Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2016 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., March 09, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the fourth quarter and year ended December 31, 2016. Loss from operations for the three months and year ended December 31, 2016 was $8.1 million and $36.5 million, respectively. As of December 31, 2016, cash, cash equivalents and marketable securities totaled $42.6 million.

“We are making meaningful progress in advancing our two lead programs, vosaroxin and SNS-062, in areas of unmet need in hematologic malignancies,” said Daniel Swisher, Chief Executive Officer of Sunesis. “Our European Marketing Authorization Application is on track; we are working diligently to submit responses this quarter to the Day 180 List of Outstanding Issues and we are preparing to go before the Scientific Advisory Group’s Oncology Division (SAG-O) in April, culminating in a likely CHMP decision by mid-year. We continue, in parallel, to advance active dialogues with potential pharma collaborators toward the goal of supporting a potential market launch of vosaroxin in Europe in the second half of this year.”

Mr. Swisher continued, “Our BTK inhibitor program is advancing as planned. The IND for SNS-062 is now active and we expect to initiate a Phase 1B/2 study in patients with advanced B-cell malignancies in the second quarter. We were encouraged by the data from the Phase 1A Healthy Volunteer study and the level of interest generated at our ASH 2016 presentation.”

Fourth Quarter 2016 and Recent Highlights

- ***Continued Progress with the Marketing Authorization Application (MAA) for Vosaroxin in Europe.*** In January, Sunesis announced that it had received the Day 180 List of Outstanding Issues from the European Medicines Agency (EMA), issued by the Committee for Medicinal Products for Human Use (CHMP) as part of the centralized review process. The Company plans to submit its response to the list by the end of the first quarter. In addition, the Company announced that it will go before the Scientific Advisory Group’s Oncology Division (SAG-O) in April, which will assist the CHMP in its evaluation of the MAA. Sunesis anticipates an approval decision on vosaroxin by mid-year.

- ***Announced Active IND for SNS-062 and Trial Initiation Plans in Phase 1B/2 Study in Patients with Advanced B-Cell Malignancies.*** In January, Sunesis announced that its Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) was active, supporting the initiation of a Phase 1B/2 study to assess the candidate's safety and efficacy in patients with advanced B-cell malignancies after prior ibrutinib exposure, including in patients with C481S mutations. Phase 1A of the study examined the safety, pharmacodynamics, and pharmacokinetics of SNS-062 and was completed during the fourth quarter of 2016, and the Company plans to begin dosing patients in the Phase 1B/2 study within the first half of 2017.

- ***Announced Poster Presentation on BTK Inhibitor SNS-062 at the AACR Annual Meeting.*** Today, Sunesis announced a poster presentation at the American Association for Cancer Research 2017 Annual Meeting to be held April 1-5 in Washington, D.C. The poster, titled “SNS-062 demonstrates efficacy in chronic lymphocytic leukemia in vitro and inhibits C481S mutated Bruton tyrosine kinase” (Poster Number 22, Abstract Number 1207, Convention Center, Halls A-C, Poster Section 6), details results from an Ohio State University-sponsored preclinical study, conducted in collaboration with Sunesis, that examines the potency of SNS-062 versus ibrutinib and acalabrutinib, specifically relating to the C481S mutation. The results will be presented in a session titled “Reversal of Drug Resistance” on Monday, April 3, 2017 from 8:00 AM to 12:00 PM Eastern Time.

- ***Presentation of Updated Results from the VALOR Trial Evaluating Vosaroxin in AML and Completed Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK Inhibitor SNS-062 at ASH Annual Meeting.*** In December 2016, Sunesis presented updated results from the VALOR Trial examining overall survival in patients age 60 years and older with relapsed/refractory acute myeloid leukemia (AML), as well results from the Company's Phase 1A study in healthy volunteers evaluating oral non-covalent reversible BTK inhibitor SNS-062 at the 58th American Society of Hematology Annual Meeting in San Diego, California. The oral presentation, titled "Durable Overall Survival Benefit in Patients ≥ 60 Years with Relapsed or Refractory AML Treated with Vosaroxin/Cytarabine Vs Placebo/Cytarabine: Updated Results from the Valor Trial" and the poster titled "First-in-Human Phase 1a Study of the Safety, Pharmacokinetics, and Pharmacodynamics of the Noncovalent Bruton's Tyrosine Kinase (BTK) Inhibitor SNS-062 in Healthy Subjects," are 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 Organizational Updates.*** Today, Sunesis announced two management additions, Judy Fox Ph.D., to the position of Chief Scientific Officer and Pietro Taverna, Ph.D. to Executive Director, Translational Medicine. Dr. Fox brings over 25 years of experience both as a scientist and program leader at leading life science companies. At Sunesis, she and her team will develop and implement strategic research roadmaps to support the advancement of Sunesis' product portfolio. She obtained her Ph.D. in Biological Chemistry from M.I.T. Pietro Taverna, Ph.D. returns to Sunesis from Astex/Otsuka Pharmaceuticals, where he led the Translational Pharmacology department and was responsible for biomarker strategy and the translation of research insights into optimal clinical development. He holds a Ph.D. from M. Negri Institute for Pharmacological Research in Milan. Additionally, Jennifer Troia was promoted to Vice President, Human Resources. Jennifer brings over 25 years of related HR experience, including at Gilead Sciences, COR Therapeutics, CoMentis and Sunesis.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $42.6 million as of December 31, 2016, as compared to $46.4 million as of December 31, 2015. The decrease of $3.8 million was primarily due to $37 million of net cash used in operating activities and $7.2 million of final payments against notes payable and $0.8 million of principal payments against notes payable, partially offset by net proceeds of $25.9 million from the underwritten offering and $14.8 million in net loan proceeds, and $0.3 million from the sale of our common stock through the Sales Agreement with Cantor and exercise of stock options.

- Revenues for the three months and year ended December 31, 2016 were $0.7 million and $2.5 million, as compared to $0.7 million and $3.1 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 expenses were $4.8 million and $22.9 million for the three months and year ended December 31, 2016, as compared to $7.6 million and $23.7 million for the same periods in 2015. The decrease of $0.8 million in 2016 was primarily due to a decrease of $2.2 million in personnel costs partially offset by increases in professional services, clinical trials and medical affairs expenses.

- General and administrative expenses for the three months and year ended December 31, 2016 were $3.9 million and $16 million, as compared to $4.4 million and $18.7 million for the same periods in 2015. The decrease of $2.6 million in 2016 was primarily due to decrease in professional services and personnel costs.

- Interest expense was $0.5 million and $1.7 million for the three months and year ended December 31, 2016, as compared to $0.2 million and $0.9 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 $0.2 million in 2016 as compared to $3.6 million in 2015. The 2015 amount was primarily comprised of net non-cash credit for the revaluation of warrants issued in the 2010 Offering.

- Cash used in operating activities was $37.0 million for the year ended December 31, 2016, as compared to $38.7 for the same period in 2015. Net cash used in operating activities in 2016 resulted primarily from the net loss of $38.0 million and net adjustment for the non-cash items of $5.2 million offset by changes in operating assets and liabilities of $4.1 million (including $2.4 million related to recognition of deferred revenue under the Royalty Agreement).

- Sunesis reported loss from operations of $8.1 million and $36.5 million for the three months and year ended December 31, 2016, as compared to $11.3 million and $39.3 million for the same periods in 2015. Net loss was $8.5 million and $38.0 million for the three months and year ended December 31, 2016, as compared to $11.6 million and $36.7 million for the same periods in 2015.

Conference Call Information

Sunesis will host an update conference call today, March 9th 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 59899543. 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, the regulatory development, timing of SNS-062 clinical development, SNS-062 clinical potential, Sunesis' response to Day 180 List of Outstanding Issues and the timing thereof, and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe. Words such as "advancing," "anticipate," "expect," "goal," "potential," "progress," "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 SNS-062 or vosaroxin in the U.S. or Europe, that Sunesis' development activities for SNS-062 or 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 SNS-062, 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 SNS-062, 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, 2016 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, 2016	2015
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 8,056	$ 26,886
Marketable securities	34,532	19,544
Prepaids and other current assets	643	558
Total current assets	43,231	46,988
Property and equipment, net	3	14
Total assets	$ 43,234	$ 47,002

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,871	$ 2,453
Accrued clinical expense	1,434	1,954
Accrued compensation	2,000	1,606
Other accrued liabilities	1,691	2,711
Current portion of deferred revenue	610	2,441
Current portion of notes payable	3,333	7,834
Total current liabilities	10,939	18,999
Non-current portion of deferred revenue	-	610
Non-current portion of notes payable	11,102	
Non-current other liabilities	169	
Commitments		
Stockholders' equity:		
Convertible preferred stock	18,808	16,459
Common stock	2	1
Additional paid-in capital	599,632	570,317
Accumulated other comprehensive loss	(22)	(11)
Accumulated deficit	(597,396)	(559,373)
Total stockholders' equity	21,024	27,393
Total liabilities and stockholders' equity	43,234	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 December 31,		**Year ended December 31,**	
	2016	**2015**	**2016**	**2015**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Note 2)**
Revenue:				
License and other revenue	$ 676	$ 670	$ 2,536	$ 3,061
Total revenues	676	670	2,536	3,061
Operating expenses:				
Research and development	4,815	7,628	22,881	23,701

General and administrative	3,934	4,382	16,115	18,662
Total operating expenses	8,749	12,010	38,996	42,363
Loss from operations	(8,073)	(11,340)	(36,460)	(39,302)
Interest expense	(474)	(234)	(1,721)	(939)
Other income (expense), net	10	(4)	158	3,565
Net loss	(8,537)	(11,578)	(38,023)	(36,676)
Unrealized gain (loss) on available-for-sale securities	(9)	(9)	(11)	(4)
Comprehensive loss	$ (8,546)	$ (11,587)	$ (38,034)	$ (36,680)
Basic and diluted loss per common share:				
Net loss:				
Basic	$ (8,537)	$ (11,578)	$ (38,023)	$ (36,676)
Diluted	$ (8,537)	$ (11,578)	$ (38,023)	$ (36,676)
Shares used in computing net loss per common share:				
Basic	19,285	12,781	15,688	15,688
Diluted	19,285	12,781	15,688	15,688
Net loss per common share:				
Basic	$ (0.44)	$ (0.91)	$ (2.42)	$ (2.34)
Diluted	$ (0.44)	$ (0.91)	$ (2.42)	$ (2.34)

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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