Sunesis Pharmaceuticals Reports Second Quarter 2014 Financial Results and Recent Highlights

August 5, 2014 7:00 AM ET

VALOR Trial Reaches Prespecified Events for Unblinding

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

SOUTH SAN FRANCISCO, Calif., Aug. 5, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended June 30, 2014. Loss from operations for the three and six months ended June 30, 2014 was $11.6 million and $20.6 million, respectively. As of June 30, 2014, cash, cash equivalents and marketable securities totaled $58.5 million.

"As we near unblinding of our pivotal, Phase 3 VALOR trial in first relapsed or refractory AML, an increasing focus of our resources is the advancement of our QINPREZOâ„¢ regulatory, commercial and lifecycle management strategies," said Daniel Swisher, Chief Executive Officer of Sunesis. "With the recently announced acceptance by the EMA of a Pediatric Investigation Plan, our regulatory strategies in both Europe and the U.S. are now well defined. On the commercial front, we continue to make significant progress as we refine the key elements of a comprehensive U.S. commercial plan and build out a preeminent oncology team with key hires."

Mr. Swisher added: "Having now reached the prespecified number of events, we continue to expect unblinding of the VALOR trial in the second half of 2014. Our progress with the QINPREZO program, together with our growing pipeline of novel and differentiated therapeutic programs and a strong balance sheet, position Sunesis to reach our goal of becoming a leading, integrated oncology company."

Second Quarter 2014 and Recent Highlights

- ***VALOR trial reaches prespecified number of events for unblinding.*** VALOR recently reached the prespecified milestone of 562 events. Sunesis is currently working closely with its VALOR investigators and study sites to finalize and lock the study database.Â Sunesis continues to expect a top-line readout of VALOR in the second half of 2014.
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- ***Announced acceptance of Pediatric Investigation Plan (PIP) by EMA for QINPREZO^{TM} (vosaroxin).*** In June 2014, Sunesis announced that theÂ Pediatric CommitteeÂ of theÂ European Medicines AgencyÂ (EMA) issued a positive opinion on the company's Pediatric Investigation Plan (PIP) for QINPREZO. A PIP is part of the EMA approval process and must be accepted prior to submission of a Marketing Authorization Application (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 as a deferral for completion has been received.
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- ***Announced presentation of positive updated results from MD Anderson Cancer Center-sponsored trial at ASCO 2014.*** In June 2014, Sunesis announced the presentation of updated 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 (MDS). The results were presented at the American Society of Clinical Oncology Annual Meeting 2014 (ASCO) in Chicago, Illinois. The combination of vosaroxin and decitabine showed robust clinical benefit and good tolerability in older patients with AML and high-risk MDS. The poster, titled "Phase I/II study of vosaroxin and decitabine in older patients with acute myeloid leukemia (AML) and high risk myelodysplastic syndrome (MDS)," is available on the Sunesis website at www.sunesis.com.
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- ***Appointed Parvinder S. Hyare Vice President, Market Access.*** In July 2014, Sunesis appointed Parvinder S. Hyare

to the newly created position of Vice President, Market Access. Mr. Hyare brings over 14 years of experience in managing commercial strategies to provide pricing, reimbursement and access for oncology and specialty products promoted among hospital, group purchasing organization (GPO), commercial, trade and government payers. Prior to joining Sunesis, Mr. Hyare was Executive Director, Managed Markets & Reimbursement at AMAG Pharmaceuticals, Inc. and previously served as National Sales Director for that company.Â Prior to AMAG, Mr. Hyare was Region Business Director at Johnson & Johnson.Â He began his career at Merck & Co. as a Sales Representative/Vaccine Specialist.

Financial Highlights

- Cash and investments totaled $58.5 million as of June 30, 2014, as compared to $39.3 million as of December 31, 2013. The increase of $19.2 million was primarily due to net proceeds of $45.5 million from equity financing arrangements and the exercise of warrants and stock options, partially offset by $21.6 million of net cash used in operating activities and $4.6 million of principal payments against notes payable. As of June 30, 2014, outstanding debt totaled $13.8 million.
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- Revenue for the three and six months ended June 30, 2014 and 2013 was $2.0 million and $4.0 million. Revenue in each period was due to deferred revenue recognized related to the royalty agreement with Royalty Pharma.
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- Research and development expense was $7.2 million and $14.8 million for the three and six months ended June 30, 2014, as compared to $7.7 million and $15.1 million for the same periods in 2013, primarily relating to the QINPREZO development program in each period. Partially offset by spending on our kinase inhibitor programs, the decreases between the three and six month periods were primarily due to lower clinical trial expenses.
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- General and administrative expenses for the three and six months ended June 30, 2014 were $6.4 million and $9.8 million, as compared to $2.9 million and $5.3 million for the same periods in 2013. The increases between the three and six month periods were primarily due to higher personnel and consulting costs related to commercial planning and medical affairs.
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- Interest expense was $0.5 million and $1.0 million for the three and six months ended June 30, 2014, as compared to $0.8 million and $1.6 million for the same periods in 2013. The decreases in 2014 were due to the reduced principal balance outstanding on notes payable.
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- Net other income was $0.3 million for the three months ended June 30, 2014, as compared to $1.2 million for the same period in 2013. Net other expense was $4.8 million for the six months ended June 30, 2014, as compared to $1.8 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.
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- Cash used in operations was $21.6 million for the six months ended June 30, 2014, as compared to $19.0 million for the same period in 2013. Net cash used in 2014 resulted primarily from the net loss of $26.4 million and changes in operating assets and liabilities of $2.9 million, partially offset by net adjustments for non-cash items of $7.6 million.
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- Net loss was $11.8 million and $26.4 million for the three and six months ended June 30, 2014, as compared to $8.2 million and $19.8 million for the same periods in 2013.

Conference Call Information

Sunesis will host an update conference call today, August 5th 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 41527679. 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 vosaroxin 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 QINPREZOâ„¢ (vosaroxin)

QINPREZO 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. 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 QINPREZO has been conditionally accepted by the FDA and the EMA as the proprietary name for the company's 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, 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 and the commercial potential for QINPREZOâ„¢ (vosaroxin). Words such as "anticipate," "approximately," "believe," "continue," "could," "estimate," "expect," "position," "potential," 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,Â and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 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)

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Â	**June 30,**	**December 31,**
Â	**2014**	**2013**
ASSETS	**(Unaudited)**	**(Note 1)**
Current assets:	Â	Â
Cash and cash equivalents	Â $Â 26,761	Â $Â 15,121
Marketable securities	Â 31,782	Â 24,172
Prepaids and other current assets	Â 1,133	Â 1,199
Total current assets	Â 59,676	Â 40,492
Property and equipment, net	Â 35	Â 23
Deposits and other assets	Â 2	Â 10
Total assets	Â $Â 59,713	Â $Â 40,525
Â	Â	Â
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)Â		Â
Current liabilities:	Â	Â
Accounts payable	Â $Â 513	Â $Â 953
Accrued clinical expense	Â 3,938	Â 4,750
Accrued compensation	Â 1,288	Â 1,719
Other accrued liabilities	Â 4,238	Â 1,645
Current portion of deferred revenue	Â 7,690	Â 7,956
Current portion of notes payable	Â 9,573	Â 9,018
Warrant liability	Â 12,400	Â 7,931
Total current liabilities	Â 39,640	Â 33,972

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Non-current portion of deferred revenue	Â --Â	Â 3,712
Non-current portion of notes payable	Â 4,234	Â 9,025
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Commitments	Â	Â
Â	Â	Â
Stockholders' equity (deficit):	Â	Â
Common stock	Â 6	Â 5
Additional paid-in capital	Â 521,889	Â 473,509
Accumulated other comprehensive loss	Â (7)	Â (3)
Accumulated deficit	Â (506,049)	Â (479,695)
Total stockholders' equity (deficit)Â	Â 15,839	Â (6,184)
Total liabilities and stockholders' equity (deficit)Â	Â $Â 59,713	Â $Â 40,525
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Note 1:Â 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.

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SUNESIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE LOSSÂ

(In thousands, except per share amounts)

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Â	**Three months ended June 30,**		**Six months ended June 30,**	
Â	**2014**	**2013**	**2014**	**2013**
Â	**(Unaudited)**		**(Unaudited)**	
Revenue:	Â	Â	Â	Â
License and other revenue	Â $Â 1,989	Â $Â 1,989	Â $Â 3,984	Â $Â 3,978
Total revenues	Â 1,989	Â 1,989	Â 3,984	Â 3,978
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Operating expenses:	Â	Â	Â	Â
Research and development	Â 7,206	Â 7,674	Â 14,758	Â 15,051
General and administrative	Â 6,387	Â 2,889	Â 9,804	Â 5,333
Total operating expenses	Â 13,593	Â 10,563	Â 24,562	Â 20,384
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Loss from operations	Â (11,604)	Â (8,574)	Â (20,578)	Â (16,406)
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Interest expense	Â (470)	Â (768)	Â (1,017)	Â (1,599)
Other income (expense), net	Â 293	Â 1,152	Â (4,759)	Â (1,809)
Net loss	Â (11,781)	Â (8,190)	Â (26,354)	Â (19,814)
Unrealized gain (loss) on available-for-sale securities	Â (11)	Â (17)	Â (4)	Â (38)
Comprehensive loss	Â $Â (11,792)	Â $Â (8,207)	Â $Â (26,358)	Â $Â (19,852)
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Basic and diluted loss per common share:	Â	Â	Â	Â
Â	Â	Â	Â	Â
Net loss:	Â	Â	Â	Â
Basic	Â $Â (11,781)	Â $Â (8,190)	Â $Â (26,354)	Â $Â (19,814)
Diluted	Â $Â (12,114)	Â $Â (9,336)	Â $Â (26,354)	Â $Â (19,814)
Â	Â	Â	Â	Â
Shares used in computing net loss per common share:	Â	Â	Â	Â
Basic	Â 60,246	Â 51,630	Â 58,291	Â 51,609
Diluted	Â 61,895	Â 53,268	Â 58,291	Â 51,609
Â	Â	Â	Â	Â
Net loss per common share:	Â	Â	Â	Â
Basic	Â $Â (0.20)	Â $Â (0.16)	Â $Â (0.45)	Â $Â (0.38)
Diluted	Â $Â (0.20)	Â $Â (0.18)	Â $Â (0.45)	Â $Â (0.38)

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