binding inhibitor of BTK with a distinct binding site and favorable pharmacokinetic profile. Based on results from these studies, the company plans to file an IND application for SNS-062 with the FDA this year.
- **Amended Loan and Security Agreement to defer principal for one year.** In February, Sunesis executed an amendment to its loan and security agreement with Oxford Finance LLC, Silicon Valley Bank, and Horizon Technology Finance Corporation. The amendment created an interest-only period from March 1, 2015 through February 1, 2016 on the remainder of Sunesis' loan balance, deferring the remaining principal payments and providing additional financial flexibility to execute the company's corporate strategy.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled \$39.8 million as of March 31, 2015, as compared to \$43.0 million as of December 31, 2014. The decrease of \$3.2 million was primarily due to \$11.6 million of net cash used in operating activities and \$1.6 million of principal payments against notes payable, partially offset by \$10.0 million raised from sales of common stock through the company's at-the-market facility with Cantor Fitzgerald & Co. A further \$7.5 million was raised in April through this facility, resulting in a pro-forma March 31 cash balance of \$47.3 million. This capital is expected to be sufficient to fund the company to the middle of 2016.
- Revenue for the three months ended March 31, 2015 was \$0.9 million, as compared to \$2.0 million for the same period in 2014. Revenue in each period was primarily due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.
- Research and development expense was \$4.5 million for the three months ended March 31, 2015 as compared to \$7.6 million for the same period in 2014. The decrease between the periods was primarily due to reductions of \$2.1 million in clinical trial expenses and \$0.7 million in other outside services and consulting costs.
- General and administrative expense was \$5.1 million for the three months ended March 31, 2015 as compared to

\$3.4 million for the same period in 2014. The increase between the periods was primarily due to increases of \$1.2 million in expenses related primarily to commercial planning and medical affairs and \$0.5 million related to non-cash stock-based compensation.

- Interest expense was \$0.2 million for the three months ended March 31, 2015 as compared to \$0.5 million for the same period in 2014. The decrease in 2015 was due to the reduced principal balance outstanding on notes payable.
- Net other expense was \$0.1 million for the three months ended March 31, 2015 as compared to \$5.1 million for the same period in 2014. The amounts for each period were primarily comprised of non-cash charges for the revaluation of warrants issued in 2010.
- Cash used in operations was \$11.6 million for the three months ended March 31, 2015 as compared to \$11.4 million for the same period in 2014. Net cash used in the 2015 period resulted primarily from the net loss of \$9.1 million and changes in operating assets and liabilities of \$4.6 million, partially offset by net adjustments for non-cash items of \$2.1 million.
- Sunesis reported loss from operations of \$8.8 million for the three months ended March 31, 2015 as compared to \$9.0 million for the same period in 2014. Net loss was \$9.1 million for the three months ended March 31, 2015 as compared to \$14.6 million for the same period in 2014.

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 (800) 591-6942 (U.S. and Canada) or (617) 614-4909 (international), and entering passcode 65529984. 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 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 that there will be approximately 20,830 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2015. 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 75,000. 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 potential 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 Sunesis' overall strategy, clinical development of our product candidates, planned meetings with the FDA and EMA to discuss the regulatory path forward for vosaroxin, subsequent NDA and MAA submissions, plans to file an IND application for SNS-062 with the FDA, the commercial potential of vosaroxin, and the sufficiency of Sunesis' cash resources and the use of the proceeds under the loan facility with Oxford Finance LLC, Horizon Technology Finance Corporation and Silicon Valley Bank. Words such as "determine," "estimate," "hope," "remain," "expect," "look forward," "potential," "plan," "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' 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, risks related to the conduct of Sunesis' clinical trials, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin, 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. 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, 2014 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2015. 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, 2015 (Unaudited)	December 31, 2014 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,784	\$ 22,186
Marketable securities	21,009	20,795
Prepays and other current assets	1,478	1,223
Total current assets	41,271	44,204
Property and equipment, net	31	42
Total assets	\$ 41,302	\$ 44,246

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 2,121	\$ 3,177
Accrued clinical expense	2,225	3,112
Accrued compensation	1,029	2,287
Other accrued liabilities	2,781	3,087
Current portion of deferred revenue	3,418	3,418
Current portion of notes payable	713	9,257
Warrant liability	3,632	3,543
Total current liabilities	15,919	27,881

Non-current portion of deferred revenue 1,709 2,563

Non-current portion of notes payable 6,881 --

Commitments

Stockholders' equity:

Common stock	7	7
Additional paid-in capital	548,616	536,499
Accumulated other comprehensive loss	(5)	(7)
Accumulated deficit	(531,825)	(522,697)
Total stockholders' equity	16,793	13,802
Total liabilities and stockholders' equity	\$ 41,302	\$ 44,246

Note 1: The consolidated balance sheet as of December 31, 2014 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, 2014.

SUNESIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

Three months ended
March 31,
2015 2014
(Unaudited) (Unaudited)

Revenue:

License and other revenue	\$ 854	\$ 1,995
Total revenues	854	1,995
Operating expenses:		
Research and development	4,512	7,552
General and administrative	5,111	3,417
Total operating expenses	9,623	10,969
Loss from operations	(8,769)	(8,974)
Interest expense	(239)	(547)
Other income (expense), net	(120)	(5,052)
Net loss	(9,128)	(14,573)
Unrealized gain (loss) on available-for-sale securities	2	7
Comprehensive loss	\$ (9,126)	\$ (14,566)
Basic and diluted loss per common share:		
Net loss	\$ (9,128)	\$ (14,573)
Shares used in computing basic and diluted loss per common share	67,641	56,313
Basic and diluted loss per common share	\$ (0.13)	\$ (0.26)

CONTACT: Investor and Media Inquiries:

David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717



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