FORM 8-K

Current report filing

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SUNESIS PHARMACEUTICALS INC

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2013

SUNESIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-51531**	**94-3295878**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

395 Oyster Point Boulevard, Suite 400 **South San Francisco, California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant' s telephone number, including area code: (650) 266-3500

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On January 10, 2013, we issued a press release announcing, among other things, our clinical trial updates and 2013 corporate strategies and milestones. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The press release is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Sunesis, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 10, 2013, entitled "Sunesis Announces Clinical Trial Updates and 2013 Milestones at the 31st Annual JP Morgan Healthcare Conference"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SUNESIS PHARMACEUTICALS, INC.

Dated: January 10, 2013

By: /s/ Eric H. Bjerkholt

Eric H. Bjerkholt

Executive Vice President, Corporate Development and Finance, Chief Financial Officer and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 10, 2013, entitled "Sunesis Announces Clinical Trial Updates and 2013 Milestones at the 31st Annual JP Morgan Healthcare Conference"

Exhibit 99.1

Investor and Media Inquiries:
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Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Announces Clinical Trial Updates and 2013 Milestones at the 31st Annual JP Morgan Healthcare Conference

VALOR Enrollment Reaches 500 Patients; Enrollment Doubles in LI-1 Trial

SOUTH SAN FRANCISCO, Calif., January 10, 2013 – Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced that Daniel Swisher, Chief Executive Officer of Sunesis, provided a corporate update, including a clinical trial enrollment update and overview of 2013 major corporate milestones, in a presentation at the 31st Annual J.P. Morgan Healthcare Conference in San Francisco. A webcast replay of the presentation, which was delivered today, January 10, at 12:00 PM Pacific Time, is archived on the Sunesis website at http://ir.sunesis.com and will be available for two weeks.

"Last year was a very productive period for Sunesis, with meaningful progress in our vosaroxin studies, including our pivotal, Phase 3 VALOR trial," said Daniel Swisher, Chief Executive Officer of Sunesis. "Looking ahead in 2013, we see a number of value-creating milestones, particularly with the advancement of vosaroxin toward commercialization. It is our goal to see vosaroxin, an unpartnered asset and one of the most advanced and promising therapies in development for AML today, change the global standard of care in this disease. With continued support and enthusiasm from our investigators and stakeholders, as well as a strong balance sheet, we remain well positioned to achieve this goal."

Clinical Trial Updates

VALOR enrollment reaches 500 patients. Enrollment in the VALOR Trial, a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial of vosaroxin plus cytarabine in patients with first relapsed or refractory acute myeloid leukemia (AML), has reached 500 patients. Target enrollment of 675 patients is expected to be complete in 2013, with unblinding expected in the first half of 2014. VALOR is the largest company-sponsored trial ever conducted in first relapsed or refractory AML.

Enrollment doubles in LI-1 trial. Enrollment in the Less Intensive 1 (LI-1) study, a Phase 3 randomized, controlled trial evaluating novel treatment regimens, including two vosaroxin-containing

regimens, in newly diagnosed elderly AML and high-risk myelodysplastic syndrome (MDS) patients, has reached 49 vosaroxin-treated patients. LI-1 is being conducted by the United Kingdom' s National Cancer Research Institute under the direction of Professor Alan K. Burnett, Head of Haematology at Cardiff University.

2013 Major Corporate Milestones

VALOR

Completion of enrollment. Sunesis remains on track to complete full enrollment of VALOR in 2013. Enrollment is currently ongoing at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand.

Interim safety analysis. Sunesis expects a planned interim safety analysis of VALOR by the trial' s independent Data and Safety Monitoring Board (DSMB) to occur in June, 2013.

LI-1

First interim analyses. Sunesis anticipates the first planned interim assessments of the LI-1 trial following enrollment of 50 patients per vosaroxin treatment arm, which are expected to occur in 2013. Currently, various treatment options are being evaluated in a randomized Phase 3 design with key endpoints including complete remission (CR), 12 month survival, and overall survival. Treatment arms that are exhibiting promising results are expected to continue enrolling up to a total of 200 patients enrolled per arm.

Vosaroxin

Initiation of investigator sponsored trials. Sunesis is evaluating additional indications and trials, and expects to support the initiation of additional investigator sponsored trials in MDS and AML at leading centers in 2013.

Expansion of the Intellectual Property Estate. Sunesis expects to secure additional patents in 2013, with the goal of supporting the Company' s vosaroxin global patent estate and intellectual property strategy. The Company' s multi-layered patent portfolio currently supports market exclusivity for vosaroxin to 2030 in the US, and beyond 2025 in multiple geographies around the world.

Kinase Inhibitor Program

Continued progress with partnered kinase inhibitor programs. Sunesis currently has partnered kinase inhibitor programs in oncology with Millennium Pharmaceuticals and immunology with Biogen Idec.

About VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial' s target enrollment is 675 patients at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are randomized one to one 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 Vosaroxin

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. 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 acute myeloid leukemia. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory acute myeloid leukemia in combination with cytarabine.

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 were approximately 13,780 new cases of AML and 10,200 deaths from AML in the U.S. in 2012. 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.

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This press release contains forward-looking statements, including statements related to: (i) the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical programs discussed in this release and (ii) Sunesis' ability to obtain additional patents to support its vosaroxin patent portfolio and related intellectual property strategy. Words such as "see," "promising," "well-positioned," "expected" "on track," "currently," "planned," "anticipates," "supports," "continue," "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 vosaroxin, 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 vosaroxin, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin 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 or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of vosaroxin and supply of the active pharmaceutical ingredients required for the conduct of the VALOR trial, the risk of third party opposition to granted patents related to vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, Sunesis' Annual Report on Form 10-K for the year ended December 31, 2011 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 the company' s expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.