Sunesis Pharmaceuticals Reports Fourth Quarter and Full-Year 2019 Financial Results and Recent Highlights

March 10, 2020

Sunesis to Host Conference Call Today at 4:30 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., March 10, 2020 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today reported financial results for the fourth quarter and year ended December 31, 2019. Loss from operations for the three months and year ended December 31, 2019 was $5.4 million and $23.3 million. As of December 31, 2019, cash and cash equivalents, restricted cash, and marketable securities totaled $34.6 million.

“We concluded 2019 having made solid progress across our portfolio. Vecabrutinib, our non-covalent BTK inhibitor, demonstrated a very favorable safety profile combined with evidence of clinical activity in patients with and without BTK C481-mutations. We continue to advance and characterize our proprietary PDK1 inhibitor, SNS-510, with findings supporting development in both hematologic and solid tumors. We are also building value in our product pipeline through partnerships. In December, we partnered vosaroxin with Denovo Biopharma and TAK-580 with DOT Therapeutics-1 to advance these programs to the market,” said Dayton Misfeldt, Interim Chief Executive Officer of Sunesis. “Looking ahead, we remain on track to complete the Phase 1b dose escalation component of our Phase 1b/2 vecabrutinib trial in the second quarter and to advance SNS-510 to an IND by the end of year.”

Vecabrutinib Phase 1b/2 Clinical Update. Since the presentation of clinical data through cohort 5 at ASH in December 2019, Sunesis has enrolled patients in cohorts 6 and 7 of the ongoing Phase 1b/2 trial of vecabrutinib.

- Cohort 5 (300mg): Sunesis announced at ASH 2019 that stable disease was observed in three of five patients from cohort 5 (300mg BID). As of today, one chronic lymphocytic leukemia (CLL) patient remains on study in cycle 8 at 300mg BID with a 47% reduction in tumor burden at their second scan, improving from their initial 41% reduction, with normalized hematology parameters.

- Cohort 6 (400mg BID): Four patients, three CLL and one diffuse large B cell lymphoma (DLBCL), were enrolled in the cohort. The DLBCL patient was nonevaluable due to disease progression during cycle one. The three CLL patients completed the safety evaluation period, remain on treatment, and results of their first response assessments will be available later this month.

- Cohort 7 (500mg BID): Six patients, four with CLL and two with mantle cell lymphoma (MCL), cleared the safety evaluation period and four of the patients remain on treatment. We expect first response assessments for these patients in the second quarter. Additional patients are being evaluated for the cohort.

- Vecabrutinib has been very well tolerated, with no Grade 3 or higher drug-related adverse events reported to date across cohorts 3 – 7.

SNS-510, first-in-class PDK1 inhibitor. *In October, at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics,* Sunesis presented data profiling the oral PDK1 inhibitor SNS-510 showing potent activity in hematologic and solid tumor cancer models. New results of in vitro combination studies indicate that SNS-510 can combine synergistically with several drugs including inhibitors of CDK4/6, KRAS G12C, and BCL2. The IND-enabling program is progressing as planned and an IND filing is targeted for the end of 2020.

Partnering TAK-580 and vosaroxin. In December, Sunesis consented to Takeda Oncology’s assignment of our agreement relating to the pan-Raf inhibitor TAK-580 to DOT Therapeutics-1, Inc. (“DOT-1”). Coincident with the transaction, Sunesis and DOT-1 entered into a new agreement covering TAK-580 and DOT-1 paid Sunesis an upfront fee of $2.0 million. Under the new TAK-580 agreement, DOT-1 agreed to pay Sunesis up to $57.0 million in pre-commercialization milestone payments, plus royalties on future sales of TAK-580. Also in December, Sunesis licensed vosaroxin to Denovo Biopharma LLC (“Denovo”). Sunesis received a $0.2 million upfront payment and is eligible to receive up to $57.0 million in regulatory and commercial milestones, plus double-digit royalties on future sales of vosaroxin.

Financial Highlights

- Cash and cash equivalents, restricted cash and marketable securities totaled $34.6 million as of December 31, 2019, compared to $13.7 million as of December 31, 2018. The increase of $20.9 million was primarily due to $45.1 million of net proceeds from the issuance of common and preferred stock, and $5.5 million of proceeds from the SVB loan, partially offset by $22.2 million net cash used in operating activities and a $7.5 million principal repayment of the prior loan from Western Alliance Bank and Solar Capital Ltd.

- Revenue was $2.1 million in 2019 compared to $0.2 million in 2018. Revenue in both periods was derived from license agreements. The increase of $2.0 million in 2019 was primarily due to revenue recognized from the upfront payments received under the license agreements with DOT-1 and Denovo.

- Research and development expense was $15.4 million in 2019 compared to $14.6 million in 2018, primarily relating to the vecabrutinib development program. The increase of $0.8 million in 2019 was primarily due to a $1.8 million increase in professional services and clinical expenses related to the preparation for the Phase 2 portion of our ongoing clinical trial for vecabrutinib, offset by a $1.0 million decrease in salary and personnel expenses.

- General and administrative expense was $9.9 million in 2019 compared to $11.3 million in 2018. The decrease of $1.4 million in 2019 was primarily due to a $1.1 million decrease in salary and personnel expenses due in large part to lower stock-based compensation and a $0.8 million decrease in professional services expenses due to lower legal and vosaroxin patent expenses. The decreases in the comparable periods were partially offset by a $0.3 million increase in insurance premiums.

- Interest expense was $0.5 million in 2019 compared to $1.2 million in 2018. The decrease in 2019 was primarily due to lower interest paid under the SVB Loan Agreement compared to the prior loan.

- Cash used in operating activities was $22.2 million in 2019, compared to $24.4 million in 2018. Cash used in the 2019 period resulted primarily from the net loss of $23.3 million and changes in operating assets and liabilities of $0.7 million, offset by net adjustments for non-cash items of $1.8 million.

- Loss from operations was $5.4 million and $23.3 for the three months and year ended December 31, 2019, compared to $5.8 million and $25.7 million for the same periods in 2018. Net loss was $5.3 million and $23.3 million for the three months and year ended December 31, 2019, compared to $6.0 million and $26.6 million for the same periods in 2018.

Conference Call Information

Sunesis will host a conference call today at 4:30 p.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 2388763. 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 Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company developing novel targeted inhibitors for the treatment of hematologic and solid cancers. Sunesis has built an experienced drug development organization committed to improving the lives of people with cancer. The Company is focused on advancing its novel kinase inhibitor pipeline, including its oral non-covalent BTK inhibitor vecabrutinib and first-in-class PDK1 inhibitor SNS-510. Vecabrutinib is currently being evaluated in a Phase 1b/2 study in adults with chronic lymphocytic leukemia and other B-cell malignancies that have progressed after prior therapies.

For additional information on Sunesis, please visit www.sunesis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Sunesis’ continued development of vecabrutinib, including the timing and results of the Phase 1b/2 trial of vecabrutinib and the therapeutic potential of vecabrutinib, further development and potential of its kinase inhibitor pipeline, including the timing of the potential IND filing for SNS-510, its ability to receive potential milestone or royalty payments under license and collaboration agreements and the timing of receipt of those payments, and sufficiency of its cash resources and financial position. Words such as “expect,” “will,” “look forward,” 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. These and other risk factors are discussed under "Risk Factors" in Sunesis' Annual Report on Form 10-K for the year ended December 31, 2019 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.

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SUNESIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS
(In thousands, except per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2019	2018	2019	2018
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenue:				
License and other revenue	$ 2,073	$ -	$ 2,073	$ 237
Total revenues	2,073	-	2,073	237
Operating expenses:				
Research and development	4,947	3,301	15,412	14,615
General and administrative	2,480	2,459	9,949	11,332
Total operating expenses	7,427	5,760	25,361	25,947
Loss from operations	(5,354)	(5,760)	(23,288)	(25,710)
Interest expense	(71)	(295)	(514)	(1,154)
Other income, net	138	58	472	249
Net loss	(5,287)	(5,997)	(23,330)	(26,615)
Unrealized gain on available-for-sale securities	1	-	1	7
Comprehensive loss	$ (5,286)	$ (5,997)	$ (23,329)	$ (26,608)
Basic and diluted loss per common share:				
Net loss	$ (5,287)	$ (5,997)	$ (23,330)	$ (26,615)
Shares used in computing basic and diluted loss per common share	111,343	37,438	87,129	35,582
Basic and diluted loss per common share	$ (0.05)	$ (0.16)	$ (0.27)	$ (0.75)

Note 1: The consolidated statement of operations and comprehensive loss for the year ended December 31, 2018 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, 2018.

SUNESIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2019	December 31, 2018
	(Unaudited)	(2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,761	$ 13,696
Restricted cash	5,500	-
Marketable securities	16,364	-
Prepaids and other current assets	1,697	1,504
Total current assets	36,322	15,200
Property and equipment, net	3	11
Operating lease right-of-use asset	817	-
Deposits and other assets	98	113
Total assets	$ 37,240	$ 15,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 791	$ 1,393
Accrued clinical expense	521	500

Accrued compensation	985	943
Other accrued liabilities	1,109	1,091
Notes payable	5,465	7,396
Operating lease liability - current	545	-
Total current liabilities	9,416	11,323
Other liabilities	9	8
Operating lease liability - long term	272	-
Total liabilities	9,697	11,331
Stockholders' equity:		
Convertible preferred stock	11,769	20,998
Common stock	11	4
Additional paid-in capital	698,562	642,460
Accumulated other comprehensive income	1	-
Accumulated deficit	(682,800)	(659,469)
Total stockholders' equity	27,543	3,993
Total liabilities and stockholders' equity	$ 37,240	$ 15,324

Note 2: The consolidated balance sheet as of December 31, 2018 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, 2018.

Source: Sunesis Pharmaceuticals, Inc.