Sunesis Pharmaceuticals Reports Third Quarter 2014 Financial Results and Recent Highlights

November 10, 2014 7:00 AM ET

Announces Submission of Letter of Intent to File MAA for Vosaroxin in Relapsed or Refractory AML With the European Medicines Agency

Announces Upcoming Presentations at ASH Annual Meeting, EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics

Sunesis to Host Conference Call Today at 10:30 AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended September 30, 2014. Loss from operations for the three and nine months ended September 30, 2014 was $13.3 million and $33.9 million, respectively. As of September 30, 2014, cash, cash equivalents and marketable securities totaled $44.7 million.

"VALOR represents the largest randomized company-sponsored dataset in the relapsed and refractory AML setting," said Daniel Swisher, Chief Executive Officer of Sunesis. "As we continue to evaluate the study results and share the findings with our investigators, we believe that the vosaroxin and cytarabine combination demonstrates clinically meaningful outcomes supported by strong response rates and a manageable safety profile. We are committed to working with regulators in making vosaroxin available to clinicians and patients in urgent need of effective new therapies."

Mr. Swisher continued: "As an important step forward in the European regulatory process, we announced today the submission of a letter of intent to file an MAA for vosaroxin in relapsed or refractory AML with the EMA. Further, we are requesting a meeting with the Food and Drug Administration to determine the appropriate regulatory path forward in the U.S., and look forward to presenting the full results of VALOR at an upcoming scientific meeting. With the upcoming presentations of MLN2480 at ENA, we look forward to continued positive progress across our emerging pipeline of kinase inhibitor product candidates."

Third Quarter 2014 and Recent Highlights

- ***Announced results from pivotal Phase 3 VALOR trial of vosaroxin and cytarabine in patients with first relapsed or refractory acute myeloid leukemia.*** In October 2014, Sunesis announced results from the Phase 3 VALOR trial, a randomized, double-blind, placebo-controlled trial of vosaroxin and cytarabine in patients with first relapsed or refractory acute myeloid leukemia (AML). At more than 100 leading international sites, the trial enrolled 711 patients, who were stratified for age, geographic region and disease status. The VALOR trial did not meet its primary endpoint of demonstrating a statistically significant improvement in overall survival, as results showed a median overall survival of 7.5 months for patients receiving vosaroxin and cytarabine compared to 6.1 months for patients receiving placebo and cytarabine (HR=0.865, p=0.06). In a pre-planned analysis accounting for the stratification factors at randomization, a significant improvement in overall survival was demonstrated (HR=0.830, p=0.02).

  Given the complexity of interpreting the impact of transplantation therapy, a predefined analysis of overall survival censoring for hematopoietic stem cell transplantation was planned. In this analysis, patients receiving the vosaroxin combination had a median overall survival of 6.7 months versus 5.3 months for patients receiving placebo and cytarabine (HR=0.809, p=0.02). The VALOR trial also demonstrated a clinically significant benefit in complete remission, or CR, rate (30.1% vs 16.3%, p=0.0000147), the secondary endpoint.

  The safety profile of the vosaroxin combination was consistent with that observed in previous company trials, and induction mortality was balanced between arms. 30-day and 60-day all-cause mortality were comparable between

the trial arms (7.9% versus 6.6% and 19.7% versus 19.4%, for the vosaroxin combination versus placebo and cytarabine, respectively).

- ***Announces submission of Letter of Intent to file a Marketing Authorization Application (MAA) for vosaroxin in relapsed or refractory AML with the European Medicines Agency (EMA).*** Sunesis announced today that the company has submitted a letter of intent describing the company's intention to file a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) seeking marketing authorization of vosaroxin plus cytarabine for the treatment of relapsed or refractory acute myeloid leukemia. The letter of intent initiates the process for the assignment of a Rapporteur and Co-Rapporteur, who are two appointed members of the Committee for Human Medicinal Products (CHMP). The CHMP is the committee responsible for preparing the EMA's opinions on questions concerning human medicines. The Rapporteur and Co-Rapporteur will assess the MAA and provide the CHMP with the result of their analysis, which will be the basis of the conclusions of the CHMP. Sunesis expects to file its MAA in the second half of 2015.

- ***Announces upcoming presentations at 56th American Society of Hematology (ASH) Annual Meeting.*** Sunesis announced today that two AML studies will be presented at the 56th ASH Annual Meeting, taking place December 6-9, 2014, in San Francisco, CA. The first study, titled "Phase I/II Study of Vosaroxin and Decitabine in Newly Diagnosed Older Patients with Acute Myeloid Leukemia and High Risk Myelodysplastic Syndrome," (Abstract #75224) will be presented in an oral session on Monday, December 8th at 10:30 a.m. The presentation will include 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 AML and high-risk myelodysplastic syndrome. The second study, titled "Prevalence and Incidence of Acute Myeloid Leukemia May be Higher than Currently Accepted Estimates Among the ≥65 Year-Old Population in the United States," (Abstract #72296) will be presented in a poster session on Saturday, December 6th at 5:30 p.m. The presentations were announced as part of the meeting's regular abstract selection schedule.

- ***Announces upcoming presentations of MLN2480 clinical and preclinical studies at the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.*** Sunesis announced today that four preclinical and clinical presentations on MLN2480, an oral, investigative agent for pan-Raf kinase inhibition, will be presented by Millennium Pharmaceuticals, Inc. ("Millennium"), a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, at the 26th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, taking place November 18-21, 2014, in Barcelona, Spain. MLN2480 is being developed by Millennium through an exclusive license from Sunesis, which includes an option for co-development by Sunesis. The presentations are expected to include data from a Phase 1, multicenter, open-label, dose escalation study designed to evaluate the safety, tolerability and maximum tolerated dose of single agent MLN2480.

- ***Announced acceptance of Pediatric Investigation Plan by EMA for vosaroxin.*** In July 2014, Sunesis announced that the Pediatric Committee of the EMA issued a positive opinion on the company's Pediatric Investigation Plan (PIP) for vosaroxin. A PIP is part of the EMA approval process and must be accepted prior to submission of an MAA for the drug in the European Union. A PIP describes how a company intends to evaluate the use of a given drug in children. The completion of studies outlined in the PIP is not required prior to any European Union approval for vosaroxin as a deferral for completion has been received.

Financial Highlights

- Cash, cash equivalents and marketable securities totaled $44.7 million as of September 30, 2014, as compared to $39.3 million as of December 31, 2013. The increase of $5.4 million was primarily due to net proceeds of $44.7 million from the sale of common stock and warrants, and $1.8 million from the exercise of warrants, stock options and stock purchase rights, partially offset by $34.2 million of net cash used in operating activities and $6.9 million

of principal payments against notes payable. As of September 30, 2014, outstanding debt totaled $11.6 million.

- Revenue for the three and nine months ended September 30, 2014 was $0.9 million and $4.8 million, as compared to $2.0 million and $6.0 million for the same periods in 2013. Revenue in each period was primarily due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.

- Research and development expense was $6.9 million and $21.7 million for the three and nine months ended September 30, 2014, as compared to $7.0 million and $22.0 million for the same periods in 2013, primarily relating to the vosaroxin development program in each period. The decreases between the comparable three and nine month periods were primarily due to reduced clinical trial expenses, partially offset by increases in personnel, drug manufacturing and other outside services costs, including those related to the company's kinase inhibitor programs.

- General and administrative expense was $7.2 million and $17.0 million for the three and nine months ended September 30, 2014, as compared to $2.8 million and $8.1 million for the same periods in 2013. The increases between the comparable three and nine month periods were primarily due to increased personnel and consulting costs, primarily related to commercial planning and medical affairs.

- Interest expense was $0.4 million and $1.4 million for the three and nine months ended September 30, 2014, as compared to $0.7 million and $2.3 million for the same periods in 2013. The decreases in 2014 were due to the reduced principal balance outstanding on notes payable.

- Net other expense was $1.6 million for the three months ended September 30, 2014, as compared to net other income of $0.9 million for the same period in 2013. Net other expense was $6.4 million for the nine months ended September 30, 2014, as compared to $0.9 million for the same period in 2013. The amounts for each period were primarily comprised of non-cash credits or charges for the revaluation of warrants issued in the October 2010 underwritten offering.

- Cash used in operations was $34.2 million for the nine months ended September 30, 2014, as compared to $27.7 million for the same period in 2013. Net cash used in the 2014 period resulted primarily from the net loss of $41.7 million and changes in operating assets and liabilities of $3.4 million, partially offset by net adjustments for non-cash items of $11.0 million.

- Net loss was $15.3 million and $41.7 million for the three and nine months ended September 30, 2014, as compared to $7.6 million and $27.4 million for the same periods in 2013.

Conference Call Information

Sunesis will host an update conference call today, November 10th at 10:30 a.m. Eastern Time. The call can be accessed by dialing (877) 280-4954 (U.S. and Canada) or (857) 244-7311 (international), and entering passcode 29531783. 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 QINPREZO 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 QINPREZO for the treatment of AML. Additionally, QINPREZO has been granted fast track designation by the FDA for the potential

treatment of relapsed or refractory AML in combination with cytarabine. QINPREZO 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 AML

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom and Japan) is over 50,000. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors typically die within one year, resulting in an acute need for new treatment options for these patients.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the 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.

This press release contains forward-looking statements, including statements related to Sunesis' regulatory strategy (including plans to commence a marketing authorization filing with the EMA), Sunesis' preliminary analysis, assessment and conclusions of the results of the VALOR trial, and the efficacy and commercial potential of vosaroxin and clinical progress of other product candidates. It is possible that such results or conclusions may change based on further analysis of the VALOR data. Words such as "approximately," "believe," "continue," "could," "determine," "estimate," "expect," "intends," "may," "plans," "potential," "seek," "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' preliminary analysis, assessment and conclusions of the results of the VALOR trial set forth in this release may change based on further analysis of such data, the risk that Sunesis' plans to commence a marketing authorization filing with the EMA may change or such filing may be rejected by the EMA, and the risk that Sunesis' clinical studies for vosaroxin and other product candidates may not lead to regulatory approval. 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, 2013, Sunesis' Quarterly Report on Form 10-Q for the Quarter ended June 30, 2014 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, when available. 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, 2014	December 31, 2013
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 20,807	$ 15,121
Marketable securities	23,912	24,172
Prepaids and other current assets	1,279	1,199
Total current assets	45,998	40,492
Property and equipment, net	53	23
Deposits and other assets	--	10
Total assets	$ 46,051	$ 40,525
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 772	$ 953
Accrued clinical expense	3,621	4,750
Accrued compensation	1,995	1,719
Other accrued liabilities	3,967	1,645
Current portion of deferred revenue	3,418	7,956
Current portion of notes payable	9,859	9,018
Warrant liability	13,673	7,931
Total current liabilities	37,305	33,972
Non-current portion of deferred revenue	3,418	3,712
Non-current portion of notes payable	1,713	9,025
Commitments		
Stockholders' equity (deficit):		
Common stock	6	5
Additional paid-in capital	524,992	473,509
Accumulated other comprehensive loss	(9)	(3)
Accumulated deficit	(521,374)	(479,695)
Total stockholders' equity (deficit)	3,615	(6,184)
Total liabilities and stockholders' equity (deficit)	$ 46,051	$ 40,525

Note 1: The consolidated balance sheet as of December 31, 2013 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, 2013.

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,	
	2014	2013	2014	2013
	(Unaudited)		(Unaudited)	
Revenue:				
License and other revenue	$ 854	$ 1,989	$ 4,838	$ 5,967
Total revenues	854	1,989	4,838	5,967
Operating expenses:				
Research and development	6,939	6,957	21,697	22,008
General and administrative	7,226	2,807	17,030	8,140
Total operating expenses	14,165	9,764	38,727	30,148
Loss from operations	(13,311)	(7,775)	(33,889)	(24,181)
Interest expense	(391)	(695)	(1,408)	(2,294)
Other income (expense), net	(1,623)	863	(6,382)	(946)
Net loss	(15,325)	(7,607)	(41,679)	(27,421)
Unrealized gain (loss) on available-for-sale securities	(2)	9	(6)	(29)
Comprehensive loss	$ (15,327)	$ (7,598)	$ (41,685)	$ (27,450)
Basic and diluted loss per common share:				
Net loss:				
Basic	$ (15,325)	$ (7,607)	$ (41,679)	$ (27,421)
Diluted	$ (15,325)	$ (8,329)	$ (41,679)	$ (27,421)
Shares used in computing net loss per common share:				
Basic	60,549	51,698	59,052	51,639
Diluted	60,549	53,271	59,052	51,639
Net loss per common share:				
Basic	$ (0.25)	$ (0.15)	$ (0.71)	$ (0.53)
Diluted	$ (0.25)	$ (0.16)	$ (0.71)	$ (0.53)

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