Sunesis Pharmaceuticals Reports Second Quarter 2015 Financial Results and Recent Highlights

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SOUTH SAN FRANCISCO, Calif., July 30, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the second quarter ended June 30, 2015. Loss from operations for the three and six months ended June 30, 2015 was $10.6 million and $19.4 million, respectively. As of June 30, 2015, cash, cash equivalents and marketable securities totaled $39.6 million.

"We remain committed to moving vosaroxin forward as an important new therapy for patients with AML, and to realizing the value of this product candidate for all our constituents," said Daniel Swisher, Chief Executive Officer of Sunesis. "As part of this effort, we are moving forward rapidly toward the filing of a marketing authorization application in Europe and are carefully evaluating and refining our plans to gain marketing approval in the U.S. As we continue to advance these strategies and work toward key milestones with our kinase inhibitor pipeline, we are also evaluating and prioritizing our spending to ensure our ability to realize the value of our portfolio."

Second Quarter 2015 Highlights

- ***Received European regulatory guidance regarding potential marketing authorization application for Vosaroxin in AML.*** 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.

- ***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.

- ***Announced presentation of new data at EHA 2015 from predefined subgroup of patients age 60 years and older enrolled in VALOR.*** In June 2015, Sunesis announced the presentation of results from predefined subgroups of patients age 60 years and older enrolled in VALOR. The results were presented at the 20th Congress of the European Society of Hematology in Vienna, Austria. The poster, titled "Improved survival in patients ≥60 with first relapsed/refractory acute myeloid leukemia treated with vosaroxin plus cytarabine vs placebo plus cytarabine: results from the Phase 3 VALOR study," as well as an additional poster presented at the meeting, titled "Allogeneic transplant in patients ≥60 years of age with first relapsed or refractory acute myeloid leukemia after treatment with vosaroxin or placebo plus cytarabine: results from VALOR," are available on the Sunesis website as www.sunesis.com.

- ***Announced presentation of VALOR trial subgroup analysis at ASCO 2015.*** In May 2015, Sunesis announced the presentation of results from a post hoc subgroup analysis of patients age 60 years and older who underwent allogeneic hematopoietic cell transplant (HCT) in the VALOR trial. The poster, titled "Allogeneic hematopoietic cell transplant (HCT) in patients (pts) ≥ 60 years of age with first relapsed or refractory acute myeloid leukemia (R/R AML) after treatment with vosaroxin plus cytarabine (pla/cyt): results from VALOR", is available on the Sunesis website at www.sunesis.com.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $39.6 million as of June 30, 2015, as compared to $43.0

million as of December 31, 2014. The decrease of $3.4 million was primarily due to $19.8 million of net cash used in operating activities and $1.6 million of principal payments against notes payable, partially offset by $18.0 million raised from the sale of common stock through the company's at-the-market facility with Cantor Fitzgerald & Co. and from option exercises. A further $0.4 million was raised in July through this facility, resulting in a pro-forma June 30, 2015 cash balance of $40.0 million. This capital is expected to be sufficient to fund the company to the middle of 2016.

- Revenue for the three and six months ended June 30, 2015 was $0.9 million and $1.7 million as compared to $2.0 million and $4.0 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 $6.3 million and $10.8 million for the three and six months ended June 30, 2015 as compared to $7.2 million and $14.8 million for the same periods in 2014. The decreases between the comparable three and six month periods were primarily due to reductions in clinical trial expenses in each case.

- General and administrative expense was $5.2 million and $10.3 million for the three and six months ended June 30, 2015 as compared to $6.4 million and $9.8 million for the same periods in 2014. The decrease between the comparable three month periods was primarily due to decreases in personnel costs and outside services costs. The increase between the comparable six month periods was primarily due to an increase in outside services costs.

- Interest expense was $0.2 million and $0.5 million for the three and six months ended June 30, 2015 as compared to $0.5 million and $1.0 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 $1.9 million and $1.8 million for the three and six months ended June 30, 2015 as compared to $0.3 million of net other income and $4.8 million of net other expense 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.

- Cash used in operations was $19.8 million for the six months ended June 30, 2015 as compared to $21.6 million for the same period in 2014. Net cash used in the 2015 period resulted primarily from the net loss of $18.1 million and changes in operating assets and liabilities of $3.4 million, partially offset by net adjustments for non-cash items of $1.7 million.

- Sunesis reported loss from operations of $10.6 million and $19.4 million for the three and six months ended June 30, 2015 as compared to $11.6 million and $20.6 million for the same periods in 2014. Net loss was $8.9 million and $18.1 million for the three and six months ended June 30, 2015 as compared to $11.8 million and $26.4 million for the same periods in 2014.

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.

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This press release contains forward-looking statements, including statements related to Sunesis' overall strategy, the design, conduct and results of Sunesis' clinical trials, including the analysis, assessment and conclusions of the results of the VALOR trial, the commercial potential of vosaroxin, and the need for and the role of vosaroxin as a new treatment options, Sunesis' plans to gain marketing approval of vosaroxin in the U.S. and Europe, and the sufficiency of Sunesis' cash resources. Words such as "estimate," "expect," "potential," "will," "believe, "plan" 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' 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)

	June 30, 2015	**December 31, 2014**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 20,302	$ 22,186
Marketable securities	19,254	20,795
Prepaids and other current assets	1,165	1,223
Total current assets	40,721	44,204
Property and equipment, net	19	42
Total assets	$ 40,740	$ 44,246

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,282	$ 3,177
Accrued clinical expense	2,249	3,112
Accrued compensation	1,245	2,287
Other accrued liabilities	4,072	3,087
Current portion of deferred revenue	3,418	3,418
Current portion of notes payable	3,253	9,257
Warrant liability	1,765	3,543
Total current liabilities	18,284	27,881
Non-current portion of deferred revenue	854	2,563
Non-current portion of notes payable	4,421	--
Commitments		
Stockholders' equity:		
Common stock	7	7
Additional paid-in capital	557,953	536,499
Accumulated other comprehensive loss	(5)	(7)
Accumulated deficit	(540,774)	(522,697)
Total stockholders' equity	17,181	13,802
Total liabilities and stockholders' equity	$ 40,740	$ 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 June 30,		**Six months ended June 30,**	
	2015	**2014**	**2015**	**2014**
	(Unaudited)		**(Unaudited)**	
Revenue:				

License and other revenue	$ 854	$ 1,989	$ 1,708	$ 3,984
Total revenues	854	1,989	1,708	3,984
Operating expenses:				
Research and development	6,302	7,206	10,814	14,758
General and administrative	5,175	6,387	10,286	9,804
Total operating expenses	11,477	13,593	21,100	24,562
Loss from operations	(10,623)	(11,604)	(19,392)	(20,578)
Interest expense	(233)	(470)	(472)	(1,017)
Other income (expense), net	1,907	293	1,787	(4,759)
Net loss	(8,949)	(11,781)	(18,077)	(26,354)
Unrealized gain (loss) on available-for-sale securities	--	(11)	2	(4)
Comprehensive loss	$ (8,949)	$ (11,792)	$ (18,075)	$ (26,358)
Basic and diluted loss per common share:				
Net loss:				
Basic	$ (8,949)	$ (11,781)	$ (18,077)	$ (26,354)
Diluted	$ (10,816)	$ (12,114)	$ (18,077)	$ (26,354)
Shares used in computing net loss per common share:				
Basic	72,513	60,246	70,090	58,291
Diluted	72,525	61,895	70,090	58,291
Net loss per common share:				
Basic	$ (0.12)	$ (0.20)	$ (0.26)	$ (0.45)
Diluted	$ (0.15)	$ (0.20)	$ (0.26)	$ (0.45)

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