Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2015 Financial Results and Recent Highlights

March 10, 2016 7:01 AM ET

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

SOUTH SAN FRANCISCO, Calif., March 10, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the fourth quarter and year ended December 31, 2015. Loss from operations for the three months and year ended December 31, 2015 was $11.3 million and $39.3 million, respectively. As of December 31, 2015, cash, cash equivalents and marketable securities totaled $46.4 million.

“In the fourth quarter, we achieved a top 2015 corporate milestone with the submission and validation of our Marketing Authorization Application in Europe for vosaroxin to treat relapsed/refractory AML,” said Daniel Swisher, Chief Executive Officer of Sunesis. “We are committed to bringing this important new therapy to a patient population with so few options. We will be providing updates later this year on the progress in Europe and in other major regions, including North America.”

Mr. Swisher added: “Another key milestone for Sunesis is the progress of our pipeline of kinase inhibitors representing targeted new approaches to the treatment of cancer. Soon, we expect to initiate clinical development of SNS-062, our differentiated non-covalent BTK inhibitor with a European Phase 1A clinical trial in healthy volunteers, followed by a Phase 1B/2 in B-cell malignancy patients later this year. We also look forward to seeing data from the ongoing multi-arm combination study for the Takeda-partnered pan-RAF inhibitor, TAK-580, and to advancing our PDK-1 inhibitor, SNS-229, through IND-enabling toxicology studies to an IND.”

Fourth Quarter 2015 and Recent Highlights

- ***Submission of Marketing Authorization Application for Vosaroxin for the Treatment of Acute Myeloid Leukemia (AML) in Europe.*** In December 2015, Sunesis submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for Vosaroxin for the treatment of relapsed/refractory AML in patients aged 60 years and older. The application was validated by the EMA on December 31, 2015, confirming that the submission was complete and initiating 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.

- ***Presentation of Results from MD Anderson Sponsored Trial in AML and Washington University Sponsored Phase 1/2 Trial of Vosaroxin in MDS at ASH Annual Meeting.*** In December 2015, Sunesis presented results from an ongoing Phase 1B/2 University of Texas MD Anderson Cancer Center-sponsored trial of vosaroxin in combination with decitabine in older patients with previously untreated acute myeloid leukemia (AML) and high-risk myelodyplastic syndrome (MDS), as well as results from a Washington University-sponsored Phase 1 trial of vosaroxin plus azacitidine in patients with myelodysplastic syndrome, at the 57th American Society of Hematology Annual Meeting in Orlando, Florida. The oral presentation, titled “Phase I/II Study of Vosaroxin and Decitabine in Newly Diagnosed Older Patients (pts) with Acute Myeloid Leukemia (AML) and High Risk Myelodyplastic Syndrome (MDS)” and the poster “A Phase I Study of Vosaroxin plus Azacitidine for Patients with Myelodysplastic Syndrome,” are available on the Sunesis website at www.sunesis.com.

- ***Partnership with Clinigen Group to Initiate Compassionate Use Program for Patients with AML.*** In December 2015, Sunesis initiated a global Compassionate Use Program for vosaroxin. The program is available to eligible patients diagnosed with relapsed or refractory acute myeloid leukemia (AML) and is being managed by Clinigen Group's Idis Managed Access division.

- ***First Patient Treated in Indiana University Study of Vosaroxin and Cytarabine in Adults Age 60 Years and Older***

With Previously Untreated AML. In December 2015, the first patient was treated in an investigator-sponsored study of vosaroxin and cytarabine in adult patients age 60 years and older with previously untreated acute myeloid leukemia (AML). The trial is being conducted at the Melvin and Bren Simon Cancer Center at Indiana University under the direction of Seyed Hamid Sayar, M.D., Assistant Professor of Clinical Medicine.

- ***European Patent Covering Vosaroxin Combination Use in AML and Other Hematological Malignancies.*** In November 2015, the European Patent Office (EPO) granted European Patent No. 2 049 109 B1, claiming certain combined uses of vosaroxin and cytarabine, at doses of 10-120 mg/m^2 and 5-1500 mg/m^2, respectively, for the treatment of acute myelogenous leukemia and acute myeloblastic leukemia. The patent further provides for combinations of vosaroxin and cytarabine with other therapies, such as radiation, or other chemotherapeutics, including anti-cancer agents, in hematologic disorders, whether administered simultaneously or sequentially. Sunesis is proceeding to validate this patent in multiple EPO member states. The resulting national patents would expire in the third quarter of 2027, but could be eligible for supplementary patent term in EPO member states beyond this date. Related patent applications are pending in several countries, including the United States and Japan.

- ***Poster Presentation of VALOR Responder Survival Analysis at the Chemotherapy Foundation Symposium.*** In November, Sunesis presented results from a responder survival analysis of the VALOR trial at the 2015 Chemotherapy Foundation Symposium (CFS) in New York City. The analysis examined the impact of complete remission status on overall survival. Results showed that CR status was the strongest independent predictor of overall survival in patients enrolled in the study, regardless of study arm, with median survival for patients in CR lasting more than 12 months longer than patients without a CR. Furthermore, the addition of vosaroxin to cytarabine demonstrated a two-fold increase in CR rate by day 60. The poster presentation, titled “Impact of Complete Remission on Overall Survival in Patients with Refractory/Relapsed Acute Myeloid Leukemia Treated with Vosaroxin Plus Cytarabine or Placebo Plus Cytarabine: Responder Analysis for the Phase 3 VALOR Trial,” is available at www.sunesis.com.

- ***Presentations at the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.*** In November 2015, two poster presentations from the company’s proprietary kinase inhibitor programs were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. The presentations included preclinical data from the company’s selective PDK1 inhibitors SNS-229 and SNS-510, as well as the company’s potent noncovalent second-generation BTK inhibitor, SNS-062.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $46.4 million as of December 31, 2015, as compared to $43.0 million as of December 31, 2014. The increase of $3.4 million was primarily due to net proceeds of $43.8 million from the sale of common and preferred shares and from the exercise of warrants, stock options and stock purchase rights, partially offset by $38.7 million of net cash used in operating activities and $1.7 million of principal payments against notes payable. This capital is expected to be sufficient to fund operations through the first quarter of 2017.

- Revenues for the three months and year ended December 31, 2015 were $0.7 million and $3.1 million, as compared to $0.9 million and $5.7 million for the same periods in 2014. Revenue in each period was primarily due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.

- Research and development expenses were $7.6 million and $23.7 million for the three months and year ended December 31, 2015, from $6.0 million and $27.7 million for the same periods in 2014, primarily relating to the vosaroxin development program in each year. The decrease of $4.0 million in 2015 was primarily due to a decrease of $5.4 million in clinical trial expenses, partially offset by increases of $0.9 million in personnel costs (including an increase of $0.5 million in stock-based compensation expense), and $0.5 million in other outside

services and consulting costs.

- General and administrative expenses for the three months and year ended December 31, 2015 were $4.4 million and $18.7 million, as compared to $6.1 million and $23.1 million in 2014. The decrease of $4.5 million in 2015 was due to a decrease of $4.5 million in professional services and personnel costs.

- Interest expense was $0.2 million and $0.9 million for the three months and year ended December 31, 2015 as compared to $0.3 million and $1.7 million for the same periods in 2014. The decreases in 2015 were due to the reduced principal balance outstanding on notes payable to the Lenders under the Loan Agreement.

- Net other income was nil and $3.6 million for the three months and year ended December 31, 2015, as compared to $10.1 million and $3.8 million for the same periods in 2014. The 2014 and 2015 amounts were primarily comprised of non-cash credits for the revaluation of warrants issued in an underwritten offering in 2010.

- Cash used in operations was $38.7 million for the year ended December 31, 2015, as compared to $43.2 million for the same period in 2014.

- Sunesis reported loss from operations of $11.3 million and $39.3 million for the three months and year ended December 31, 2015, as compared to $11.2 million and $45.0 million for the same periods in 2014. Net loss was $11.6 million and $36.7 million for the three months and year ended December 31, 2015, as compared to $1.3 million and $43.0 million for the same periods in 2014.

Conference Call Information

Sunesis will host an update conference call today, March 10th 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 49218884. 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.

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This press release contains forward-looking statements, including statements related to Sunesis' estimated timelines for regulatory interactions and regulatory progress, including the anticipated progress and potential approval of vosaroxin by the EMA, clinical development of SNS-062; Sunesis' overall strategy in Europe and other major regions and plans to gain marketing approval of vosaroxin in the U.S., the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, and potential advancements of SNS-229 to an IND, the need for and the role of vosaroxin as a potential new treatment option, , 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, Sunesis' Annual Report on Form 10-K for the year ended December 31, 2015, 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)

	December 31, 2015 (Unaudited)	2014 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,387	$ 22,186
Marketable securities	21,043	20,795
Prepaids and other current assets	558	1,223
Total current assets	46,988	44,204
Property and equipment, net	14	42
Deposits and other assets	-	-
Total assets	$ 47,002	$ 44,246
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		

Accounts payable	$ 2,453	$ 3,177
Accrued clinical expense	1,954	3,112
Accrued compensation	1,606	2,287
Other accrued liabilities	2,711	3,087
Current portion of deferred revenue	2,441	3,418
Current portion of notes payable	7,834	9,257
Warrant liability	-	3,543
Total current liabilities	18,999	27,881
Non-current portion of deferred revenue	610	2,563
Non-current portion of notes payable	-	-
Commitments		
Stockholders' equity (deficit):		
Convertible preferred stock	16,459	-
Common stock	9	7
Additional paid-in capital	570,309	536,499
Accumulated other comprehensive loss	(11)	(7)
Accumulated deficit	(559,373)	(522,697)
Total stockholders' equity (deficit)	27,393	13,802
Total liabilities and stockholders' equity (deficit)	$ 47,002	$ 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 December 31,		**Year ended December 31,**	
	2015	**2014**	**2015**	**2014**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Note 2)**
Revenue:				
License and other revenue	$ 670	$ 896	$ 3,061	$ 5,734
Total revenues	670	896	3,061	5,734
Operating expenses:				
Research and development	7,628	5,968	23,701	27,665
General and administrative	4,382	6,082	18,662	23,112
Total operating expenses	12,010	12,050	42,363	50,777
Loss from operations	(11,340)	(11,154)	(39,302)	(45,043)
Interest expense	(234)	(311)	(939)	(1,719)

Other income (expense), net	(4)	10,142	3,565	3,760
Net loss	(11,578)	(1,323)	(36,676)	(43,002)
Unrealized gain (loss) on available-for-sale securities	(9)	2	(4)	(4)
Comprehensive loss	$ (11,587)	$ (1,321)	$ (36,680)	$ (43,006)
Basic and diluted loss per common share:				
Net loss:				
Basic	$ (11,578)	$ (1,323)	$ (36,676)	$ (43,002)
Diluted	$ (11,578)	$ (1,323)	$ (36,676)	$ (46,894)
Shares used in computing net loss per common share:				
Basic	76,683	63,041	72,933	60,057
Diluted	76,683	63,041	72,933	60,510
Net loss per common share:				
Basic	$ (0.15)	$ (0.02)	$ (0.50)	$ (0.72)
Diluted	$ (0.15)	$ (0.02)	$ (0.50)	$ (0.76)

Note 2: The consolidated statement of operations and comprehensive loss for the year ended 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.

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

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals Inc