Sunesis Pharmaceuticals Reports First Quarter 2014 Financial Results and Recent Highlights

May 7, 2014 7:00 AM ET

Receives FDA Acceptance for Trademark Name Qinprezo™

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

SOUTH SAN FRANCISCO, Calif., May 7, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended March 31, 2014. Loss from operations for the three months ended March 31, 2014 was $9.0 million. As of March 31, 2014, cash, cash equivalents and marketable securities totaled $70.7 million. Sunesis also announced today that it has received U.S. Food and Drug Administration (FDA) acceptance for the use of Qinprezo™ as the trademark name for its vosaroxin product candidate. The company received a similar acceptance from the European Medicines Agency in 2013.

"We have made tremendous progress in the last several quarters across all our programs, bringing Sunesis closer to becoming an integrated oncology company leading with Qinprezo and a growing pipeline of novel and differentiated therapeutic programs," said Daniel Swisher, Chief Executive Officer of Sunesis. "A cornerstone of our strategy is the successful conclusion of our pivotal, Phase 3 VALOR trial of Qinprezo in first relapsed or refractory AML. We expect to unblind the VALOR trial in the third or fourth quarter of 2014, an event which, with a positive outcome, would transform the treatment of a difficult disease that has seen little innovation in the last 40 years."

Mr. Swisher added: "The coming quarters will also be important for the development of our pipeline, which now includes three proprietary programs and two partnered programs. Supporting this progress is a strong balance sheet, reinforced by a $43 million financing completed in March. This financing includes $95 million in potential future equity funding."

First Quarter 2014 and Recent Highlights

- ***Continued progress of VALOR trial.*** Unblinding of the pivotal, Phase 3 VALOR trial of Qinprezo plus cytarabine in first relapsed or refractory acute myeloid leukemia (AML) is expected in the third or fourth quarter of 2014, after reaching 562 events and locking the final study database. The updated guidance for unblinding of the trial reflects a slowing rate of events among the pool of patients in follow up.

- ***Announced data from ongoing MD Anderson Cancer Center-sponsored trial of Qinprezo and decitabine in frontline AML and high-risk MDS at AACR.*** In March 2014, Sunesis announced the presentation of updated results from an ongoing Phase 1b/2 University of Texas MD Anderson Cancer Center-sponsored trial of Qinprezo in combination with decitabine in older patients with previously untreated AML and high-risk myelodysplastic syndrome (MDS). The combination of Qinprezo and decitabine showed robust clinical benefit and good tolerability in older patients with AML and high-risk MDS. The poster presented at the American Association for Cancer Research Annual Meeting 2014 (AACR), titled "Phase I/II study of vosaroxin and decitabine in older patients (pts) with acute myeloid leukemia (AML) and high risk myelodysplastic syndrome (MDS)," is available on the Sunesis website at www.sunesis.com.

- ***Announced updated data from MD Anderson Cancer Center-sponsored trial will be presented at ASCO 2014 Annual Meeting (Poster #383).*** Updated data from the ongoing MD Anderson Cancer Center-sponsored study will be presented at the 2014 American Society of Clinical Oncology Annual Meeting (ASCO) in Chicago, Illinois. The poster titled "Phase I/II study of vosaroxin and decitabine in older patients with AML and high-risk MDS," will be presented at McCormick Place, S Hall A2, during the Leukemia, Myelodysplasia, and Transplantation Poster Session on Monday, June 2, 2014 from 1:15 p.m. to 5:00 p.m. Central Time.

- ***Appointed Chief Commercial Officer.*** In February 2014, Sunesis announced the appointment of Joseph I. DePinto to the newly created position of Executive Vice President and Chief Commercial Officer. Mr. DePinto brings over two decades of experience in global commercial operations, including the leadership of the commercial, marketing and strategic development efforts behind a number of prominent oncology products.

- ***Expanded oncology franchise through global licensing agreements with Biogen and Takeda/Millennium.*** In

January 2014, Sunesis announced that it expanded its oncology franchise through separate global licensing agreements for two preclinical kinase inhibitor programs. The first agreement, with Biogen Idec, is for global commercial rights to SNS-062, a potent and selective non-covalently binding oral inhibitor of BTK (Bruton's tyrosine kinase). BTK is a mediator of B-cell receptor signaling, which is integral to the pathogenesis of B-cell malignancies. Sunesis anticipates filing an investigational new drug (IND) application for SNS-062 with the FDA within one year to begin human clinical trials.

The second agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceuticals Company Limited, is for global commercial rights to several potential first-in class, pre-clinical inhibitors of the novel target PDK1 (phosphoinositide-dependent kinase-1). PDK1 is a key kinase and mediator of PI3K/AKT signaling, a pathway involved in cell growth, proliferation, differentiation, motility and survival. Sunesis anticipates selecting a lead PDK1 development candidate this year to take into IND-enabling studies.

Financial Highlights

- On March 4, 2014, Sunesis completed a $43.0 million underwritten offering of 4,650,000 shares of common stock together with two warrants, each to purchase one share of the company's common stock. The public offering price of each share of common stock and two accompanying warrants was $9.25. Net proceeds from the sale were approximately $40.0 million, after deducting the underwriting discount and estimated offering expenses.

  The warrants may only be exercised for cash following unblinding of the VALOR trial. The per share exercise price of the first warrant (Series A warrants) is $8.50 and that of the second warrant (Series B warrants) is $12.00. The warrants could result in additional net proceeds to Sunesis of up to $95.3 million if exercised in full.

- Cash and investments totaled $70.7 million as of March 31, 2014, as compared to $39.3 million as of December 31, 2013. The increase of $31.4 million was primarily due to net proceeds of $45.0 million from equity financing arrangements and the exercise of warrants and stock options, partially offset by $11.4 million of net cash used in operating activities and $2.3 million of principal payments against notes payable. As of March 31, 2014, outstanding debt totaled $16.0 million.

- Revenue for the three months ended March 31, 2014 and 2013 was $2.0 million in each period. Revenue in both periods was due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.

- Research and development expense was $7.6 million for the three months ended March 31, 2014, as compared to $7.4 million for the same period in 2013, primarily relating to the Qinprezo development program in each period. The increase between the periods was primarily due to increases in personnel, licensing, drug manufacturing and consulting costs, partially offset by a reduction in clinical trial expenses.

- General and administrative expenses for the three months ended March 31, 2014 were $3.4 million, as compared to $2.4 million for the same period in 2013. The increase between the periods was primarily due to an increase in personnel costs, including non-cash stock-based compensation expenses, and from the addition of commercial and medical affairs staff.

- Interest expense was $0.5 million for the three months ended March 31, 2014, as compared to $0.8 million for the same period in 2013. The decrease in 2014 was due to the reduced principal balance outstanding on notes payable.

- Net other expense was $5.1 million for the three months ended March 31, 2014, as compared to $3.0 million for the same period in 2013. The amounts for each period were primarily comprised of non-cash charges for the revaluation of warrants issued in the October 2010 underwritten offering.

- Cash used in operations was $11.4 million for the three months ended March 31, 2014, as compared to $9.5 million for the same period in 2013. Net cash used in 2014 resulted primarily from the net loss of $14.6 million and changes in operating assets and liabilities of $3.2 million, partially offset by net adjustments for non-cash items of $6.4 million.

- Net loss was $14.6 million for the three months ended March 31, 2014, as compared to $11.6 million for the same period in 2013.

Conference Call Information

Sunesis will host an update conference call today, May 7th at 11:00 a.m. Eastern Time. The call can be accessed by dialing (866) 515-2915 (U.S. and Canada) or (617) 399-5129 (international), and entering passcode 37605187. 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 VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial enrolled 712 patients at more than 100 leading sites in the U.S., Canada, Europe, Australia, New Zealand and South Korea. Patients were randomized in a ratio of 1:1 to receive either Qinprezo on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

About Qinprezo™

Qinprezo™ (vosaroxin) is a first-in-class anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Both the 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.

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, Qinprezo, 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' overall strategy, the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical trials, the sufficiency of Sunesis' financial resources and the commercial potential for Qinprezo™ (vosaroxin). Words such as "anticipate," "approximately," "assume," "becoming," "believe," "could," "expect," "potential," "transform," 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of Qinprezo, risks related to whether outstanding warrants will be exercised in the future, 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 Qinprezo, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk that Sunesis' development activities for Qinprezo could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for Qinprezo 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, the risk that Sunesis' nonclinical studies and clinical studies may not satisfy the requirements of the FDA, European Commission or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of Qinprezo and supply of the active pharmaceutical ingredients required for the conduct of Sunesis' clinical trials,

the risk of third party opposition to granted patents related to Qinprezo, and the risk that Sunesis' proprietary rights may not adequately protect Qinprezo. 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 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 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)

	March 31, 2014	**December 31, 2013**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:		
Cash and cash equivalents	$ 50,354	$ 15,121
Marketable securities	20,302	24,172
Prepaids and other current assets	1,099	1,199
Total current assets	71,755	40,492
Property and equipment, net	41	23
Deposits and other assets	33	10
Total assets	$ 71,829	$ 40,525
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,011	$ 953
Accrued clinical expense	3,637	4,750
Accrued compensation	871	1,719
Other accrued liabilities	2,169	1,645
Current portion of deferred revenue	7,956	7,956
Current portion of notes payable	9,293	9,018
Warrant liability	12,733	7,931
Total current liabilities	37,670	33,972
Non-current portion of deferred revenue	1,724	3,712
Non-current portion of notes payable	6,671	9,025
Commitments		
Stockholders' equity (deficit):		
Common stock	6	5
Additional paid-in capital	520,022	473,509
Accumulated other comprehensive income (loss)	4	(3)

Accumulated deficit	(494,268)	(479,695)
Total stockholders' equity (deficit)	25,764	(6,184)
Total liabilities and stockholders' equity (deficit)	$ 71,829	$ 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 March 31,	
	2014	**2013**
	(Unaudited)	
Revenue:		
License and other revenue	$ 1,995	$ 1,989
Total revenues	1,995	1,989
Operating expenses:		
Research and development	7,552	7,377
General and administrative	3,417	2,444
Total operating expenses	10,969	9,821
Loss from operations	(8,974)	(7,832)
Interest expense	(547)	(831)
Other income (expense), net	(5,052)	(2,961)
Net loss	(14,573)	(11,624)
Unrealized gain (loss) on available-for-sale securities	7	(21)
Comprehensive loss	$ (14,566)	$ (11,645)
Basic and diluted loss per common share:		
Net loss	$ (14,573)	$ (11,624)
Shares used in computing basic and diluted net loss per common share	56,313	51,587
Basic and dliuted loss per common share	$ (0.26)	$ (0.23)

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