Sunesis Pharmaceuticals Reports Third Quarter 2016 Financial Results and Recent Highlights

November 3, 2016 7:01 AM ET

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

SOUTH SAN FRANCISCO, Calif., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the third quarter ended September 30, 2016. Loss from operations for the three months ended September 30, 2016 was $8.5 million. As of September 30, 2016, cash, cash equivalents and marketable securities totaled $24.3 million.

"Since the beginning of the third quarter we have made significant progress in advancing both our vosaroxin and BTK inhibitor programs. In addition, in October, we secured the financial resources from leading life sciences investors which will help us reach several potential value inflection points," said Daniel Swisher, Chief Executive Officer of Sunesis. "The potential milestones include a marketing authorization decision on vosaroxin in Europe, the potential for a corresponding partnership and product launch in this territory, and the initiation and prosecution of a Phase 1B/2 study of SNS-062, our differentiated, non-covalent BTK-inhibitor, in patients with B-cell malignancies."

"The European regulatory review of vosaroxin has now resumed, following our response to the Day 120 List of Questions, and we look forward to receiving the EMA Day 180 List of Outstanding Issues before year-end. We were also pleased to present Phase 1A Healthy Volunteer Study results demonstrating a favorable safety, pharmacokinetic and pharmacodynamic profile for SNS-062 at the ESH Conference on New Concepts in B-Cell Malignancies in September."

Third Quarter 2016 and Recent Highlights

- ***Submission of Responses to the EMA Day 120 List of Questions for the Marketing Authorization Application for Vosaroxin.*** In October, Sunesis announced that it submitted its responses to European Medicines Agency (EMA) Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use (CHMP) as part of the centralized review process of the Marketing Authorization Application (MAA) for vosaroxin based on data from the VALOR trial, as a treatment for relapsed/refractory acute myeloid leukemia (AML) in patients aged 60 years and older. Sunesis expects to receive the EMA Day 180 List of Outstanding Issues before year-end.

- ***Presentation of Dose Escalation Results from the Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK inhibitor SNS-062.*** In September, Sunesis announced results from the Company's Phase 1A study in healthy volunteers evaluating oral non-covalent BTK inhibitor SNS-062. The study demonstrated a favorable safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile for SNS-062 in healthy subjects. The results were presented on Saturday, September 10th at the European School of Haematology's (ESH) 2nd International Conference on New Concepts in B-Cell Malignancies at the Estoril Congress Centre in Estoril, Portugal. The presentation, titled "A Phase 1A Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the Noncovalent Bruton Tyrosine Kinase (BTK) Inhibitor SNS-062 in Healthy Subjects: Preliminary Results" is available on the Sunesis website at www.sunesis.com.

- ***Completion of $25.9 million Financing.*** In October, Sunesis announced the completion of an equity financing with net proceeds of $25.9 million. The financing attracted participation from leading biotechnology investors.

- ***Announced Publication in "Drugs" Detailing Molecular and Pharmacologic Properties of Vosaroxin.*** In August, Sunesis announced the publication of an article detailing the molecular and pharmacologic properties of vosaroxin as a new therapeutic for acute myeloid leukemia (AML) in the journal *Drugs*. Vosaroxin is the first quinolone-based topoisomerase II inhibitor studied in clinical trials in oncology. The article, titled "Molecular and Pharmacologic Properties of the Anticancer Quinolone Derivative Vosaroxin: A New Therapeutic for Acute Myeloid Leukemia," is available online and appeared in the September 2016 print issue of *Drugs*. The authors describe how the unique

chemical and pharmacologic characteristics of vosaroxin may contribute to the efficacy and safety profile observed in Sunesis' Phase 3 VALOR trial in first relapsed or refractory AML.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $24.3 million as of September 30, 2016, as compared to $46.4 million as of December 31, 2015. The decrease of $22.1 million was primarily due to $28.9 million of net cash used in operating activities, $8.0 million of payments against notes payable, partially offset by $14.8 million in net loan proceeds. An additional $25.9 million in net proceeds was raised in the October 2016 equity financing, resulting in pro-forma September 30, 2016 cash, cash equivalents and marketable securities of $50.2 million. This capital is expected to be sufficient to fund operations into 2018.

- Revenue for the three and nine months ended September 30, 2016 was $0.6 million and $1.9 million as compared to $0.7 million and $2.4 million for the same periods in 2015. The decrease between the periods was primarily due to the extension of the amortization period of our deferred revenue.

- Research and development expense was $5.3 million and $18.1 million for the three and nine months ended September 30, 2016 as compared to $5.3 million and $16.1 million for the same periods in 2015. The increase of $2.0 million between the comparable nine month periods was primarily due to an increase in professional services, clinical trials and medical affairs expenses.

- General and administrative expense was $3.9 million and $12.2 million for the three and nine months ended September 30, 2016 as compared to $4.0 million and $14.3 million for the same periods in 2015. The decrease of $0.1 million between the comparable three month periods was primarily due to a decrease in personnel expenses. The decrease of $2.1 million between the comparable nine month periods was primarily due to decrease in outside service costs.

- Interest expense was $0.5 million and $1.2 million for the three and nine months ended September 30, 2016 as compared to $0.2 million and $0.7 million for the same periods in 2015. The increases in the 2016 periods were primarily due to the increase in the notes payable.

- Net other income was nil and $0.1 million for the three and nine months ended September 30, 2016 as compared to net other income of $1.8 million and $3.6 million for the same period in 2015. The decrease in net other income is related to the quarterly re-valuation of warrant liabilities.

- Cash used in operating activities was $29.0 million for the nine months ended September 30, 2016, as compared to $29.5 million for the same period in 2015. Net cash used in the 2016 period resulted primarily from the net loss of $29.5 million and changes in operating assets and liabilities of $3.6 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 $4.1 million. 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 $8.5 million and $28.4 million for the three and nine months ended September 30, 2016 as compared to $8.6 million and $28.0 million for the same periods in 2015. Net loss was $9.0 million and $29.5 million for the three and nine months ended September 30, 2016, as compared to $7.0 million and $25.1 million for the same periods in 2015.

Conference Call Information

Sunesis will host an update conference call today, November 3rd at 11:00 a.m. Eastern Time. The call can be accessed by dialing (844) 296-7720 (U.S. and Canada) or (574) 990-1148 (international) and entering passcode 6564483. 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/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. This alternate binding site potentially provides 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 has been 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 the reported successful study outcome, SNS-062 is proceeding to a Phase 1B/2 study in patients with B-cell malignancies.

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 regulatory development and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe and clinical development of SNS-062. Words such as "expect," "may," "potential"

“advancing,” “progress” 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, the risk that Sunesis' clinical studies for SNS-062, 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, 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 September 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)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,825	$ 26,886
Marketable securities	18,427	19,544
Prepaids and other current assets	840	558
Total current assets	25,092	46,988
Property and equipment, net	6	14
Total assets	$ 25,098	$ 47,002
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 2,526	$ 2,453
Accrued clinical expense	1,635	1,954
Accrued compensation	1,487	1,606
Other accrued liabilities	1,549	2,711
Current portion of deferred revenue	1,221	2,441
Current portion of notes payable	2,083	7,834
Total current liabilities	10,501	18,999

Non-current portion of deferred revenue	-	610
Non-current other accrued liabilities	113	
Non-current portion of notes payable	12,273	-
Commitments		
Stockholders' equity:		
Preferred stock	16,459	16,459
Common stock	1	1
Additional paid-in capital	574,615	570,317
Accumulated other comprehensive income (loss)	(5)	(11)
Accumulated deficit	(588,859)	(559,373)
Total stockholders' equity	2,211	27,393
Total liabilities and stockholders' equity	$ 25,098	$ 47,002

Note 1: The consolidated balance sheet as of December 31, 2015 (as adjusted for the Reverse Split), 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 September 30,		**Nine months ended September 30,**	
	2016	**2015**	**2016**	**2015**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Note 2)**
Revenue:				
License and other revenue	$ 610	$ 683	$ 1,860	$ 2,391
Total revenues	610	683	1,860	2,391
Operating expenses:				
Research and development	5,251	5,259	18,066	16,073
General and administrative	3,889	3,994	12,181	14,280
Total operating expenses	9,140	9,253	30,247	30,353
Loss from operations	(8,530)	(8,570)	(28,387)	(27,962)
Interest expense	(473)	(233)	(1,247)	(705)

Other income (expense), net	49	1,782	148	3,569
Net loss	(8,954)	(7,021)	(29,486)	(25,098)
Unrealized gain (loss) on available-for-sale securities	(6)	3	6	5
Comprehensive loss	$ (8,960)	$ (7,018)	$ (29,480)	$ (25,093)
Basic and diluted loss per common share:				
Net loss	$ (8,954)	$ (7,021)	$ (29,486)	$ (25,098)
Shares used in computing basic and diluted loss per common share	14,503	12,463	14,480	11,945
Basic and diluted loss per common share	$ (0.62)	$ (0.56)	$ (2.04)	$ (2.10)

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.

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

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals Inc