Sunesis Pharmaceuticals Reports Third Quarter 2015 Financial Results and Recent Highlights

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

SOUTH SAN FRANCISCO, Calif., Nov. 5, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the third quarter ended September 30, 2015. Loss from operations for the three and nine months ended September 30, 2015 was $8.6 million and $28.0 million, respectively. As of September 30, 2015, cash, cash equivalents and marketable securities totaled $30.5 million.

"We continue to work diligently to complete and submit an MAA by year end for approval of vosaroxin in Europe as a treatment for AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "We believe the European market opportunity is significant, and remain encouraged by the strong support from within the international AML investigator community to bring this important new therapy to a patient population that has seen little improvement in treatment standards in the last 40 years. While this effort remains our central priority, we are also carefully evaluating and refining our plans to gain marketing approval in the U.S., and working toward key milestones with our kinase inhibitor pipeline, including data at the upcoming AACR-NCI-EORTC Conference followed by an upcoming CTA filing and Phase 1 study for SNS-062 in Europe."

Third Quarter 2015 Highlights

- ***Received European regulatory guidance regarding potential marketing authorization application for Vosaroxin in AML and Announced Expected Submission of MAA Filing before Year End.*** In July 2015, Sunesis announced that, following pre-submission advisory meetings to discuss the potential submission of a Marketing Authorization Application (MAA) for vosaroxin in Europe, the company is proceeding with an MAA filing. The MAA will focus on the indication of relapsed/refractory acute myeloid leukemia (AML) in patients age 60 years and older, a population with the greatest medical need and for whom the greatest benefit was observed in the vosaroxin/cytarabine treatment arm of VALOR, the company's pivotal Phase 3 study of vosaroxin in adult patients with relapsed or refractory AML. In October, the company confirmed that it intends to submit an MAA for vosaroxin by the end of 2015.

- ***Announced Poster Presentation of VALOR Responder Survival Analysis at the Chemotherapy Foundation Symposium.*** Yesterday, Sunesis announced that results from a responder survival analysis of the VALOR trial were presented in a poster presentation 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 CR benefit conveyed by vosaroxin was consistently beneficial across all pre-specified subgroups, including in patients with the high unmet medical need, such as those over 60 years of age and those with refractory or relapsed disease. 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," will be available at www.sunesis.com following the conclusion of the symposium.

- ***Announced Presentations at the Upcoming AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.*** Sunesis recently announced that two poster presentations from the company's proprietary kinase inhibitor programs will be presented at the upcoming AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 5-9 in Boston, Massachusetts. The presentations on November 8th will include 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.

- ***Announced Oral Presentation of VALOR Analysis at the 77th Annual Meeting of the Japanese Society of Hematology.*** In October, Sunesis announced that data from an analysis of the company's VALOR trial, evaluating vosaroxin in older patients with AML, were presented at the AML Clinical Trial Oral Session of the 77th Annual Meeting of the Japanese Society of Hematology (JSH) in Kanazawa, Japan. The data presented at JSH, which show a compelling survival benefit, durable responses and tolerability profile in patients age 60 years and older, were first presented at the European Hematology Association Congress in June 2015.

- ***Announced Publication of Vosaroxin Phase 3 VALOR Trial Results in The Lancet Oncology.*** In August, Sunesis announced that results from the company's Phase 3 VALOR trial were published in *The Lancet Oncology*. The article, titled "Vosaroxin plus cytarabine versus placebo plus cytarabine in patients with first relapsed or refractory acute myeloid leukemia (VALOR): a randomised, controlled, double-blind, multinational, phase 3 study" is available online and appeared in the September 2015 print issue of The Lancet Oncology. The published results describe how although overall survival (OS) did not reach a significant difference based on the primary unstratified log-rank analysis of the endpoint, vosaroxin plus cytarabine, based on other prespecified analyses did show an overall survival benefit in relapsed/refractory AML, with the greatest benefit observed in patients older than 60 years, a population with limited treatment options.

- ***Received feedback from FDA regarding NDA filing for Vosaroxin in AML.*** In July 2015, Sunesis announced that, following a recent meeting with the U.S. Food and Drug Administration (FDA), the FDA recommended that the company provide additional clinical evidence to support a future NDA submission. The company is currently evaluating and refining its plan to gain marketing approval in the U.S. based on this feedback.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $30.5 million as of September 30, 2015, as compared to $43.0 million as of December 31, 2014. The decrease of $12.5 million was primarily due to $29.5 million of net cash used in operating activities and $1.6 million of principal payments against notes payable, partially offset by $18.6 million raised from the sale of common stock through the company's at-the-market facility with Cantor Fitzgerald & Co. and from option exercises. This capital is expected to be sufficient to fund the company to the middle of 2016.

- Revenue for the three and nine months ended September 30, 2015 was $0.7 million and $2.4 million as compared to $0.9 million and $4.8 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 expense was $5.3 million and $16.1 million for the three and nine months ended September 30, 2015 as compared to $6.9 million and $21.7 million for the same periods in 2014. The decreases between the comparable three and nine month periods were primarily due to reductions in clinical trial expenses, consulting and other outside services costs in each case.

- General and administrative expense was $4.0 million and $14.3 million for the three and nine months ended September 30, 2015 as compared to $7.2 million and $17.0 million for the same periods in 2014. The decreases between the comparable three and nine month periods were primarily due to decreases in outside services and personnel costs.

- Interest expense was $0.2 million and $0.7 million for the three and nine months ended September 30, 2015 as compared to $0.4 million and $1.4 million for the same periods in 2014. The decreases in the 2015 periods were due to the reduced principal balance outstanding on notes payable.

- Net other income was $1.8 million and $3.6 million for the three and nine months ended September 30, 2015 as compared to net other expense of $1.6 million and $6.4 million for the same periods in 2014. The amounts for each period were primarily comprised of non-cash credits or charges for the revaluation of warrants issued in 2010, which expired in October 2015.

- Cash used in operations was $29.5 million for the nine months ended September 30, 2015 as compared to $34.2 million for the same period in 2014. Net cash used in the 2015 period resulted primarily from the net loss of $25.1 million and changes in operating assets and liabilities of $5.6 million, partially offset by net adjustments for non-cash items of $1.2 million.

- Sunesis reported loss from operations of $8.6 million and $28.0 million for the three and nine months ended September 30, 2015 as compared to $13.3 million and $33.9 million for the same periods in 2014. Net loss was $7.0 million and $25.1 million for the three and nine months ended September 30, 2015 as compared to $15.3 million and $41.7 million for the same periods in 2014.

Conference Call Information

Sunesis will host an update conference call today, November 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 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 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.

This press release contains forward-looking statements, including statements related to Sunesis' estimated timelines for regulatory interactions and regulatory progress, including the anticipated submission of the MAA for vosaroxin with the EMA, CTA filing for SNS-062 in Europe and plans to gain marketing approval of vosaroxin in the U.S., Sunesis' overall strategy, the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, the need for and the role of vosaroxin as a potential new treatment option, and Sunesis' clinical development of vosaroxin,

including the analysis of the results from the VALOR clinical trial, the commercial potential of vosaroxin in Europe and the U.S., and the sufficiency of Sunesis' cash resources. Words such as "believe," "expect," "intends," "plan," "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 submit timely the MAA to the EMA, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval 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 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 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' Quarterly Report on Form 10-Q for the quarter ended June 30, 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)

	September 30, 2015	**December 31, 2014**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 16,801	$ 22,186
Marketable securities	13,702	20,795
Prepaids and other current assets	796	1,223
Total current assets	31,299	44,204
Property and equipment, net	17	42
Total assets	$ 31,316	$ 44,246
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,790	$ 3,177
Accrued clinical expense	1,909	3,112
Accrued compensation	1,491	2,287
Other accrued liabilities	2,652	3,087
Current portion of deferred revenue	2,441	3,418
Current portion of notes payable	5,861	9,257
Warrant liability	--	3,543
Total current liabilities	16,144	27,881

Non-current portion of deferred revenue	1,221	2,563
Non-current portion of notes payable	1,893	--
Commitments		
Stockholders' equity:		
Common stock	8	7
Additional paid-in capital	559,847	536,499
Accumulated other comprehensive loss	(2)	(7)
Accumulated deficit	(547,795)	(522,697)
Total stockholders' equity	12,058	13,802
Total liabilities and stockholders' equity	$ 31,316	$ 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 September 30,		**Nine months ended September 30,**	
	2015	**2014**	**2015**	**2014**
	(Unaudited)		**(Unaudited)**	
Revenue:				
License and other revenue	$ 683	$ 854	$ 2,391	$ 4,838
Total revenues	683	854	2,391	4,838
Operating expenses:				
Research and development	5,259	6,939	16,073	21,697
General and administrative	3,994	7,226	14,280	17,030
Total operating expenses	9,253	14,165	30,353	38,727
Loss from operations	(8,570)	(13,311)	(27,962)	(33,889)
Interest expense	(233)	(391)	(705)	(1,408)
Other income (expense), net	1,782	(1,623)	3,569	(6,382)
Net loss	(7,021)	(15,325)	(25,098)	(41,679)
Unrealized gain (loss) on available-for-sale securities	3	(2)	5	(6)
Comprehensive loss	$ (7,018)	$ (15,327)	$ (25,093)	$ (41,685)
Basic and diluted loss per common share:				
Net loss	$ (7,021)	$ (15,325)	$ (25,098)	$ (41,679)

Shares used in computing basic and diluted loss per common share	74,776	60,549	71,670	59,052
Basic and diluted loss per common share	$ (0.09)	$ (0.25)	$ (0.35)	$ (0.71)

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