Sunesis Pharmaceuticals Reports Second Quarter 2016 Financial Results and Recent Highlights

July 29, 2016 7:00 AM ET

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

SOUTH SAN FRANCISCO, Calif., July 29, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the second quarter ended June 30, 2016. Loss from operations for the three months ended June 30, 2016 was $10.0 million. As of June 30, 2016, cash, cash equivalents and marketable securities totaled $33.1 million.

"During the second quarter, we strengthened the foundation of our oncology pipeline through the advancement of our vosaroxin program and lead proprietary BTK kinase inhibitor, SNS-062. Achievement of upcoming milestones from both these programs we believe will unlock significant value for the company," said Daniel Swisher, Chief Executive Officer of Sunesis

"We are progressing our regulatory efforts to bring vosaroxin to market in Europe as a treatment for relapsed/refractory AML, and in parallel are maintaining an active dialogue with potential European collaborators toward the goal of supporting a market launch in 2017." Mr. Swisher continued: "As for SNS-062, our differentiated, non-covalent BTK-inhibitor, we look forward to presenting results from our Phase 1A dose escalation study in healthy volunteers at the upcoming International Conference on New Concepts in B-Cell Malignancies in September. We are actively finalizing our protocol with investigator input to begin a Phase 1B/2 study in patients with B-cell malignancies around year-end."

Second Quarter 2016 and Recent Highlights

- ***Presentation of Updated Results from MD Anderson Sponsored Trial in AML and high-risk MDS at EHA Annual Meeting.*** In June 2016, 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) were presented at the 21st Congress of the European Hematology Association (EHA) in Copenhagen, Denmark. At the optimized induction dose of 70 mg/m2 of vosaroxin (n=41), the combination of vosaroxin and decitabine demonstrated a compelling CR/CRp/CRi rate of 76% and a median overall survival of 16.1 months. The oral presentation, titled "Phase I/ll study of vosaroxin and decitabine in newly diagnosed older patients with acute myeloid leukemia and high-risk myelodysplastic syndrome," is available on the Sunesis website at www.sunesis.com.

- ***Presentation of Results Evaluating the Value of Complete Remission Prior to HCT in Patients with AML at ASCO Annual Meeting.*** In June 2016, Sunesis presented results from a study conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) at the Medical College of Wisconsin demonstrating the significant value of achieving complete remission prior to allogeneic hematopoietic cell transplantation (HCT) in patients with acute myeloid leukemia (AML) at the 2016 American Society of Clinical Oncology. The study was funded jointly by Sunesis and CIBMTR. The poster presentation, titled "Allogeneic transplantation for advanced myelogenous leukemia: The value of complete remission," is available on the Sunesis website at www.sunesis.com.

- ***Strengthened Executive Management Team and Board of Directors.*** In June 2016, Sunesis announced the appointment of Linda Neuman, M.D., as Vice President, Clinical Development. In March 2016, Sunesis announced the appointment of Geoffrey Parker to the Sunesis Board of Directors.

- ***Supported First-Ever AML Awareness Month.*** In May 2016, Sunesis announced its support for the first-ever AML Awareness Month, which was held in June with AML spokesperson and sportscaster Craig Sager. The company provided an educational grant to support the sponsor of the campaign, *CancerCare*.

- ***First Subject Dosed in Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK-inhibitor SNS-062.*** In March 2016, the first patient was dosed in a Phase 1A, randomized, double-blind, placebo-controlled dose-ranging study to investigate the safety, pharmacokinetics and pharmacodynamics of its oral, next-generation, non-covalently binding BTK-inhibitor, SNS-062, in healthy subjects.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $33.1 million as of June 30, 2016, as compared to $46.4 million as of December 31, 2015. The decrease of $13.3 million was primarily due to $20.1 million of net cash used in operating activities and $8.0 million of principal and final payments against notes payable, partially offset by $14.8 million raised from debt financing. This capital is expected to be sufficient to fund operations to the middle of 2017.

- Revenue for the three and six months ended June 30, 2016 was $0.6 million and $1.2 million as compared to $0.9 million and $1.7 million for the same periods in 2015. The decrease between the periods was primarily due to the increase in estimated performance period through which the remaining balance of deferred revenue will be amortized.

- Research and development expense was $6.6 million and $12.8 million for the three and six months ended June 30, 2016 as compared to $6.3 million and $10.8 million for the same periods in 2015. The increase of $0.3 million and $2.0 million between the comparable three- and six-month periods, respectively, was primarily related to medical scientific affairs activities.

- General and administrative expense was $4.0 million and $8.3 million for the three and six months ended June 30, 2016 as compared to $5.2 million and $10.3 million for the same periods in 2015. The decrease of $1.2 million and $2.0 million between the comparable three- and six-month periods, respectively, was primarily due to decrease in outside services costs.

- Interest expense was $0.5 million and $0.8 million for the three and six months ended June 30, 2016 as compared to $0.2 million and $0.5 million for the same periods in 2015.

- Net other income was nil and $0.1 million for the three and six months ended June 30, 2016 as compared to net other income of $1.9 million and $1.8 million for the same period in 2015. The increases in 2015 periods were primarily comprised of non-cash credits or charges for the revaluation of warrants issued in the October 2010 underwritten offering.

- Cash used in operating activities was $20.1 million for the six months ended June 30, 2016, as compared to $19.8 million for the same period in 2015. Net cash used in the 2016 period resulted primarily from the net loss of $20.5 million and changes in operating assets and liabilities of $2.5 million, including the payment of a final fee of $1.2 million under the Oxford Loan Agreement, partially offset by net adjustments for non-cash items of $2.9 million. 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 $10.0 million and $19.9 million for the three and six months ended June 30, 2016 as compared to $10.6 million and $19.4 million for the same periods in 2015. Net loss was $10.4 million and $20.5 million for the three and six months ended June 30, 2016, as compared to $8.9 million and $18.0 million for the same periods in 2015.

Conference Call Information

Sunesis will host an update conference call today, July 29th 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 48017419. 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.

Vosaroxin's Marketing Authorization Application for relapsed refractory AML is currently under review by the European Medicines Agency, and a regulatory decision regarding approval is expected in 2017.

The trademark name QINPREZO is conditionally accepted by the FDA and the EMA as the proprietary name for the vosaroxin drug product candidate.

About SNS-062

SNS-062 is a novel, second-generation BTK inhibitor, a class of kinase inhibitors that selectively inhibits the enzyme Bruton's tyrosine kinase (BTK). This target mediates signaling through the B-cell receptor, which is critical for adhesion, migration, proliferation and survival of normal and malignant B-lineage lymphoid cells. Unlike other drugs in its class, SNS-062 has a distinct kinase selectivity profile and binds non-covalently to the BTK enzyme, potentially providing an opportunity to address the leading resistance mechanism, a mutation in the enzyme's binding site required for covalent binding. In preclinical studies, SNS-062 demonstrated potent activity against Cys-481S mutated B-cell malignancies, and is currently being studied in healthy subjects in a Phase 1A, randomized, double-blind, placebo-controlled dose-ranging study to investigate the drug's safety, pharmacokinetics, and pharmacodynamics. With a successful study outcome, SNS-062 is expected to proceed to a Phase 1B/2 study in patients with B-cell malignancies around year end 2016.

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 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, as well as advancing its novel kinase-inhibitor pipeline, which includes its proprietary 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 Sunesis' corporate objectives, including the anticipated progress and potential approval of vosaroxin by the EMA, timing of potential market launch in

Europe for vosaroxin, and further clinical development of vosaroxin and SNS-062. Words such as "believe," "goal," "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' Annual Report on Form 10-K for the year ended December 31, 2015, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, 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)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,447	$ 26,886
Marketable securities	23,674	19,544
Prepaids and other current assets	831	558
Total current assets	33,952	46,988
Property and equipment, net	8	14
Total assets	$ 33,960	$ 47,002
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,759	$ 2,453
Accrued clinical expense	2,006	1,954
Accrued compensation	1,113	1,606
Other accrued liabilities	1,858	2,711
Current portion of deferred revenue	1,831	2,441
Current portion of notes payable	833	7,834
Total current liabilities	10,400	18,999

Non-current portion of deferred revenue	-	610
Non-current other accrued liabilities	56	
Non-current portion of notes payable	13,444	-
Commitments		
Stockholders' equity:		
Preferred stock	16,459	16,459
Common stock	9	9
Additional paid-in capital	573,496	570,309
Accumulated other comprehensive income (loss)	1	(11)
Accumulated deficit	(579,905)	(559,373)
Total stockholders' equity	10,060	27,393
Total liabilities and stockholders' equity	$ 33,960	$ 47,002

Note 1: The consolidated balance sheet as of December 31, 2015 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, 2015.

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,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015 (Note 2)
Revenue:				
License and other revenue	$ 610	$ 854	$ 1,250	$ 1,708
Total revenues	610	854	1,250	1,708
Operating expenses:				
Research and development	6,606	6,302	12,815	10,814
General and administrative	3,997	5,175	8,292	10,286
Total operating expenses	10,603	11,477	21,107	21,100
Loss from operations	(9,993)	(10,623)	(19,857)	(19,392)
Interest expense	(476)	(233)	(774)	(472)
Other income (expense), net	23	1,907	99	1,787
Net loss	(10,446)	(8,949)	(20,532)	(18,077)
Unrealized gain (loss) on available-for-sale securities	(1)	-	12	2
Comprehensive loss	$ (10,447)	$ (8,949)	$ (20,520)	$ (18,075)

Basic and diluted loss per common share:				
Net loss				
Basic	$ (10,446)	$ (8,949)	$ (20,532)	$ (18,077)
Diluted	$ (10,446)	$ (10,816)	$ (20,532)	$ (18,077)
Shares used in computing basic and diluted loss per common share				
Basic	86,960	72,513	86,810	70,090
Diluted	86,960	72,525	86,810	70,090
Basic and diluted loss per common share				
Basic	$ (0.12)	$ (0.12)	$ (0.24)	$ (0.26)
Diluted	$ (0.12)	$ (0.15)	$ (0.24)	$ (0.26)

Note 2: The consolidated statement of operations and comprehensive loss for the year ended December 31, 2015 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, 2015.

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