

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

Form 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Year Ended December 31, 2012
OR
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 000-51531

SUNESIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3295878
(I.R.S. Employer Identification Number)

395 Oyster Point Boulevard, Suite 400
South San Francisco, California 94080
(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:

Common Stock, par value \$0.0001 per share

Name of Each Exchange on Which Registered:

The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting
company)

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2.) Yes No

The aggregate market value of common stock held by non-affiliates of the registrant, based on the closing sales price for such stock on June 30, 2012, as reported by The Nasdaq Stock Market, was \$93,233,442. The calculation of the aggregate market value of voting and non-voting stock excludes 14,517,871 shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The total number of shares outstanding of the registrant's common stock, \$0.0001 par value per share, as of February 28, 2013, was 51,583,785.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the 2013 Annual Meeting of Stockholders of Sunesis Pharmaceuticals, Inc. (hereinafter referred to as "Proxy Statement") are incorporated by reference in Part III of this report. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's year ended December 31, 2012.

SUNESIS PHARMACEUTICALS, INC.

TABLE OF CONTENTS

	<u>Page</u> <u>No.</u>
<i>PART I</i>	
ITEM 1. Business	3
ITEM 1A. Risk Factors	18
ITEM 1B. Unresolved Staff Comments	35
ITEM 2. Properties	35
ITEM 3. Legal Proceedings	35
ITEM 4. Mine Safety Disclosures	35
<i>PART II</i>	
ITEM 5. Market For Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	36
ITEM 6. Selected Financial Data	38
ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	40
ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk	50
ITEM 8. Financial Statements and Supplementary Data	51
ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	75
ITEM 9A. Controls and Procedures	75
ITEM 9B. Other Information	78
<i>PART III</i>	
ITEM 10. Directors, Executive Officers and Corporate Governance	78
ITEM 11. Executive Compensation	78
ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
ITEM 13. Certain Relationships and Related Transactions, and Director Independence	79
ITEM 14. Principal Accounting Fees and Services	79
<i>PART IV</i>	
ITEM 15. Exhibits, Financial Statement Schedules	80
Signatures	81
Exhibit Index	83

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the information we incorporate by reference, contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which involve risks, uncertainties and assumptions. All statements, other than statements of historical facts, are “forward-looking statements” for purposes of these provisions, including without limitation any statements relating to our strategy, including our plans with respect to unblinding the VALOR trial, presenting clinical data and initiating clinical trials, our future research and development activities, including clinical testing and the costs and timing thereof, sufficiency of our cash resources, our ability to raise additional funding when needed, any statements concerning anticipated regulatory activities or licensing or collaborative arrangements, our research and development and other expenses, our operations and legal risks, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as “anticipates,” “believe,” “continue,” “estimates,” “expects,” “intend,” “look forward,” “may,” “could,” “seeks,” “plans,” “potential,” or “will” or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under “Risk Factors,” and elsewhere in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements included in this report are based on information available to us on the date of this report, and we assume no obligation to update any forward-looking statements contained in this report.

In this report, “Sunesis,” the “Company,” “we,” “us,” and “our” refer to Sunesis Pharmaceuticals, Inc. and its wholly owned subsidiary, Sunesis Europe Limited, except where it is made clear that the term refers only to the parent company.

ITEM 1. BUSINESS

General

We are a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. Our efforts are currently focused primarily on the development of vosaroxin for the treatment of acute myeloid leukemia, or AML. Vosaroxin is a first-in-class anti-cancer quinolone derivative, or AQD—a class of compounds that has not been used previously for the treatment of cancer. AQDs have been shown to mediate anti-tumor activity by targeting mammalian topoisomerase II, an enzyme critical for cell replication. We have built a highly experienced cancer drug development organization committed to advancing vosaroxin in multiple indications to improve the lives of people with cancer.

In December 2010, we commenced enrollment of a Phase 3, multi-national, randomized, double-blind, placebo-controlled, pivotal trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML, or the VALOR trial. The VALOR trial is designed to evaluate the effect of vosaroxin in combination with cytarabine, a widely used chemotherapy in AML, on overall survival as compared to placebo in combination with cytarabine, and is being conducted at more than 100 study sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand.

In September 2012, following the recommendation of the trial’s independent Data and Safety Monitoring Board, or DSMB, after the DSMB’s completion of a single, pre-planned interim analysis of unblinded efficacy and safety data sets from the VALOR trial, we implemented a one-time, 225 patient sample size increase to the

[Table of Contents](#)

VALOR trial, bringing target enrollment to approximately 675 patients. This pre-specified sample size increase is designed to maintain adequate statistical power over a broader range of survival outcomes. We anticipate reaching full enrollment of the VALOR trial in 2013, and unblinding in the first half of 2014, after reaching 562 events in the trial and locking the final database.

We are also preparing the final clinical study reports and manuscripts for two completed clinical trials of vosaroxin: (a) the Phase 2 portion of a Phase 1b/2 trial of vosaroxin in combination with cytarabine for the treatment of patients with relapsed or refractory AML, and (b) a Phase 2 trial in previously untreated patients age 60 years or older with AML, or REVEAL-1, which explored three dosing schedules of vosaroxin.

In March 2012, patient dosing commenced in the LI-1 trial, a Phase 2/3 randomized, controlled, multi-center trial evaluating novel treatment regimens against low-dose cytarabine, or LoDAC, in patients older than 60 years with AML or high-risk myelodysplastic syndrome, or MDS. In this trial sponsored by Cardiff University and conducted by the NCRI Haematological Oncology Study Group, several treatments, including two regimens containing vosaroxin, are being evaluated for the primary endpoints of overall survival, complete remission rate and duration of response. Treatment arms meeting efficacy criteria as determined by the Data Monitoring and Ethics Committee at the first interim analysis will be expanded initially from 50 to 100 patients per arm. A second interim analysis will then take place, and for treatments showing promising survival trends, an additional 100 patients per arm will be enrolled, and the trial for these treatment arms will transition into a Phase 3 design with the primary endpoint of overall survival for the aggregate of 200 patients enrolled in each treatment arm versus 200 in the LoDAC control arm.

We own worldwide development and commercialization rights to vosaroxin. In April 2012, the European Commission granted orphan drug designation to vosaroxin for the treatment of AML, which may provide for 10 years of marketing exclusivity in all member countries of the European Union following product approval for this indication in Europe. In 2009, vosaroxin received orphan drug designation for the treatment of AML from the U.S. Food and Drug Administration, or FDA. In February 2011, the FDA granted fast track designation to vosaroxin for the potential treatment of relapsed or refractory AML in combination with cytarabine. We have been granted, or notified of allowance of, a number of key patents for vosaroxin, details of which are provided in the “Intellectual Property” section below.

In March 2011, we entered into three agreements as part of a series of agreements between Biogen Idec MA Inc., or Biogen Idec, Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Millennium, and ourselves, (details of event-based and royalty payments, as well as development and promotion rights, are provided in the “Outlicense, Collaboration and Royalty Agreements” section below):

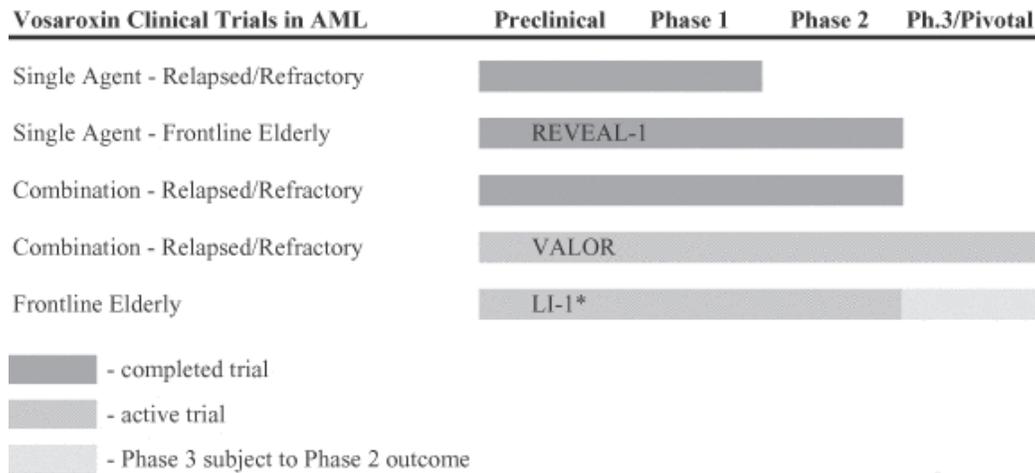
- A license agreement with Millennium, or the Millennium Agreement, pursuant to which we granted Millennium exclusive licenses for the development of our oral, selective pan-Raf kinase inhibitor and one additional undisclosed kinase inhibitor program in oncology that were previously a part of our August 2004 collaboration agreement with Biogen Idec, or the Original Biogen Idec Agreement. In September 2011, we announced that Millennium had initiated a Phase 1 clinical study of an oral investigative drug selective for pan-Raf kinase inhibition, MLN2480, which was licensed to them under the Millennium Agreement.
- An amendment and restatement of the Original Biogen Idec Agreement, or the Restated Biogen Idec Agreement, to provide for the discovery, development and commercialization of small molecule inhibitors of a unique preclinical kinase inhibitor program involved in immunology.
- A termination and transition agreement with Biogen Idec and Millennium, which terminated Biogen Idec’s exclusive rights under the Original Biogen Idec Agreement to all discovery programs under such agreement other than the abovementioned preclinical kinase inhibitor program.

Vosaroxin

Vosaroxin is a first-in-class AQD—a class of compounds that has not been used previously for the treatment of cancer. AQDs have been shown to mediate anti-tumor activity by targeting mammalian topoisomerase II, an enzyme critical for cell replication. Vosaroxin acts by DNA intercalation and inhibition of topoisomerase II in replicating cancer cells. The resulting site-selective DNA damage rapidly causes the cancer cells to stop dividing and die. In preclinical studies, vosaroxin demonstrated broad anti-tumor activity and exhibited additive or synergistic activity when combined with several therapeutic agents currently used in the treatment of cancer, including cytarabine. Clinical activity is observed in both solid and hematologic malignancies. We licensed worldwide development and commercialization rights to vosaroxin from Daiippon Sumitomo Pharma Co., Ltd., or Daiippon, in 2003.

Vosaroxin Clinical Trials in AML

The following chart summarizes the status of clinical trials in AML that have been conducted or are currently being conducted with vosaroxin:



* Sponsored by Cardiff University, and being conducted by the NCRI Haematological Oncology Study Group

VALOR. In December 2010, we commenced enrollment of the VALOR trial, a Phase 3, randomized, double-blind, placebo-controlled, pivotal clinical trial of vosaroxin in combination with cytarabine to evaluate overall survival in patients with relapsed or refractory AML, which is being conducted at more than 100 study sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. In September 2012, following the recommendation of the trial’s independent DSMB after their completion of a single, pre-planned interim analysis of unblinded efficacy and safety data sets from the VALOR trial, we implemented a one-time, 225 patient sample size increase to the VALOR trial, bringing target enrollment to approximately 675 patients. This pre-specified sample size increase is designed to maintain adequate statistical power over a broader range of survival outcomes. The safety review conducted at the time of the interim analysis was the fourth safety analysis of the VALOR trial to date. We anticipate reaching full enrollment of the VALOR trial in 2013, and unblinding in the first half of 2014, after reaching 562 events in the trial and locking the final database.

LI-1. In March 2012, patient dosing commenced in the LI-1 trial, a Phase 2/3 randomized, controlled, multi-center trial evaluating novel treatment regimens against LoDAC, in patients older than 60 years with AML or high-risk MDS. In this trial sponsored by Cardiff University and conducted by the NCRI Haematological Oncology Study Group, several treatments, including two regimens containing vosaroxin, are being evaluated for

[Table of Contents](#)

the primary endpoints of overall survival, complete remission rate and duration of response. Treatment arms meeting efficacy criteria as determined by the Data Monitoring and Ethics Committee at the first interim analysis will be expanded initially from 50 to 100 patients per arm. A second interim analysis will then take place, and for treatments showing promising survival trends, an additional 100 patients per arm will be enrolled, and the trial for these treatment arms will transition into a Phase 3 design with the primary endpoint of overall survival for the aggregate of 200 patients enrolled in each treatment arm versus 200 in the LoDAC control arm.

Phase 2 Combination. We are currently preparing the final clinical study report and manuscript for a completed Phase 1b/2 clinical trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML. The trial was designed to evaluate the safety, pharmacokinetics and anti-leukemic activity of escalating doses of vosaroxin administered in combination with cytarabine given either as a continuous intravenous, or IV, infusion or a two-hour IV infusion. A pooled set of 69 patients with first relapsed (n=36) or primary refractory (n=33) AML were evaluated for efficacy outcomes. The median overall survival was 6.9 months, the complete remission, or CR, rate was 26%, and the combined complete remission rate was 29% including CR, CR without full platelet recovery, or CRp, and CR with incomplete recovery, or CRi. The two regimens of vosaroxin in combination with cytarabine were generally well tolerated. The most common severe non-hematologic toxicities were related to infections. Severe stomatitis or oral mucositis was observed in 15% of patients, and was manageable with standard supportive care. All-cause mortality was low, at 3% at 30 days and 9% at 60 days.

Phase 2 Single-Agent. We are currently preparing the final clinical study report and manuscript for a completed Phase 2 single-agent clinical trial of vosaroxin in previously untreated patients aged 60 years or older with AML. The trial evaluated three dosing schedules. Based on the safety and efficacy results, vosaroxin at 72 mg/m² administered on days one and four was the recommended dose schedule for further study. For this schedule, median survival was 7.7 months and one-year survival was 38%. The CR plus CRp rate for this schedule was 35% and 30-day all-cause mortality was 7%.

Phase 1 Single-Agent. Prior to 2009, we conducted a Phase 1 clinical trial to evaluate safety, pharmacokinetics, and preliminary clinical activity of two dose schedules of vosaroxin in patients with relapsed or refractory acute leukemia. Anti-leukemic activity was observed in both schedules, and the most common dose-limiting toxicity was stomatitis. The maximum tolerated dose was 72 mg/m² for a once weekly for three weeks schedule and 40 mg/m² for a twice weekly for two weeks schedule.

Vosaroxin Clinical Trials in Ovarian Cancer and Other Solid Tumors

In mid-2010, we completed a Phase 2 single-agent trial of vosaroxin in platinum-resistant ovarian cancer. Three doses in two schedules of vosaroxin were studied:

- 48 mg/m² given every three weeks (n=65)
- 60 mg/m² given every four weeks (n=37)
- 75 mg/m² given every four weeks (n=35)

Encouraging, durable anti-tumor activity was observed across all doses. For patients treated with 48, 60 and 75 mg/m², respectively, the overall response rate, or ORR, was 11%, 11% and 9%, respectively; disease control, defined as stable disease for 12 weeks or more, was 46%, 46% and 51%, respectively; and the median progression-free survival, or PFS, was 83, 61 and 103 days, respectively. Based on clinical activity and tolerability, the 60 mg/m² dose and schedule was selected for future consideration. Overall, vosaroxin was generally well tolerated, with more than 10% of patients experiencing severe neutropenia, febrile neutropenia, fatigue, and anemia.

[Table of Contents](#)

Prior to 2009, we conducted two Phase 1 clinical trials to evaluate different dosing schedules of vosaroxin in patients with advanced solid tumors. We also conducted two Phase 2 studies in non-small cell lung cancer and small cell lung cancer. Although objective responses were observed in both lung cancer studies, it was determined that vosaroxin could be administered with greater dose intensity given the low incidence of severe neutropenia. The studies were halted and we may consider future vosaroxin studies in lung cancer or other solid tumors, as well as in hematologic malignancies.

Inlicense Agreement

In October 2003, we entered into an agreement with Dainippon to acquire exclusive worldwide development and marketing rights for vosaroxin. In January 2011, we made a \$0.5 million milestone payment to Dainippon as a result of the initiation of our VALOR trial in December 2010. In the future we may be required to make additional milestone payments of up to \$7.0 million in aggregate to Dainippon for (a) filing new drug applications, or NDAs, in the U.S., Europe and Japan, and (b) for receiving regulatory approvals in these regions, for cancer-related indications. If vosaroxin is approved for a non-cancer indication, an additional milestone payment will become payable to Dainippon.

The agreement also provides for royalty payments to Dainippon at rates based on total annual net sales. Under the agreement, we may reduce our royalty payments to Dainippon if a third party markets a competitive product and we must pay royalties for third-party intellectual property rights necessary to commercialize vosaroxin. Royalty obligations under the agreement continue on a country-by-country and product-by-product basis until the later of the date on which no valid patent claims relating to a product exist or 10 years from the date of the first sale of the product.

If we discontinue seeking regulatory approval and/or the sale of the product in a region, we are required to return its rights to the product in that region to Dainippon. The agreement may be terminated by either party for the other party's uncured breach or bankruptcy.

Outlicense, Collaboration and Royalty Agreements

Overview

Over the past three years, we have generated revenue primarily through license and collaboration agreements with Biogen Idec, Millennium, and SARcode Bioscience, Inc., or SARcode, and a Revenue Participation Agreement, or the Royalty Agreement, with RPI Finance Trust, or RPI, an entity related to Royalty Pharma.

In 2011, we recorded revenues of \$4.0 million related to a license agreement with Millennium and \$1.0 million associated with the license of certain intellectual property rights to SARcode, which represented 80% and 20% of 2011 revenues, respectively. In 2012, we recognized \$2.3 million of revenue related to the Royalty Agreement with RPI and \$1.5 million related to the Restated Biogen Idec Agreement, which represented 60% and 40% of 2012 revenues, respectively.

Royalty Agreement

On March 29, 2012, we entered into the Royalty Agreement with RPI. On September 18, 2012, as a result of the recommendation by the DSMB to increase the sample size for the VALOR trial, RPI made a \$25.0 million cash payment to us in exchange for a 6.75% royalty on any future net sales of vosaroxin. In conjunction with the Royalty Agreement, we issued two five-year warrants to RPI, each to purchase 1,000,000 shares of our common stock, at exercise prices of \$3.48 and \$4.64 per share, respectively. Of the \$25.0 million, \$21.9 million was categorized as deferred revenue and is being amortized to revenue over the related performance period of the Royalty Agreement. The remaining \$3.1 million represents the fair value of the warrants.

Biogen Idec and Millennium

In August 2004, we entered into the Original Biogen Idec Agreement to discover, develop and commercialize small molecule inhibitors of Raf kinase and up to five additional targets that play a role in oncology and immunology indications or in the regulation of the human immune system. Pursuant to the terms of the Original Biogen Idec Agreement, we applied our fragment-based drug discovery technology, Tethering, to generate small molecule leads during the research term, for which we received research funding, which was paid in advance to support some of our scientific personnel. In connection with our June 2008 restructuring, the parties agreed to terminate the research term and related funding as of June 30, 2008. A total of \$20.0 million of research funding was received through this date. We received a total of \$3.0 million in milestone payments for meeting certain preclinical milestones through March 2011, including a \$1.5 million milestone received in cash in July 2009 for Biogen Idec's selection of a Raf kinase inhibitor development candidate for the treatment of cancer.

In March 2011, we entered into a series of agreements between Biogen Idec, Millennium and ourselves, including:

- The Millennium Agreement, pursuant to which we granted Millennium exclusive licenses for the development of our oral, selective pan-Raf kinase inhibitor and one additional undisclosed kinase inhibitor program in oncology that were previously a part of the Original Biogen Idec Agreement. Under this agreement, in the future we may receive up to \$59.3 million in pre-commercialization event-based payments related to the development of the first two indications for each of the licensed products directed against the two exclusively licensed targets, and royalty payments depending on future product sales. The Millennium Agreement also provides us with future co-development and co-promotion rights. In September 2011, we announced that Millennium had initiated a Phase 1 clinical study of an oral investigative drug selective for pan-Raf kinase inhibition, MLN2480, which was licensed to them under the Millennium Agreement.
- The Restated Biogen Idec Agreement, to provide for the discovery, development and commercialization of small molecule inhibitors of a unique preclinical kinase inhibitor program involved in immunology. In June 2012, we received an event-based payment of \$1.5 million from Biogen Idec for the advancement of pre-clinical work under this agreement. We are eligible to receive up to an additional \$58.5 million in pre-commercialization event-based payments related to the development of the first two indications for licensed products against the specified immunology target under the Restated Biogen Idec Agreement, and royalty payments depending on future product sales. We also retain future co-development and co-promotion rights.
- A termination and transition agreement with Biogen Idec and Millennium, which provides for the termination of Biogen Idec's exclusive rights under the Original Biogen Idec Agreement to all discovery programs under such agreement other than a preclinical kinase inhibitor program involved in immunology, the permitted assignment of assets and rights to Millennium as provided in the Millennium Agreement, and the upfront, non-refundable payment of \$4.0 million to us as consideration for the above, which was received in April 2011.

SARcode

In March 2006, we licensed our lymphocyte function-associated antigen-1, or LFA-1, patents and related know-how to SARcode, a privately-held biopharmaceutical company. In March 2009, the license agreement was terminated and SARcode paid us \$2.0 million in cash for this intellectual property, which was recorded as revenue in April 2009. Following the termination of the license agreement, SARcode fully satisfied its obligations to us and we have no further rights to the intellectual property transferred to SARcode. In August 2011, SARcode repaid three promissory notes that had been issued to us upon entering into the original license

[Table of Contents](#)

agreement. The total amount received was \$1.2 million, which comprised the aggregate principal value of the three notes of \$1.0 million, plus \$0.2 million of accrued interest, which we recorded as revenue and interest income, respectively, upon receipt.

Manufacturing

We do not have internal manufacturing capabilities for the production of clinical or commercial quantities of vosaroxin. To date, we have relied on, and we expect to continue to rely on, a limited number of third-party contract manufacturers for the production of clinical and commercial quantities of the vosaroxin active pharmaceutical ingredient, or API, the finished drug product incorporating the API, or FDP, and the placebo used in the VALOR trial. We do not have commercial supply agreements with any of these third parties, and our agreements with these parties may include provisions that allow for termination at will by either party following a relatively short notice period.

We currently rely on two contract manufacturers for the vosaroxin API. We also currently rely on a single contract manufacturer to formulate the vosaroxin API and fill and finish vials of the vosaroxin FDP. Because the vosaroxin API is classified as a cytotoxic substance, the number of available manufacturers for the API and FDP is limited. We believe at least five contract manufacturers in North America have suitable facilities to manufacture the vosaroxin API, and at least four have suitable facilities to manufacture the vosaroxin FDP. A number of manufacturers outside of North America have suitable facilities, including one that currently manufactures our vosaroxin API. If we are unable to obtain sufficient quantities of the vosaroxin API and FDP from our current manufacturers, it may take time to engage alternative manufacturers, which could delay the development of and impair our ability to commercialize vosaroxin.

To date, vosaroxin has been manufactured in quantities appropriate for preclinical studies and clinical trials, including the manufacture of registration batches of API and FDP. Prior to submission for FDA review and approval for commercial sale, we will need to perform process validation studies and stability assessments on these registration batches. If the results of these process validation studies and stability assessments do not meet preset criteria, the regulatory approval or commercial launch of vosaroxin may be delayed.

Competition

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching, developing and marketing products designed to address the treatment of cancer, including AML. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in the clinical testing of, obtaining regulatory approvals for, and marketing drugs.

We believe that our ability to successfully compete in the marketplace with vosaroxin and any future product candidates, if any, will depend on, among other things:

- our ability to develop novel compounds with attractive pharmaceutical properties and to secure, protect and maintain intellectual property rights based on our innovations;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;

[Table of Contents](#)

- our ability to obtain, and the timing and scope of, regulatory approvals;
- our ability to manufacture and sell commercial quantities of future products to the market; and
- acceptance of future products by physicians and other healthcare providers.

Vosaroxin is a small molecule therapeutic that will compete with other drugs and therapies currently used for AML, such as nucleoside analogs, anthracyclines, hypomethylating agents, Flt-3 inhibitors, other inhibitors of topoisomerase II, and other novel agents. Additionally, other compounds currently in development could become potential competitors of vosaroxin, if approved for marketing. We expect competition with vosaroxin for the treatment of AML to increase as additional products are developed and approved for use in various patient populations.

Intellectual Property

We believe that patent protection is very important to our business and that our future success depends in part on our ability to obtain patents protecting vosaroxin or future drug candidates, if any. Historically, we have patented a wide range of technology, inventions and improvements related to our business, some of which we are no longer actively developing.

The original vosaroxin composition of matter is covered by U.S. Patent No. 5,817,669 and its counterpart patents in 43 foreign jurisdictions. This U.S. patent will expire in October 2015, while its foreign counterparts will expire in June 2015. While it is possible that patent term restoration and/or supplemental patent certificates would be available for some of these or other patents we own, we cannot guarantee that such additional protection will be obtained, and the expiration dates described here do not include such term restoration.

We have been granted, or notified of allowance of, a number of additional key patents for vosaroxin, as follows:

- In December 2009, the European Patent Office, or EPO, granted us Patent No. 1729770 covering combination products including vosaroxin and cytarabine, which will expire in 2025 and has been validated in multiple EPC member states. In June 2011, the U.S. Patent and Trademark Office, or USPTO, granted us a patent in the same family, which will expire in 2026. In March 2011, Australia granted us a patent in this family, which will expire in 2025. In September 2012, Japan also granted us a patent in this family, which will expire in 2025. Corresponding applications are pending in other major markets, including Canada.
- In November 2010, the USPTO granted us Patent No. 7,829,577 covering pharmaceutical compositions of vosaroxin, including the formulation used in our VALOR trial. This patent will expire in 2025. In January 2011, the EPO granted us a patent in the same family, which has been validated in multiple European Patent Convention, or EPC, member states. In September 2011, Australia also granted us a patent in this family. These patents will expire in 2025. Corresponding applications are pending in other major markets, including Japan and Canada.
- In August 2011, the USPTO granted us Patent No. 7,989,468 covering methods of use of vosaroxin at clinically relevant dose ranges and schedules for the treatment of leukemia. This patent will expire in 2026. Corresponding applications are pending in other major markets, including Europe, Japan, Australia and Canada.
- In February 2012, the USPTO granted us Patent No. 8,124,773 covering certain vosaroxin hydrate forms, which will expire in 2028. Corresponding applications are pending in other major markets, including Europe, Japan, Australia and Canada.

[Table of Contents](#)

- In March 2012, the USPTO granted us Patent No. 8,138,202 covering certain compositions related to vosaroxin, including vosaroxin API and FDP, which will expire in 2030. Corresponding patent applications are pending internationally.

As of December 31, 2012, we own, co-own or have rights to approximately 117 granted U.S. and foreign patents, and approximately 133 pending U.S. and foreign applications, pertaining to vosaroxin and compositions and uses thereof. When appropriate, we intend to seek patent term restoration, orphan drug status and/or data exclusivity in the United States and their equivalents in other relevant jurisdictions, to the maximum extent that the respective laws will permit at such time. In April 2012, the European Commission granted orphan drug designation to vosaroxin for the treatment of AML, which may provide for 10 years of marketing exclusivity in all member countries of the European Union following product approval for this indication in Europe. In 2009, the FDA granted orphan drug designation to vosaroxin for the treatment of AML.

Our ability to build and maintain our proprietary position for vosaroxin and any future drug candidates, if any, will depend on our success in obtaining effective claims and enforcing those claims if granted. The patent positions of biopharmaceutical companies like ours are generally uncertain and involve complex legal and factual questions for which some important legal principles remain unresolved. No consistent policy regarding the breadth of patent claims has emerged to date in the United States. The patent situation outside the United States is even more uncertain. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Even if patents are issued, they may not be sufficient to protect vosaroxin or future drug candidates, if any. The patents we own or license and those that may be issued in the future may be opposed, challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages.

Patent applications filed before November 29, 2000 in the United States are maintained in secrecy until patents issue. Later filed U.S. applications and patent applications in most foreign countries generally are not published until at least 18 months after their earliest filing date. Scientific and patent publication often occurs long after the date of the scientific discoveries disclosed in those publications. Accordingly, we cannot be certain that we were the first to invent the subject matter covered by any patent application or that we were the first to file a patent application for any inventions.

Our commercial success depends on our ability to operate without infringing patents and proprietary rights of third parties. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our ability to conduct our business. The existence of third party patent applications and patents could significantly reduce the coverage of patents owned by or licensed to us and limit our ability to obtain meaningful patent protection. If patents containing competitive or conflicting claims are issued to third parties and these claims are ultimately determined to be valid, we may be enjoined from pursuing research, development or commercialization of vosaroxin or future drug candidates, if any, or be required to obtain licenses to such patents or to develop or obtain alternative technology.

We may need to commence or defend litigation to enforce or to determine the scope and validity of any patents issued to us or to determine the scope and validity of third party proprietary rights. Litigation would result in substantial costs, even if the eventual outcome is favorable to us. An adverse outcome in litigation affecting proprietary rights we own or have licensed could present significant risk of competition for vosaroxin or future drug candidates, if any, that we market or seek to develop. Any adverse outcome in litigation affecting third party proprietary rights could subject us to significant liabilities to third parties and could require us to seek licenses of the disputed rights from third parties or to cease using the technology if such licenses are unavailable.

We also rely on trade secrets to protect our technology, especially in situations or jurisdictions in which we believe patent protection may not be appropriate or obtainable. However, trade secrets are difficult to maintain and do not protect technology against independent developments made by third parties.

[Table of Contents](#)

We seek to protect our proprietary information by requiring our employees, consultants, contractors and other advisers to execute nondisclosure and assignment of invention agreements upon commencement of their employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. There can be no assurance that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party.

We seek to protect our company name and the names of our products and technologies by obtaining trademark registrations, as well as common law rights in trademarks and service marks, in the United States and in other countries. There can be no assurance that the trademarks or service marks we use or register will protect our company name or any products or technologies that we develop and commercialize, that our trademarks, service marks, or trademark registrations will be enforceable against third parties, or that our trademarks and service marks will not interfere with or infringe trademark rights of third parties. We may need to commence litigation to enforce our trademarks and service marks or to determine the scope and validity of our or a third party's trademark rights. Litigation would result in substantial costs, even if the eventual outcome is favorable to us. An adverse outcome in litigation could subject us to significant liabilities to third parties and require us to seek licenses of the disputed rights from third parties or to cease using the trademarks or service marks if such licenses are unavailable.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, efficacy, labeling, storage, recordkeeping, approval, advertising and promotion of vosaroxin and any future drug candidates we may develop, if any. The application of these regulatory frameworks to the development, approval and commercialization of vosaroxin or our future drug candidates, if any, will take a number of years to accomplish, if at all, and involve the expenditure of substantial resources.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, as amended, and implementing regulations. The process required by the FDA before vosaroxin and any future drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, *in vivo* preclinical studies and formulation studies;
- submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before clinical trials begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of an NDA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA, including proposed labeling (package insert information) and promotional materials, prior to any commercial marketing, sale or shipment of the drug.

[Table of Contents](#)

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for vosaroxin or our future drug candidates, if any, will be granted on a timely basis, if at all.

Preclinical Testing and INDs

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. Laboratories that comply with the FDA Good Laboratory Practice regulations must conduct preclinical safety tests. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those submitted by Biogen Idec, Millennium, or our potential future licensees or collaboration partners, if any, may not result in FDA authorization to commence a clinical trial.

Clinical Trials

Clinical trials involve the administration of an investigational drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with the FDA's Protection of Human Subjects regulations and Good Clinical Practices, or GCP, under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application.

In addition, each clinical study must be conducted under the auspices of an independent institutional review board, or IRB, at each institution where the study will be conducted. Each IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The FDA, an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP requirements and regulations for informed consent.

Clinical trials are typically conducted in three sequential phases, which may overlap, sometimes followed by a fourth phase:

- *Phase 1 clinical trials* are initially conducted in a limited population to test the drug candidate for safety (adverse effects), dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a "Phase 1b" evaluation, which is a second safety-focused Phase 1 clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently approved drugs.
- *Phase 2 clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase 2b" evaluation, which is a second, confirmatory Phase 2 clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.

[Table of Contents](#)

- *Phase 3 clinical trials* are commonly referred to as pivotal trials. When Phase 2 clinical trials demonstrate that a drug candidate has potential activity in a disease or condition and has an acceptable safety profile, Phase 3 clinical trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population at multiple, geographically dispersed clinical trial sites.
- *Phase 4 (post-marketing) clinical trials* may be required by the FDA in some cases. The FDA may condition approval of an NDA for a drug candidate on a sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and efficacy after NDA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials.

New Drug Applications

The testing and approval processes are likely to require substantial cost, time and effort, and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

The results of development, preclinical testing and clinical trials, together with extensive manufacturing information and a substantial user fee, are submitted to the FDA as part of an NDA for approval of the marketing and commercial distribution of the drug. The review process routinely takes 12 months (under the latest Prescription Drug User Fee Act, or PDUFA, goals, a 10-month review period begins at the conclusion of the 60-day filing review period that begins on the date of FDA receipt of the submission), but is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical testing. Even if data from such testing is obtained and submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we, Biogen Idec, Millennium, or our potential future licensees or collaboration partners, if any, interpret data. If regulatory approval is granted, such approval may entail limitations on the indicated uses for which the product may be marketed.

Once issued, the FDA may withdraw drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Orphan Drug Designation

The United States Orphan Drug Act promotes the development of products that demonstrate promise for the diagnosis and treatment of diseases or conditions that affect fewer than 200,000 people in the United States. Upon receipt of orphan drug designation from the FDA, the sponsor is eligible for tax credits of up to 50% for qualified clinical trial expenses, the ability to apply for annual grant funding, waiver of PDUFA application fee, and upon approval, the potential for seven years of market exclusivity for the orphan-designated product for the orphan-designated indication. In October 2009, the FDA granted orphan drug designation to vosaroxin for treatment of AML.

[Table of Contents](#)

In April 2012, the European Commission granted orphan drug designation to vosaroxin for the treatment of AML, which may provide for 10 years of marketing exclusivity for this indication in Europe. In the EU, orphan status is available for therapies addressing conditions that affect five or fewer out of 10,000 people. The marketing exclusivity period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Fast Track Designation

FDA's fast track program is intended to facilitate the development, and to expedite the review, of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition.

With fast track designation, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the time period specified in the PDUFA, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast track designated drug candidate may also qualify for *priority review*. Under FDA policies, a drug candidate is eligible for priority review, or, under Prescription Drug User Fee Act V, review within eight months from the time a complete NDA is submitted (a six-month review period begins at the conclusion of the 60-day filing review period that begins on the date of FDA receipt of the submission), if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA's criteria for priority review.

In February 2011, the FDA granted fast track designation to vosaroxin for the potential treatment of relapsed or refractory AML in combination with cytarabine. We do not know whether vosaroxin or our future drug candidates, if any, will receive a priority review designation or, if a priority designation is received, whether that review or approval will be faster than conventional FDA procedures, or the ultimate impact, if any, of the fast track designation on the timing or likelihood of FDA approval of vosaroxin or our future drug candidates, if any.

Satisfaction of FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with vosaroxin, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug candidates on a timely basis, or at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Other Regulatory Requirements

Any drugs manufactured or distributed by us, Biogen Idec, Millennium, or our potential future licensees or collaboration partners, if any, pursuant to FDA approvals are subject to continuing regulation by the FDA,

[Table of Contents](#)

including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including cancer therapy. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Foreign Regulation

In addition to regulations in the United States, we are subject to foreign regulations governing clinical trials and commercial sales and distribution of vosaroxin or our future drug candidates, if any. Our VALOR trial is enrolling patients in Europe, Canada, South Korea, Australia and New Zealand. We may in the future initiate clinical trials in other countries throughout the world. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, permission to conduct clinical research is granted by the Competent Authority of each European Member State, or MS, and the applicable Ethics Committees, or EC, through the submission of a Clinical Trial Application. An EC in the European Union serves the same function as an IRB in the United States. The review times vary by MS but may not exceed 60 days. The EC has a maximum of 60 days to give its opinion on the acceptability of the Clinical Trial Application to both the governing MS and the sponsor applicant. If the application is deemed acceptable, the MS informs the applicant (or does not within the 60-day window inform the applicant of non-acceptance) and the company may proceed with the clinical trial.

Under the European Union regulatory systems, marketing authorizations for drugs that have been granted orphan drug designation for the related indication must be submitted under a centralized authorization procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states.

Under the Canadian regulatory system, Health Canada is the regulatory body that governs the sale of drugs and their use in clinical trials. Accordingly, any company that wishes to conduct a clinical trial in Canada must submit a clinical trial application to Health Canada. Health Canada reviews the application and notifies the company within 30 days if the application is found to be deficient. If the application is deemed acceptable, Health Canada will issue a no objection letter to the company within the 30-day review period which means the company may proceed with its clinical trial(s).

[Table of Contents](#)

In addition to regulations in the United States, the European Union and Canada, we will be subject to a variety of other foreign regulations governing clinical trials and commercial distribution of our product candidates. Our ability to sell drugs will also depend on the availability of reimbursement from government and private insurance companies.

Research and Development Expenses

We incurred \$29.2 million, \$22.6 million and \$14.4 million of research and development expenses in 2012, 2011 and 2010, respectively. We do not anticipate incurring any significant additional research expenses related to the discovery of additional product candidates, the development or application of fragment-based drug discovery methods, the development of in-house research capabilities, or on the clinical development of product candidates other than vosaroxin. In addition, we are no longer conducting any research activities in connection with collaboration agreements. However, we have incurred and expect to continue to incur increased levels of research and development expenses to conduct further clinical and related development of vosaroxin.

Environment

We have made, and will continue to make, expenditures for environmental compliance and protection. We do not expect that such expenditures will have a material effect on our capital expenditures or results of operations in the foreseeable future.

Employees

As of December 31, 2012, our workforce consisted of 25 full-time employees. Of our total workforce, 15 are engaged in research and development and 10 are engaged in general and administrative functions. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages.

Corporate Background

We were incorporated in Delaware in February 1998 as Mosaic Pharmaceuticals, Inc., and subsequently changed our name to Sunesis Pharmaceuticals, Inc. Our offices are headquartered at 395 Oyster Point Boulevard, Suite 400, South San Francisco, California 94080, and our telephone number is (650) 266-3500. Our website address is www.sunesis.com. Information contained in, or accessible through, our website is not incorporated by reference into and does not form a part of this report.

Available Information

Our website is located at www.sunesis.com. The contents of our website are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the Securities and Exchange Commission, or SEC, and any references to our websites are intended to be inactive textual references only. The following filings are available through our website after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15 (d) of the Securities Act. These filings are also available for download free of charge on our investor relations website. Additionally, copies of materials filed by us with the SEC may be accessed at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or at www.sec.gov. For information about the SEC's Public Reference Room, contact 1-800-SEC-0330.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and all information contained in this report in weighing a decision to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be adversely affected. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. In addition, the trading price of our common stock could decline due to the occurrence of any of these risks, and you may lose all or part of your investment. Please see “Special Note Regarding Forward-Looking Statements.”

Risks Related to Our Business

We need to raise substantial additional funding to complete the development and potential commercialization of vosaroxin.

We believe that with \$71.2 million in cash and investments as of December 31, 2012, we currently have the resources to fund our operations through 2014.

However, we will need to raise substantial additional capital to:

- complete the development and potential commercialization of vosaroxin in AML;
- fund additional clinical trials of vosaroxin and seek regulatory approvals;
- expand our development activities;
- implement additional internal systems and infrastructure; and
- build or access commercialization and additional manufacturing capabilities and supplies.

Our future funding requirements and sources will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, including the VALOR trial in particular;
- the need for additional or expanded clinical trials;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs associated with building or accessing commercialization and additional manufacturing capabilities and supplies;
- the costs of acquiring or investing in businesses, product candidates and technologies, if any;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

[Table of Contents](#)

- the effect of competing technological and market developments, and;
- the costs, if any, of supporting our arrangements with Biogen Idec, Millennium or any potential future licensees or partners.

Until we can generate a sufficient amount of licensing, collaboration or product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through equity issuances, debt arrangements, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights to vosaroxin, or a combination of the above. Any issuance of convertible debt securities, preferred stock or common stock may be at a discount from the then-current trading price of our common stock. If we issue additional common or preferred stock or securities convertible into common or preferred stock, our stockholders will experience additional dilution, which may be significant. Further, we do not know whether additional funding will be available on acceptable terms, or at all. If we are unable to raise substantial additional funding on acceptable terms or at all, we will be forced to delay or reduce the scope of our vosaroxin development program, potentially including the VALOR trial, and/or limit or cease our operations.

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We may not ever achieve or sustain profitability.

We are not profitable and have incurred losses in each year since our inception in 1998. Our net losses for the years ended December 31, 2012, 2011 and 2010 were \$44.0 million, \$20.1 million and \$24.6 million, respectively. As of December 31, 2012, we had an accumulated deficit of \$445.1 million. We do not currently have any products that have been approved for marketing, and we continue to incur substantial development and general and administrative expenses related to our operations. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase significantly as the VALOR trial progresses, as we seek regulatory approvals for vosaroxin, and as we commercialize vosaroxin, if approved. Our losses, among other things, have caused and will continue to cause our stockholders' equity and working capital to decrease.

To date, we have derived substantially all of our revenue from license and collaboration agreements. On March 31, 2011, the only remaining collaboration agreement, which was with Biogen Idec, was amended and restated to provide for the discovery, development and commercialization of small molecule inhibitors of a unique preclinical kinase inhibitor program involved in immunology. Concurrently, we entered into a license agreement with Millennium, under which we granted Millennium exclusive licenses for the development of our oral, selective pan-Raf kinase inhibitor and one additional undisclosed kinase inhibitor program in oncology. While we are entitled to certain pre-commercialization event-based and royalty payments under each of the Restated Biogen Idec Agreement and Millennium Agreement, we cannot predict whether we will receive any such payments under these agreements in the foreseeable future, or at all.

We also do not anticipate that we will generate revenue from the sale of products for the foreseeable future. In the absence of additional sources of capital, which may not be available to us on acceptable terms, or at all, the development of vosaroxin or future product candidates, if any, may be reduced in scope, delayed or terminated. If our product candidates or those of our collaborators fail in clinical trials or do not gain regulatory approval, or if our future products do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

The development of vosaroxin could be halted or significantly delayed for various reasons; our clinical trials for vosaroxin may not demonstrate safety or efficacy or lead to regulatory approval.

Vosaroxin is vulnerable to the risks of failure inherent in the drug development process. We may need to conduct significant additional preclinical studies and clinical trials before we can attempt to demonstrate that vosaroxin is safe and effective to the satisfaction of the FDA and other regulatory authorities. Failure can occur

[Table of Contents](#)

at any stage of the development process, and successful preclinical studies and early clinical trials do not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials.

For example, we terminated two Phase 2 clinical trials of vosaroxin in small cell and non-small cell lung cancer. If our clinical trials result in unacceptable toxicity or lack of efficacy, we may have to terminate them. If clinical trials are halted, or if they do not show that vosaroxin is safe and effective in the indications for which we are seeking regulatory approval, our future growth will be limited and we may not have any other product candidates to develop.

We do not know whether our ongoing clinical trials or any other future clinical trials with vosaroxin or any of our product candidates, including the VALOR trial in particular, will be completed on schedule, or at all, or whether our ongoing or planned clinical trials will begin or progress on the time schedule we anticipate. The commencement of future clinical trials could be substantially delayed or prevented by several factors, including:

- delays or failures to raise additional funding;
- results of meetings with the FDA and/or other regulatory bodies;
- a limited number of, and competition for, suitable patients with particular types of cancer for enrollment in our clinical trials;
- delays or failures in obtaining regulatory approval to commence a clinical trial;
- delays or failures in obtaining sufficient clinical materials;
- delays or failures in obtaining approval from independent institutional review boards to conduct a clinical trial at prospective sites; or
- delays or failures in reaching acceptable clinical trial agreement terms or clinical trial protocols with prospective sites.

The completion of our clinical trials, including the VALOR trial, could be substantially delayed or prevented by several factors, including:

- delays or failures to raise additional funding;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- delays or failures in reaching the number of events pre-specified in the trial design;
- the need to expand the clinical trial;
- delays or failures in obtaining sufficient clinical materials, including vosaroxin, its matching placebo and cytarabine;
- unforeseen safety issues;
- lack of efficacy during clinical trials;

[Table of Contents](#)

- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

Additionally, our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, or ourselves. Any failure to complete or significant delay in completing clinical trials for our product candidates could harm our financial results and the commercial prospects for our product candidates.

We rely on a limited number of third-party manufacturers that are capable of manufacturing the vosaroxin active pharmaceutical ingredient, or API, and finished drug product, or FDP, to supply us with our vosaroxin API and FDP and the placebo used in the VALOR trial. If we fail to obtain sufficient quantities of these materials, the VALOR trial and the development of vosaroxin could be halted or significantly delayed. In addition, we have previously identified product impurities in the vosaroxin API that negatively impact FDP quality. Process improvements have been implemented to minimize these impurities, however there is no assurance they will not occur in the future.

We do not currently own or operate manufacturing facilities and lack the capability to manufacture vosaroxin on a clinical or commercial scale. As a result, we rely on third parties to manufacture vosaroxin API and FDP and the placebo product used in the VALOR trial. The vosaroxin API is classified as a cytotoxic substance, limiting the number of available manufacturers for both API and FDP.

We currently rely on two contract manufacturers for the vosaroxin API. We also currently rely on a single contract manufacturer to formulate the vosaroxin API and fill and finish vials of the vosaroxin FDP. If our third-party vosaroxin API or FDP manufacturers are unable or unwilling to produce the vosaroxin API or FDP or placebo we require, we would need to establish arrangements with one or more alternative suppliers. However, establishing a relationship with an alternative supplier would likely delay our ability to produce vosaroxin API or FDP. Our ability to replace an existing manufacturer would also be difficult and time consuming because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can be an approved commercial supplier. Such approval would require new testing, stability programs and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all. We expect to continue to depend on third-party contract manufacturers for all our vosaroxin API, FDP and placebo needs for the foreseeable future.

Vosaroxin requires precise, high quality manufacturing. We have observed visible particles during stability studies of two vosaroxin FDP lots. We have since identified a process impurity in the vosaroxin API that, when formulated into the packaged vial of the vosaroxin FDP, can result in the formation of particles over time. As a response to these findings, we implemented a revised manufacturing process to control the impurity and thereby prevent particle formation. Five lots of vosaroxin API manufactured using a revised manufacturing process were formulated into FDP lots that have all completed up to 24 months of stability testing at room temperature without formation of particles. Three additional lots of API have been manufactured using this improved process, and four lots of FDP have been successfully manufactured using the API resulting from the improved process. All FDP lots made with the new API have passed quality testing and have been released for use in the VALOR trial. All lots have been placed on an International Conference on Harmonization, or ICH, compliant stability program. It will take time to evaluate whether or not our revised manufacturing process for vosaroxin API will be successful in stopping the formation of particles in FDP lots over the longer term, and to evaluate whether or not such control of particle formation can also be reliably and consistently achieved in subsequent lots over the shorter or longer term. If our changes in the manufacturing process do not adequately control the formation of visible particles, we will need to discuss other possibilities with the FDA and/or other regulatory bodies, which could include a temporary clinical hold of the VALOR trial until the issue has been resolved to their satisfaction.

[Table of Contents](#)

In addition to process impurities, the failure of our contract manufacturers to achieve and maintain high manufacturing standards in compliance with cGMP regulations could result in other manufacturing errors leading to patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery. Although contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards, any such performance failures on the part of a contract manufacturer could result in the delay or prevention of filing or approval of marketing applications for vosaroxin, cost overruns or other problems that could seriously harm our business. This would deprive us of potential product revenue and result in additional losses.

To date, vosaroxin has been manufactured in quantities appropriate for preclinical studies and clinical trials, including the manufacture of registration batches of API and FDP. Prior to submission for FDA review and approval for commercial sale, we will need to perform process validation studies and stability assessments on these registration batches. If the results of these process validation studies and stability assessments do not meet preset criteria, the regulatory approval or commercial launch of vosaroxin may be delayed.

The failure to enroll patients for clinical trials may cause delays in developing vosaroxin.

We may encounter delays if we are unable to enroll enough patients to complete clinical trials of vosaroxin, including the VALOR trial. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, and the eligibility criteria for the trial. Patients participating in our trials may elect to leave our trials and switch to alternative treatments that are available to them, either commercially or on an expanded access basis, or in other clinical trials. Competing treatments include nucleoside analogs, anthracyclines and hypomethylating agents. Moreover, when one product candidate is evaluated in multiple clinical trials simultaneously, patient enrollment in ongoing trials can be adversely affected by negative results from completed trials. In the VALOR trial, vosaroxin is being tested in patients with AML, which can be a difficult patient population to recruit.

The results of preclinical studies and clinical trials may not satisfy the requirements of the FDA or other regulatory agencies.

Prior to receiving approval to commercialize vosaroxin or future product candidates, if any, in the United States or internationally, we must demonstrate with substantial evidence from well-controlled clinical trials, to the satisfaction of the FDA and other regulatory authorities, that such product candidates are safe and effective for their intended uses. The results from preclinical studies and clinical trials can be interpreted in different ways, and the favorable results from previous trials of vosaroxin may not be experienced in the VALOR trial. Even if we believe the preclinical or clinical data are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In addition, although we believe that our discussions with the FDA support the potential approval of vosaroxin for the treatment of AML based on positive results from the VALOR trial without the need to conduct additional clinical trials, the FDA has substantial discretion in the approval process and may not grant approval based on data from this trial.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or fail to meet expected deadlines, we may be unable to obtain regulatory approval for, or commercialize vosaroxin.

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our planned and existing clinical trials for vosaroxin. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for any other reason, we may need to

[Table of Contents](#)

enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

We expect to expand our development capabilities, and any difficulties hiring or retaining key personnel or managing this growth could disrupt our operations.

We are highly dependent on the principal members of our development staff. We expect to expand our development capabilities by increasing expenditures in these areas, hiring additional employees and potentially expanding the scope of our current operations. Future growth will require us to continue to implement and improve our managerial, operational and financial systems and continue to retain, recruit and train additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. The competition for qualified personnel in the biopharmaceutical field is intense. We are highly dependent on our continued ability to attract, retain and motivate highly qualified management and specialized personnel required for clinical development. Due to our limited resources, we may not be able to effectively manage any expansion of our operations or recruit and train additional qualified personnel. If we are unable to retain key personnel or manage our growth effectively, we may not be able to implement our business plan.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time consuming and could prevent us from developing or commercializing vosaroxin.

Our commercial success depends on not infringing the patents and other proprietary rights of third parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and product candidates. If a third party asserts that we are using technology or compounds claimed in issued and unexpired patents owned or controlled by the third party, we may need to obtain a license, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that a third party asserts that we infringe its patents.

If a third party asserts that we infringe its patents or other proprietary rights, we could face a number of challenges that could seriously harm our competitive position, including:

- infringement and other intellectual property claims, which would be costly and time consuming to litigate, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that vosaroxin or any future product candidates infringe a third party's patent or other proprietary rights;
- a court order prohibiting us from selling or licensing vosaroxin or any future product candidates unless a third party licenses relevant patent or other proprietary rights to us, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If our competitors develop and market products that are more effective, safer or less expensive than vosaroxin, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching, developing and marketing products designed to address the treatment of cancer, including AML. Many of our competitors have

[Table of Contents](#)

significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in the clinical testing of, obtaining regulatory approvals for, and marketing drugs.

We believe that our ability to successfully compete in the marketplace with vosaroxin and any future product candidates, if any, will depend on, among other things:

- our ability to develop novel compounds with attractive pharmaceutical properties and to secure, protect and maintain intellectual property rights based on our innovations;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- our ability to obtain, and the timing and scope of, regulatory approvals;
- our ability to manufacture and sell commercial quantities of future products to the market; and
- acceptance of future products by physicians and other healthcare providers.

Vosaroxin is a small molecule therapeutic that will compete with other drugs and therapies currently used for AML, such as nucleoside analogs, anthracyclines, hypomethylating agents, Flt-3 inhibitors, other inhibitors of topoisomerase II, and other novel agents. Additionally, other compounds currently in development could become potential competitors of vosaroxin, if approved for marketing.

We expect competition for vosaroxin for the treatment of AML to increase as additional products are developed and approved in various patient populations. If our competitors market products that are more effective, safer or less expensive than vosaroxin or our other future products, if any, or that reach the market sooner we may not achieve commercial success or substantial market penetration. In addition, the biopharmaceutical industry is characterized by rapid change. Products developed by our competitors may render vosaroxin or any future product candidates obsolete.

Our proprietary rights may not adequately protect vosaroxin or future product candidates, if any.

Our commercial success will depend on our ability to obtain patents and maintain adequate protection for vosaroxin and any future product candidates in the United States and other countries. We own, co-own or have rights to a significant number of issued U.S. and foreign patents and pending U.S. and foreign patent applications. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we generally do not exclusively control the patent prosecution of subject matter that we license to or from others. Accordingly, in such cases we are unable to exercise the same degree of control over this intellectual property as we would over our own. Moreover, the patent positions of biopharmaceutical companies are highly uncertain and involve

[Table of Contents](#)

complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

- we, our licensors or our collaboration partners were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we, our licensors or our collaboration partners were the first to file patent applications for these inventions;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' or our collaboration partners' pending patent applications will result in issued patents;
- any of our, our licensors' or our collaboration partners' patents will be valid or enforceable;
- any patents issued to us, our licensors or our collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will have an adverse effect on our business.

We also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or our collaboration partners' employees, consultants, contractors or scientific and other advisors, or those of our licensors, may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, foreign courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protection against them and our business could be harmed.

The initial composition of matter patents covering vosaroxin are due to expire in 2015. Even if vosaroxin is approved by the FDA and foreign equivalents thereof, we may not be able to recover our development costs prior to the expiration of these patents.

The vosaroxin composition of matter is covered by U.S. Patent No. 5,817,669 and its counterpart patents in 43 foreign jurisdictions. This patent is due to expire in October 2015, and most of its foreign counterparts are due to expire in June 2015. In November 2010, the USPTO granted us a patent covering pharmaceutical compositions of vosaroxin, including the formulation used in our VALOR trial. In January 2011, the European Patent Office, or EPO, granted us a similar patent, which has been validated in multiple EPC member states. These patents are due to expire in 2025. In December 2009, the EPO granted us a patent covering combinations of vosaroxin with cytarabine, which is due to expire in 2025 in multiple European Patent Convention, or EPC, member states. In June 2011, the USPTO granted us a similar patent, which is due to expire in 2026. In August 2011, the USPTO granted us a patent covering methods of use of vosaroxin at clinically relevant dose ranges and schedules for the treatment of leukemia. This patent has been granted a substantial patent term adjustment, which extends its term through late 2026. In February 2012, the USPTO granted us a patent covering certain vosaroxin hydrate forms, which is due to expire in 2028. In March 2012, the USPTO granted us a patent covering certain compositions related to vosaroxin, which is due to expire in 2030. Vosaroxin must undergo extensive clinical trials before it can be approved by the FDA. We do not know when, if ever, vosaroxin will be approved by the

[Table of Contents](#)

FDA. Even if vosaroxin is approved by the FDA in the future, we may not have sufficient time to commercialize our vosaroxin product to enable us to recover our development costs prior to the expiration of the U.S. and foreign patents covering vosaroxin. We do not know whether patent term extensions and data exclusivity periods will be available in the future for any or all of the patents we own or have licensed. Our obligation to pay royalties to Dainippon, the company from which we licensed vosaroxin, may extend beyond the patent expiration, which would further erode the profitability of this product. In addition, our potential obligation to pay RPI royalties pursuant to the Royalty Agreement could also further erode the profitability of this product.

Any future workforce and expense reductions may have an adverse impact on our internal programs, our ability to hire and retain key personnel and may be distracting to management.

We have, in the past, implemented a number of workforce reductions. Depending on our need for additional funding and expense control, we may be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. In addition, the implementation of expense reduction programs may result in the diversion of efforts of our executive management team and other key employees, which could adversely affect our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

Many of our employees were previously employed at biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or the work product of current or former personnel could hamper or prevent our ability to commercialize vosaroxin, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We currently have limited marketing staff and no sales or distribution organization. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing vosaroxin.

We currently have no sales or distribution capabilities and a limited marketing staff. We intend to establish our own sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize vosaroxin in North America, and potentially in Europe, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We plan to collaborate with third parties that have direct sales forces and established distribution systems to commercialize vosaroxin. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we marketed or sold vosaroxin directly. In addition, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize vosaroxin. If we are not successful in commercializing vosaroxin or our future product candidates, if any, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We depend on various consultants and advisors for the success and continuation of our development efforts.

We work extensively with various consultants and advisors, who provide advice and/or services in various business and development functions, including clinical development, operations and strategy, regulatory matters, biostatistics, legal and finance. The potential success of our drug development programs depends, in part, on continued collaborations with certain of these consultants and advisors. Our consultants and advisors are not our employees and may have commitments and obligations to other entities that may limit their availability to us. We do not know if we will be able to maintain such relationships or that such consultants and advisors will not enter into other arrangements with competitors, any of which could have a detrimental impact on our development objectives and our business.

If conflicts of interest arise between our current or future licensees or collaboration partners, if any, and us, any of them may act in their self-interest, which may be adverse to our interests.

If a conflict of interest arises between us and one or more of our current or potential future licensees or collaboration partners, if any, they may act in their own self-interest or otherwise in a way that is not in the interest of our company or our stockholders. Biogen Idec, Millennium, or potential future licensees or collaboration partners, if any, are conducting or may conduct product development efforts within the disease area that is the subject of a license or collaboration with our company. In current or potential future licenses or collaborations, if any, we have agreed or may agree not to conduct, independently or with any third party, any research that is competitive with the research conducted under our licenses or collaborations. Our licensees or collaboration partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates that are the subject of these licenses or collaborations. Competing products, either developed by our licensees or collaboration partners or to which our licensees or collaboration partners have rights, may result in their withdrawal of support for a product candidate covered by the license or collaboration agreement.

If one or more of our current or potential future licensees or collaboration partners, if any, were to breach or terminate their license or collaboration agreements with us or otherwise fail to perform their obligations thereunder in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates could be delayed or terminated. We do not know whether our licensees or collaboration partners will pursue alternative technologies or develop alternative product candidates, either on their own or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by licenses or collaboration agreements with our company.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure may create uncertainty regarding compliance matters. New or changed laws, regulations and standards are subject to varying interpretations in many cases. As a result, their application in practice may evolve over time. We are committed to maintaining high standards of corporate governance and public disclosure. Complying with evolving interpretations of new or changed legal requirements may cause us to incur higher costs as we revise current practices, policies and procedures, and may divert management time and attention from potential revenue-generating activities to compliance matters. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may also be harmed. Further, our board members, chief executive officer and chief financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business.

Raising funds through lending arrangements or revenue participation agreements may restrict our operations or produce other adverse results.

Our loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation, or collectively the Lenders, which we entered into on October 18, 2011, contains a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this Loan Agreement, on October 18, 2011, we granted a perfected first priority security interest in substantially all of our assets, other than intellectual property assets, to the Lenders. Additionally, following the purchase of the revenue participation right by RPI on September 18, 2012, we granted both the Lenders and RPI a security interest in certain of our assets, including our intellectual property related to vosaroxin, which may only be perfected following first product approval in any country or territory. The Lenders will retain a senior position to RPI's security interest for so long as any indebtedness under the Loan Agreement remains outstanding. Our failure to comply with the covenants in the Loan Agreement, the occurrence of a material impairment in our prospect of repayment or in the perfection or priority of the Lender's lien on our assets, as determined by the Lenders, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets and other adverse results.

In addition, following the purchase of the revenue participation right by RPI, we are required to pay RPI a specified percentage of any net sales of vosaroxin. If we fail to make timely payments due to RPI under the Royalty Agreement, RPI may require us to repurchase the Revenue Participation Right. As collateral for these payments, we granted RPI a security interest in certain of our assets, including our intellectual property related to vosaroxin, as detailed above.

Economic conditions may make it costly and difficult to raise additional capital.

There has been turmoil in the world economy, which has led to volatility on the U.S. stock market and reduced credit availability. Investors have been unwilling to buy certain corporate stocks and bonds. If economic conditions continue to affect the capital markets, our ability to raise capital, via our existing controlled equity facilities, debt facility or otherwise, may be adversely affected.

We are exposed to risks related to foreign currency exchange rates and European sovereign debt.

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with activities related to the VALOR trial that are occurring outside of the United States, and in particular in Western Europe. When the U.S. dollar weakens against the Euro or British pound, the U.S. dollar value of the foreign currency denominated expense increases, and when the U.S. dollar strengthens against the Euro or British pound, the U.S. dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the U.S. dollar, may adversely affect our results of operations. We have and may continue to purchase certain European currencies or highly-rated investments denominated in such currencies to manage the risk of future movements in foreign exchange rates that would affect such payables, in accordance with our investment policy. However, there is no guarantee that the related gains and losses will substantially offset each other, and we may be subject to significant exchange gains or losses as currencies fluctuate from quarter to quarter.

In addition, the current sovereign debt crisis concerning certain European countries and related European financial restructuring efforts may cause the value of European currencies, including the Euro, to deteriorate. Such deterioration could adversely impact our investments denominated in Euros, which had an aggregate fair value of \$4.5 million as of December 31, 2012, all of which was invested in corporate debt securities. Recent

[Table of Contents](#)

rating agency downgrades on European sovereign debt and continuing concern over the potential default of European government issuers has further contributed to this uncertainty. Should governments default on their obligations, we may experience loss of principal on any investments in European sovereign debt.

Our facilities are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities are located in the San Francisco Bay Area near known earthquake fault zones and are vulnerable to significant damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fires, floods, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities may be seriously or completely impaired and our data could be lost or destroyed.

Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approval for the commercialization of vosaroxin.

The research, testing, manufacturing, selling and marketing of product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor our present or potential future collaboration or licensing partners, if any, are permitted to market our product candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA, or in any other country without the equivalent marketing approval from such country. We have not received marketing approval for vosaroxin in any jurisdiction. None of our collaboration or licensing partners have had a product resulting from our collaboration enter clinical trials. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending NDAs, supplements to approved NDAs or their foreign equivalents.

Regulatory approval of an NDA or NDA supplement or a foreign equivalent is not guaranteed, and the approval process is expensive, uncertain and may take several years. Furthermore, the development process for oncology products may take longer than in other therapeutic areas. Regulatory authorities have substantial discretion in the drug approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for marketing approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. In particular, although we believe that our discussions with the FDA support the potential approval of vosaroxin for the treatment of AML based on positive results from the VALOR trial without the need to conduct additional clinical trials, the FDA has substantial discretion in the approval process and may not grant approval based on data from this trial.

The FDA or a foreign regulatory authority can delay, limit or deny approval of a drug candidate for many reasons, including:

- the drug candidate may not be deemed safe or effective;
- regulatory officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA or foreign regulatory authority might not approve our or our third-party manufacturers' processes or facilities; or

[Table of Contents](#)

- the FDA or foreign regulatory authority may change its approval policies or adopt new regulations.

We may be subject to costly claims related to our clinical trials and may not be able to obtain adequate insurance.

Because we conduct clinical trials in humans, we face the risk that the use of vosaroxin or future product candidates, if any, will result in adverse side effects. We cannot predict the possible harms or side effects that may result from our clinical trials. Although we have clinical trial liability insurance for up to \$10.0 million in aggregate, our insurance may be insufficient to cover any such events. We do not know whether we will be able to continue to obtain clinical trial coverage on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage. There is also a risk that third parties that we have agreed to indemnify could incur liability. Any litigation arising from our clinical trials, even if we were ultimately successful, would consume substantial amounts of our financial and managerial resources and may create adverse publicity.

Even if we receive regulatory approval to sell vosaroxin, the market may not be receptive to vosaroxin.

Even if vosaroxin obtains regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors and/or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- efficacy of our product;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of vosaroxin, both in absolute terms and relative to alternative treatments; and
- availability of reimbursement from health maintenance organizations and other third-party payors.

For example, the potential toxicity of single and repeated doses of vosaroxin has been explored in a number of animal studies that suggest the dose-limiting toxicities in humans receiving vosaroxin may be similar to some of those observed with approved cytotoxic agents, including reversible toxicity to bone marrow cells, the gastrointestinal system and other systems with rapidly dividing cells. In our Phase 1 and Phase 2 clinical trials of vosaroxin, we have witnessed the following side effects, irrespective of causality, ranging from mild to more severe: lowered white blood cell count that may lead to a serious or possibly life-threatening infection, hair loss, mouth sores, fatigue, nausea with or without vomiting, lowered platelet count, which may lead to an increase in bruising or bleeding, lowered red blood cell count (anemia), weakness, tiredness, shortness of breath, diarrhea and intestinal blockage.

If vosaroxin fails to achieve market acceptance, due to unacceptable side effects or any other reasons, we may not be able to generate significant revenue or to achieve or sustain profitability.

Even if we receive regulatory approval for vosaroxin, we will be subject to ongoing FDA and other regulatory obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize vosaroxin.

Any regulatory approvals that we or our potential future collaboration partners receive for vosaroxin or our future product candidates, if any, may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing trials. In addition, even if approved, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for any product will be subject to extensive and ongoing regulatory requirements. The subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Regulatory policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market vosaroxin or our future products and we may not achieve or sustain profitability.

The coverage and reimbursement status of newly approved drugs is uncertain, and failure to obtain adequate coverage and reimbursement could limit our ability to market vosaroxin and decrease our ability to generate revenue.

There is significant uncertainty related to the third party coverage and reimbursement of newly approved drugs both nationally and internationally. The commercial success of vosaroxin and our future products, if any, in both domestic and international markets depends on whether third-party coverage and reimbursement is available for the ordering of our future products by the medical profession for use by their patients. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to manage healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our future products. These payors may not view our future products as cost-effective, and reimbursement may not be available to consumers or may not be sufficient to allow our future products to be marketed on a competitive basis. Likewise, legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs could result in lower prices or rejection of our future products. Changes in coverage and reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our future products may reduce any future product revenue.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing vosaroxin abroad.

We intend to market vosaroxin in international markets either directly or through a potential future collaboration partner, if any. In order to market vosaroxin in the European Union, Canada and many other foreign jurisdictions, we or a potential future collaboration partner must obtain separate regulatory approvals. We have, and potential future collaboration partners may have, had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing at significant cost. The time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval processes may include all of the risks associated with obtaining FDA approval. We or a potential future collaboration partner may not obtain foreign regulatory approvals on a timely basis, if at all. We or a potential future collaboration partner may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize vosaroxin or any other future products in any market.

Foreign governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market vosaroxin in both the United States and foreign jurisdictions either directly or through one or more potential future collaboration partners. If we or a potential future collaboration partner obtain approval in one or more foreign jurisdictions, we or the potential future collaboration partner will be subject to rules and regulations in those jurisdictions relating to vosaroxin. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we or a potential future collaboration partner may be required to conduct a clinical trial that compares the cost-effectiveness of vosaroxin to other available therapies. If reimbursement of vosaroxin is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We, through third-party contractors, use hazardous chemicals and radioactive and biological materials in our business and are subject to a variety of federal, state, regional and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials. Although we believe our safety procedures for handling and disposing of these materials and waste products comply with these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage, which is limited for pollution cleanup and contamination.

Risks Related to Our Common Stock

The price of our common stock may continue to be volatile, and the value of an investment in our common stock may decline.

In 2012, our common stock traded as low as \$1.17 and as high as \$6.85. Factors that could cause continued volatility in the market price of our common stock include, but are not limited to:

- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangement;
- results from, and any delays in or discontinuance of, ongoing and planned clinical trials for vosaroxin;
- announcements of FDA non-approval of vosaroxin, delays in filing regulatory documents with the FDA or other regulatory agencies, or delays in the review process by the FDA or other foreign regulatory agencies;
- announcements relating to restructuring and other operational changes;
- delays in the commercialization of vosaroxin or our future products, if any;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- issuance of new or changed securities analysts' reports or recommendations;
- developments or disputes concerning our intellectual property or other proprietary rights;

Table of Contents

- clinical and regulatory developments with respect to potential competitive products;
- failure to maintain compliance with the covenants in the Loan Agreement;
- introduction of new products by our competitors;
- issues in manufacturing vosaroxin drug substance or drug product, or future products, if any;
- market acceptance of vosaroxin or our future products, if any;
- announcements relating to our arrangements with Biogen Idec, Millennium or RPI;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of analysts;
- third-party healthcare reimbursement policies;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of vosaroxin or future products, if any;
- failure to develop or sustain an active and liquid trading market for our common stock;
- sales of our common stock by our officers, directors or significant stockholders; and
- additions or departures of key personnel.

If we fail to maintain compliance with the continued listing requirements of The NASDAQ Stock Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock currently trades on The NASDAQ Stock Market under the symbol “SNSS.” This market has continued listing standards that we must comply with in order to maintain the listing of our common stock. The continued listing standards include, among others, a minimum bid price requirement of \$1.00 per share and any of: (i) a minimum stockholders’ equity of \$2.5 million; (ii) a market value of listed securities of at least \$35.0 million; or (iii) net income from continuing operations of \$500,000 in the most recently completed fiscal year or in the two of the last three fiscal years. Our results of operations and fluctuating stock price directly impact our ability to satisfy these continued listing standards. In the event we are unable to maintain these continued listing standards, our common stock may be subject to delisting from The NASDAQ Stock Market.

We have been out of compliance with the minimum bid price requirement in the past, and as discussed above, the price of our common stock can be volatile; accordingly, there can be no assurance that we will continue to meet the minimum \$1.00 bid price requirement or the other NASDAQ continued listing requirements in the future, and we may be subject to delisting as a result. If we are delisted, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a reduced amount of analyst coverage for us;

[Table of Contents](#)

- a decreased ability to issue additional securities or obtain additional financing in the future;
- reduced liquidity for our stockholders;
- potential loss of confidence by collaboration partners and employees; and
- loss of institutional investor interest.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our stockholders, and could make it more difficult to change management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders might otherwise consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- limitations on our stockholders' ability to call special meetings of stockholders;
- an advance notice requirement for stockholder proposals and nominations; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Provisions in our charter documents and provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

The ownership of our capital stock is highly concentrated, and your interests may conflict with the interests of our existing stockholders.

Our executive officers and directors together with their affiliates beneficially owned approximately 33.7% of our outstanding capital stock as of December 31, 2012, assuming the exercise in full of the outstanding warrants to purchase common stock held by these stockholders as of such date. Accordingly, these stockholders, acting as a group, could have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We have never paid dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, under the terms of our Loan Agreement with the Lenders, we are precluded from paying cash dividends without the prior written consent of the Lenders. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In December 2006, we leased approximately 15,000 square feet of office space in a building at 395 Oyster Point Boulevard in South San Francisco, California, which is currently our corporate headquarters. The lease was due to expire on April 30, 2013. In January 2013, we extended the term of the lease until January 31, 2014. We believe that our current facility will be sufficient to meet our needs through at least 2013.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us because of the defense costs, diversion of management resources and other factors.

We believe there is no litigation pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is listed on The NASDAQ Stock Market under the symbol "SNSS." The following table sets forth the range of the high and low sales prices by quarter, as reported by NASDAQ, after giving retroactive effect to the one-for-six reverse split of shares of our capital stock, or the Reverse Split, outstanding immediately prior to the effective time of the Reverse Split on February 14, 2011.

<u>Year-Ended December 31, 2011</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 3.21	\$ 1.66
Second Quarter	\$ 3.16	\$ 1.88
Third Quarter	\$ 2.15	\$ 1.17
Fourth Quarter	\$ 1.50	\$ 1.01
<u>Year-Ended December 31, 2012</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 3.17	\$ 1.17
Second Quarter	\$ 3.19	\$ 2.45
Third Quarter	\$ 5.98	\$ 2.30
Fourth Quarter	\$ 6.85	\$ 3.60

As of February 28, 2013, there were approximately 161 holders of record of our common stock. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in nominee or in "street name" accounts through brokers. On February 28, 2013, the last sale price reported on The NASDAQ Stock Market for our common stock was \$5.22 per share.

Dividend Policy

We have never paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. While subject to periodic review, the current policy of our board of directors is to retain cash and investments primarily to provide funds for our future growth. In addition, under the terms of our loan and security agreement with Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation, we are precluded from paying cash dividends without the prior written consent of the lenders.

Recent Sales of Unregistered Securities

None.

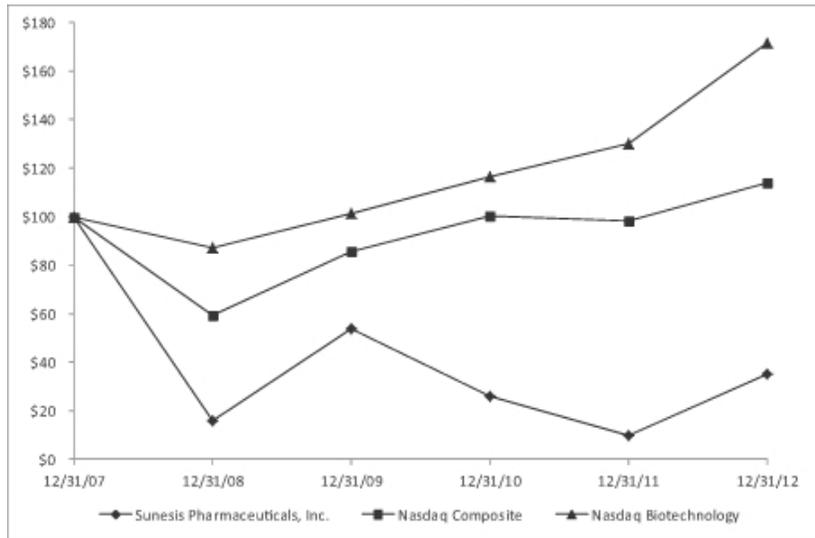
Stock Performance Graph

The following stock performance graph compares the cumulative total return to security holders of our common shares with the comparable cumulative returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes the investment of \$100 on December 31, 2007 and the reinvestment of all dividends, if any. Points on the graph represent the performance as of the last business day of each of the fiscal years indicated.

The following performance graph is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing by us under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. The stock price performance shown on the graph is not necessarily indicative of future price performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Sunesis Pharmaceuticals, Inc., the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



* \$100 invested on 12/31/07 in stock or index, including reinvestment of any dividends.

[Table of Contents](#)

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and notes to those statements included elsewhere in this report. The historical results presented below are not necessarily indicative of future results.

Consolidated Statement of Operations:	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(In thousands, except per share amounts)				
Revenue:					
Collaboration revenue	\$ —	\$ —	\$ 27	\$ 1,550	\$ 4,917
License and other revenue	3,754	5,000	6	2,212	500
Total revenues	3,754	5,000	33	3,762	5,417
Operating expenses:					
Research and development	29,185	22,563	14,433	13,247	26,285
General and administrative	9,175	8,303	7,005	7,748	11,524
Restructuring charges	—	—	—	1,916	5,783
Total operating expenses	38,360	30,866	21,438	22,911	43,592
Loss from operations	(34,606)	(25,866)	(21,405)	(19,149)	(38,175)
Interest expense	(1,855)	(259)	—	—	—
Other income (expense), net(1)	(7,490)	5,984	(3,182)	(21,077)	989
Net loss	(43,951)	(20,141)	(24,587)	(40,226)	(37,186)
Deemed distribution to preferred stockholders(2)	—	—	—	(27,563)	—
Loss attributable to common stockholders	<u>\$(43,951)</u>	<u>\$ (20,141)</u>	<u>\$(24,587)</u>	<u>\$(67,789)</u>	<u>\$(37,186)</u>
Shares used in computing basic and diluted loss attributable to common stockholders per common share	48,146	46,412	24,860	5,747	5,731
Basic and diluted loss attributable to common stockholders per common share	<u>\$ (0.91)</u>	<u>\$ (0.43)</u>	<u>\$ (0.99)</u>	<u>\$ (11.80)</u>	<u>\$ (6.49)</u>

- (1) During 2012 we recorded net non-cash charges of \$7.5 million, during 2011 we recorded net non-cash credits of \$5.9 million, and during 2010 we recorded a non-cash charge of \$3.7 million, related to the revaluation of the liability for warrants issued in connection with the underwritten offering in October 2010 (see Note 10 of the accompanying consolidated financial statements).

During 2009, we recorded non-cash charges of \$21.0 million related to the accounting for the fair values of securities issued as part of the Private Placement (see Note 10 of the accompanying consolidated financial statements). The non-cash charges consisted of \$7.5 million recorded upon the initial closing of \$10.0 million of units in April 2009 and \$13.5 million upon the revaluation in June 2009 of the options to participate in the second closing of \$5.0 million of units and the third closing of up to \$28.5 million of common stock, which occurred in October 2009 and June 2010, respectively.

[Table of Contents](#)

- (2) During 2009, we recorded deemed distributions to preferred stockholders totaling \$27.6 million, related to the accounting for the Private Placement. Of this amount, \$26.4 million was due to the revaluation of certain securities upon an amendment of the Private Placement agreements in June 2009, and \$1.2 million was due to the write-off of a discount for a beneficial conversion feature on the convertible preferred stock issued as part of the second closing in October 2009.

Consolidated Balance Sheet Data:	As of December 31,				
	2012	2011	2010	2009	2008
			(In thousands)		
Cash, cash equivalents and marketable securities	\$ 71,227	\$ 44,115	\$ 53,396	\$ 4,259	\$ 10,619
Working capital	41,191	37,282	42,118	1,807	5,371
Total assets	73,017	45,869	54,858	5,169	12,784
Non-current portion of deferred revenue	11,668	—	—	—	—
Current portion of notes payable	6,610	—	—	—	—
Non-current portion of notes payable	17,651	9,453	—	—	—
Convertible preferred stock	—	—	—	60,005	—
Common stock and additional paid-in capital	457,016	429,147	423,267	298,473	322,675
Accumulated deficit	(445,097)	(401,146)	(381,005)	(356,418)	(316,192)
Total stockholders' equity	11,957	28,020	42,247	2,060	6,491

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition as of December 31, 2012 and results of operations for the year ended December 31, 2012 should be read together with our consolidated financial statements and related notes included elsewhere in this report. This discussion and analysis contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which involve risks, uncertainties and assumptions. All statements, other than statements of historical facts, are "forward-looking statements" for purposes of these provisions, including without limitation any statements relating to our strategy, including our plans with respect to unblinding the VALOR trial, presenting clinical data and initiating clinical trials, our future research and development activities, including clinical testing and the costs and timing thereof, sufficiency of our cash resources, our ability to raise additional funding when needed, any statements concerning anticipated regulatory activities or licensing or collaborative arrangements, our research and development and other expenses, our operations and legal risks, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "anticipates," "believe," "continue," "estimates," "expects," "intend," "look forward," "may," "could," "seeks," "plans," "potential," or "will" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under "Risk Factors," and elsewhere in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements included in this report are based on information available to us on the date of this report, and we assume no obligation to update any forward-looking statements contained in this report.

Overview

We are a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. Our efforts are currently focused primarily on the development of vosaroxin for the treatment of acute myeloid leukemia, or AML. In December 2010, we commenced enrollment of a Phase 3, multi-national, randomized, double-blind, placebo-controlled, pivotal trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML, or the VALOR trial.

The VALOR trial is designed to evaluate the effect of vosaroxin in combination with cytarabine, a widely used chemotherapy in AML, on overall survival as compared to placebo in combination with cytarabine, and is being conducted at more than 100 study sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand.

In September 2012, following the recommendation of the trial's independent Data and Safety Monitoring Board, or DSMB, after the DSMB's completion of a single, pre-planned interim analysis of unblinded efficacy and safety data sets from the VALOR trial, we implemented a one-time, 225 patient sample size increase to the VALOR trial, bringing target enrollment to approximately 675 patients. This pre-specified sample size increase is designed to maintain adequate statistical power over a broader range of survival outcomes. We anticipate reaching full enrollment of the VALOR trial in 2013, and unblinding in the first half of 2014, after reaching 562 events in the trial and locking the final database.

We are also preparing the final clinical study reports and manuscripts for two completed clinical trials of vosaroxin: (a) the Phase 2 portion of a Phase 1b/2 trial of vosaroxin in combination with cytarabine for the treatment of patients with relapsed or refractory AML, and (b) a Phase 2 trial in previously untreated patients age 60 years or older with AML, or REVEAL-1, which explored three dosing schedules of vosaroxin.

[Table of Contents](#)

In March 2012, patient dosing commenced in the LI-1 Trial, a Phase 2/3 randomized, controlled, multi-center trial evaluating novel treatment regimens against low-dose cytarabine, or LoDAC, in patients older than 60 years with AML or high-risk myelodysplastic syndrome, or MDS. In this trial sponsored by Cardiff University and conducted by the NCRI Haematological Oncology Study Group, several treatments, including two regimens containing vosaroxin, are being evaluated for the primary endpoints of overall survival, complete remission rate and duration of response. Treatment arms meeting efficacy criteria as determined by the Data Monitoring and Ethics Committee at the first interim analysis will be expanded initially from 50 to 100 patients per arm. A second interim analysis will then take place, and for treatments showing promising survival trends, an additional 100 patients per arm will be enrolled, and the trial for these treatment arms will transition into a Phase 3 design with the primary endpoint of overall survival for the aggregate of 200 patients enrolled in each treatment arm versus 200 in the LoDAC control arm.

In June 2012, we received an event-based payment of \$1.5 million from Biogen Idec for the advancement of pre-clinical work under the Restated Biogen Idec Agreement.

We own worldwide development and commercialization rights to vosaroxin. In April 2012, the European Commission granted orphan drug designation to vosaroxin for the treatment of AML, which may provide for 10 years of marketing exclusivity in all member countries of the European Union following product approval for this indication in Europe. In 2009, vosaroxin received orphan drug designation for the treatment of AML from the U.S. Food and Drug Administration, or FDA. In February 2011, the FDA granted fast track designation to vosaroxin for the potential treatment of relapsed or refractory AML in combination with cytarabine. During 2012, we were granted, or notified of allowance of, a number of key patents for vosaroxin, as follows:

- In February 2012, the USPTO granted us Patent No. 8,124,773 covering certain vosaroxin hydrate forms, which will expire in 2028. Corresponding applications are pending in other major markets, including Europe, Japan, Australia and Canada.
- In March 2012, the USPTO granted us Patent No. 8,138,202 covering certain compositions related to vosaroxin, which will expire in 2030. Corresponding patent applications are pending internationally.

Recent Financial History

Royalty Agreement

On March 29, 2012, we entered into the Royalty Agreement with RPI, an entity related to Royalty Pharma. On September 18, 2012, as a result of the recommendation by the DSMB to increase the sample size for the VALOR trial, RPI made a \$25.0 million cash payment to us in exchange for a 6.75% royalty on any future net sales of vosaroxin. In conjunction with the Royalty Agreement, we issued two five-year warrants to RPI, each to purchase 1,000,000 shares of our common stock, at exercise prices of \$3.48 and \$4.64 per share, respectively.

Loan Agreement

On October 18, 2011, we entered into the Loan Agreement with the Lenders, and received the first tranche of \$10.0 million from the Lenders. On September 19, 2012, following the recommendation by the DSMB to increase the sample size for the VALOR trial, we drew the second tranche of \$15.0 million from the Lenders. In connection with this drawdown, we issued warrants to purchase an aggregate of 194,915 shares of our common stock to the Lenders at an exercise price of \$3.85 per share. Payments under both tranches were interest-only until February 1, 2013, with the following 32 equal monthly payments of principal and interest being paid monthly in arrears through the scheduled maturity date of October 1, 2015.

Equity Financing

In April 2010 and August 2011, we entered into two controlled equity offering sales agreements with Cantor Fitzgerald & Co., or Cantor, pursuant to each of which we could issue and sell shares of our common stock having an aggregate offering price of up to \$20.0 million under each agreement from time to time through Cantor acting as agent and/or principal, or the 2010 Cantor Facility and the 2011 Cantor Facility, respectively, and collectively the Cantor Facilities. We agreed to pay Cantor a commission of 3.0% of the gross proceeds from sales under each facility.

During 2012, we sold an aggregate of 3,713,813 shares of common stock under the Cantor Facilities at an average price of approximately \$4.88 per share for gross proceeds of \$18.1 million and net proceeds of \$17.6 million, after deducting Cantor's commission. As of December 31, 2012, the 2010 Cantor Facility had been fully utilized and \$3.9 million of common stock remained available to be sold under the 2011 Cantor Facility.

During 2012, an aggregate of 561,166 shares of common stock were issued following the exercise of warrants issued in connection with the underwritten offering completed in October 2010, or the 2010 Offering, for cash at \$2.52 per share, resulting in proceeds to us of \$1.4 million.

Capital Requirements

We have incurred significant losses in each year since our inception. As of December 31, 2012, we had cash, cash equivalents and marketable securities of \$71.2 million and an accumulated deficit of \$445.1 million. We expect to continue to incur significant losses for the foreseeable future as we continue the development process and seek regulatory approvals for vosaroxin.

We believe that we currently have the resources to fund our operations through 2014. We will need to raise substantial additional capital to complete the development and potential commercialization of vosaroxin, and expect to finance our future cash needs primarily through equity issuances, debt arrangements, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights to vosaroxin, or a combination of the above. However, we do not know whether additional funding will be available on acceptable terms, or at all. If we are unable to raise required funding on acceptable terms or at all, we will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to vosaroxin, outlicense intellectual property rights to vosaroxin, sell unsecured assets, or a combination of the above, or be forced to delay or reduce the scope of our vosaroxin development program, potentially including the VALOR trial, and/or limit or cease our operations.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires our management to make estimates, assumptions and judgments that affect the amounts reported in our financial statements and accompanying notes, including reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates, assumptions and judgments on an ongoing basis. We base our estimates on historical experience and on various other assumptions we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from these estimates under different assumptions or conditions.

[Table of Contents](#)

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included elsewhere in this report. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our consolidated financial statements.

Accounting for Equity Financing

In October 2010, we completed the 2010 Offering, in which we sold our common stock and warrants to purchase our common stock for aggregate gross proceeds of \$15.5 million. Due to the potential for the warrants to be settled in cash upon the occurrence of certain transactions specified in the warrant agreements, the warrants are being accounted for as a derivative liability as opposed to permanent equity. Outstanding warrants under this arrangement are revalued to their fair value at each period end, with the change in fair value recorded to other income (expense) in the statements of operations and comprehensive income (loss). The Black-Scholes model was selected as the most appropriate method to estimate both the initial and subsequent fair values of the warrants. The determination of initial and subsequent fair values is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. Changes in these input variables have, and will continue to, affect the income or expense recorded each period for the revaluation of outstanding warrants. As a result, fluctuations in our stock price or other input variables may significantly affect our financial results.

Accounting for Royalty Agreement

In March 2012, we entered into the Royalty Agreement with RPI, and in September 2012, as a result of the recommendation by the DSMB to increase the sample size for the VALOR trial, RPI made a \$25.0 million cash payment to us in exchange for a 6.75% royalty on any future net sales of vosaroxin. In conjunction with the Royalty Agreement, we issued two five-year warrants to RPI, each to purchase 1,000,000 shares of our common stock.

The payment of \$25.0 million by RPI is non-refundable, and no revenue participation right payments will be made unless vosaroxin successfully completes the VALOR trial and is subsequently commercialized. Accordingly, the payment, less a portion representing the fair value of the warrants of \$3.1 million, is being accounted for as consideration for our commitment to use commercially reasonable efforts to complete the VALOR trial and commercialize vosaroxin. The net amount of \$21.9 million has therefore been classified as deferred revenue and is being amortized to revenue over the related estimated performance period, and the fair value of the warrants has been recorded to additional paid-in capital. The Black-Scholes model was selected as the most appropriate method to estimate the fair value of the warrants. The Black-Scholes model requires several subjective inputs such as expected term and share price volatility, which require significant analysis and judgment to develop.

Revenue Recognition

Revenue arrangements with multiple deliverables are accounted for in accordance with Financial Accounting Standards Board Accounting Standards Codification Subtopic 605-25, *Multiple-Element Arrangements*, or ASC 605-25. Under ASC 605-25, revenue arrangements with multiple deliverables are divided into separate units of accounting based on whether certain criteria are met, including whether the delivered item has stand-alone value to the customer. Consideration is allocated among the separate units of accounting based on their respective fair value, and the applicable revenue recognition is applied to each of the separate units.

Non-refundable fees where we have no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where continuing performance obligations exist, non-refundable fees are deferred and recognized ratably over the projected performance period.

[Table of Contents](#)

Milestone payments from license or collaboration agreements which are substantive and at risk at the time the agreement is executed are recognized upon completion of the applicable milestone event. Royalty revenues, if any, will be recognized based on reported product sales by third-party licensees. Research funding from any future agreement will be recognized as the related research services are performed.

Clinical Trial Accounting

We record accruals for estimated clinical trial costs, which include payments for work performed by contract research organizations, or CROs, and participating clinical trial sites. These costs are generally a significant component of research and development expense. Costs incurred for setting up clinical trial sites for participation in trials are generally non-refundable, and are expensed as incurred, with any refundable advances related to enrollment of the first patient recorded as prepayments and assessed for recoverability on a quarterly basis. Costs related to patient enrollment are accrued as patients progress through the clinical trial, including amortization of any first-patient prepayments. This amortization generally matches when the related services are rendered, however, these cost estimates may or may not match the actual costs incurred by the CROs or clinical trial sites, and if we have incomplete or inaccurate information, our clinical trial accruals may not be accurate. The difference between accrued expenses based on our estimates and actual expenses have not been significant to date.

Overview of Revenues

We have not generated, and do not expect to generate in the near future, any revenue from sales of commercial products.

We cannot predict whether we will receive any additional pre-commercialization event-based or royalty payments from these agreements in the foreseeable future, or at all.

Overview of Operating Expenses

Research and development expense. Most of our operating expenses to date have been for research and development activities, and include costs incurred:

- in the preparation and execution of clinical trials, including those for vosaroxin;
- in the discovery and development of novel small molecule therapeutics;
- in the development of novel fragment-based drug discovery methods;
- in the development and use of in-house research, preclinical study and development capabilities;
- in connection with in-licensing activities; and
- in the conduct of activities related to strategic collaborations.

We are currently focused solely on the development of vosaroxin for the treatment of AML. Based on results of translational research, our own and investigator-sponsored trials, regulatory and competitive concerns and our overall financial resources, we anticipate that we will make determinations as to which indications to pursue and patient populations to treat in the future, and how much funding to direct to each indication, which will affect our research and development expense.

We do not anticipate incurring any significant additional research expenses related to the discovery of additional product candidates, the development or application of fragment-based drug discovery methods, the development of in-house research capabilities, or on the clinical development of product candidates other than

[Table of Contents](#)

vosaroxin. In addition, we are no longer conducting any research activities in connection with collaboration agreements. However, we have incurred and expect to continue to incur increased levels of research and development expenses to conduct further clinical and related development of vosaroxin.

If we engage a development or commercialization partner for our vosaroxin program, or if, in the future, we acquire additional product candidates, our research and development expenses could be significantly affected. We cannot predict whether future licensing or collaborative arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Under an amended and restated agreement with Biogen Idec executed in March 2011 to provide for the discovery, development and commercialization of small molecule inhibitors of a unique preclinical kinase inhibitor program involved in immunology, or the Restated Biogen Idec Agreement, and a license agreement entered into with Millennium Pharmaceuticals, Inc. in March 2011 pursuant to which we granted Millennium exclusive licenses for the development of our oral, selective pan-Raf kinase inhibitor and one additional undisclosed kinase inhibitor program in oncology, or the Millennium Agreement, we have the right to participate in co-development and co-promotion activities for the related product candidates. If we were to exercise our option on one or more product candidates, our research and development expense would increase significantly.

As of December 31, 2012, we had incurred \$129.7 million of expenses in the development of vosaroxin since it was licensed from Dainippon Sumitomo Pharma Co., Ltd., or Dainippon, in October 2003. We expect to continue to incur significant expenses related to the development of vosaroxin in 2013 and future years. Due to the above uncertainties and other risks inherent in the development process, we are unable to estimate the costs we will incur in the vosaroxin development program in the future.

General and administrative expense. General and administrative expense consists primarily of personnel costs for the related employees, including non-cash stock-based compensation; professional service costs, including fees paid to outside legal advisors, marketing consultants and our independent registered public accounting firm; facilities expenses; and other administrative costs.

Results of Operations

Years Ended December 31, 2012 and 2011

Revenue. Total revenue was \$3.8 million in 2012 as compared to \$5.0 million in 2011. Revenue in 2012 was comprised of \$1.5 million received from Biogen Idec in June 2012 for the advancement of pre-clinical work under the Restated Biogen Idec Agreement and \$2.3 million of deferred revenue recognized in 2012 related to the Royalty Agreement with RPI. Revenue in 2011 was comprised of an upfront payment of \$4.0 million that we received from Millennium in relation to the termination and transition agreement that we entered into with Biogen Idec and Millennium in March 2011, and \$1.0 million that we received as a result of the repayment by SARcode of three promissory notes that had been issued to us upon entering into a license agreement with them in March 2006. We expect our revenue to be higher in 2013 as compared to 2012, due to continued recognition of deferred revenue related to the Royalty Agreement with RPI.

Research and Development Expense. Research and development expense was \$29.2 million in 2012 as compared to \$22.6 million in 2011, substantially all relating to the vosaroxin development program in each year. The increase of \$6.6 million in 2012 was primarily due to increases of \$3.5 million in clinical trial expenses, \$2.5 million in outside services and consulting costs, and \$0.7 million in personnel costs.

General and administrative expense. General and administrative expense was \$9.2 million in 2012 as compared to \$8.3 million in 2011. The increase of \$0.9 million in 2012 was primarily due to higher non-cash stock-based compensation expense and other personnel-related costs.

[Table of Contents](#)

Interest expense. Interest expense was \$1.9 million in 2012 as compared to \$0.3 million in 2011. The increase in 2012 was due to the timing of the first and second tranche draw-downs from the Lenders under the Loan Agreement.

Other income (expense), net. Net other expense was \$7.5 million in 2012 as compared to net other income of \$6.0 million in 2011. The amounts for each period were primarily comprised of non-cash charges or credits for the revaluation of warrants issued in the 2010 Offering.

Years Ended December 31, 2011 and 2010

Revenue. Total revenue was \$5.0 million in 2011 as compared to \$33,000 in 2010. As noted above, revenue in 2011 was comprised of an upfront payment of \$4.0 million from Millennium and \$1.0 million received from SARcode.

Research and development expense. Research and development expense was \$22.6 million in 2011 as compared to \$14.4 million in 2010, substantially all relating to the vosaroxin development program in each year. The increase of \$8.2 million in 2011 was primarily due to increases of \$7.0 million in clinical trial expenses as a result of the ramp-up of the VALOR trial and \$1.6 million for drug manufacturing activities, partially offset by a reduction in milestone payments of \$0.5 million.

General and administrative expense. General and administrative expense was \$8.3 million in 2011 as compared to \$7.0 million in 2010. The increase of \$1.3 million in 2011 was primarily due to increases of \$0.6 million in personnel costs and \$0.5 million in professional service costs.

Interest expense. Interest expense was \$0.3 million in 2011 as compared to nil in 2010. The expense in 2011 was due to the first tranche draw-down from the Lenders under the Loan Agreement.

Other income (expense), net. Net other income was \$6.0 million in 2011 as compared to net other expense of \$3.2 million in 2010. Net other income in 2011 was primarily comprised of net non-cash credits of \$5.9 million for the revaluation of warrants issued in the 2010 Offering. Net other expense in 2010 was primarily due to a non-cash charge of \$3.7 million for the revaluation of warrants issued in the 2010 Offering, partially offset by the receipt of a tax credit of \$0.2 million.

Income Taxes

Deferred tax assets or liabilities may arise from differences between the tax basis of assets or liabilities and their basis for financial reporting. Deferred tax assets or liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Our policy is to recognize interest charges and penalties as other expense.

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision for income taxes for any of the periods presented. As of December 31, 2012, we had net operating loss carry-forwards for federal and state income tax purposes of \$292.3 million and \$190.3 million, respectively. We also had federal and state research and development tax credit carry-forwards of \$6.5 million and \$6.0 million, respectively. If not utilized, the federal net operating loss and tax credit carry-forwards will expire at various dates beginning in 2018 and the state net operating loss will begin to expire in 2013. The state research and development tax credit carry-forwards do not expire. Utilization of these net operating loss and tax credits carry-forwards may be subject to a substantial annual limitation due to ownership change rules under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations are applicable if an "ownership change," as defined in the Code, is deemed to have occurred or occurs in the future. The annual limitation may result in the expiration of net operating loss and credit carry-forwards before they can be utilized.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through the issuance of common and preferred stock, debt financings, and the receipt of funds from our collaboration partners, the sale of revenue participation rights, and research grants.

Our cash, cash equivalents and marketable securities totaled \$71.2 million as of December 31, 2012, as compared to \$44.1 million as of December 31, 2011. The increase of \$27.1 million was primarily due to the receipt of \$25.0 million from RPI; the draw-down of the second tranche loan of \$15.0 million from the Lenders; net proceeds from sales of our common stock under the Cantor Facilities of \$17.6 million; and proceeds from the exercise of warrants, stock options and stock purchase rights of \$1.9 million, partially offset by other net operating cash outflows.

On September 18, 2012, pursuant to the Royalty Agreement we entered into with RPI, and as a result of the recommendation by the DSMB to increase the sample size for the VALOR trial, RPI made a \$25.0 million cash payment to us in exchange for a 6.75% royalty on any future net sales of vosaroxin.

On September 19, 2012, we drew down the \$15.0 million second tranche from the Lenders under the Loan Agreement. We previously drew down the \$10.0 million first tranche upon execution of the Loan Agreement in October 2011. Payments under both tranches were interest-only until February 1, 2013, with the following 32 equal monthly payments of principal and interest being paid monthly in arrears through the scheduled maturity date of October 1, 2015. A final payment equal to 3.75% of the aggregate amount drawn will be due on October 1, 2015, or earlier under certain conditions.

During 2012, we sold an aggregate of 3,713,813 shares of common stock under the Cantor Facilities at an average price of approximately \$4.88 per share for gross proceeds of \$18.1 million and net proceeds of \$17.6 million, after deducting Cantor's commission. As of December 31, 2012, the 2010 Cantor Facility was fully utilized and \$3.9 million of common stock remained available to be sold under the 2011 Cantor Facility, subject to certain conditions as specified in the agreement.

Cash Flows

Net cash used in operating activities was \$10.6 million in 2012 as compared to \$22.8 million in 2011 and \$19.4 million in 2010. Net cash used in 2012 resulted primarily from the net loss of \$44.0 million, partially offset by net adjustments for non-cash items of \$10.6 million (including net charges of \$7.5 million for the revaluation of warrants issued in the 2010 Offering and \$2.7 million of stock-based compensation), and changes in operating assets and liabilities of \$22.7 million (including a net increase in deferred revenue of \$19.6 million related to the receipt of the \$25.0 million payment from RPI, and an increase of \$3.1 million in accrued clinical expenses related to the VALOR trial). Net cash used in 2011 resulted primarily from the net loss of \$20.1 million and net adjustments for non-cash items of \$4.2 million (including a net credit of \$5.9 million for the revaluation of warrants issued in the 2010 Offering, partially offset by \$1.4 million of stock-based compensation), partially offset by changes in operating assets and liabilities of \$1.5 million, primarily as a result of an increase in accrued clinical expenses related to the VALOR trial. Net cash used in 2010 resulted primarily from the net loss of \$24.6 million, partially offset by net adjustments for non-cash items of \$4.5 million (including \$3.7 million of charges for the revaluation of warrants issued in the 2010 Offering).

Net cash used in investing activities was \$21.4 million in 2012 as compared to \$4.2 million provided by investing activities in 2011 and \$39.1 million used in investing activities in 2010. Net cash used in 2012 and

[Table of Contents](#)

2010 consisted primarily of purchases of marketable securities, partially offset by proceeds from maturities of marketable securities. Net cash provided in 2011 consisted primarily of proceeds from maturities of marketable securities, partially offset by purchases of marketable securities.

Net cash provided by financing activities was \$37.6 million in 2012 as compared to \$13.7 million in 2011, and \$68.4 million in 2010. Net cash provided in 2012 included net proceeds from the draw-down of the second tranche loan of \$15.0 million from the Lenders; \$17.6 million from sales of our common stock through the Cantor Facilities; \$3.1 million of the \$25.0 million payment allocated to the fair value of warrants issued to RPI, and \$1.9 million from the exercise of warrants, stock options and stock purchase rights. Net cash provided in 2011 consisted primarily of net proceeds of \$9.6 million from the Loan Agreement and \$4.1 million from sales of our common stock through Cantor. Net cash provided in 2010 consisted primarily of net proceeds of \$27.5 million from sales of our common stock through Cantor, \$26.7 million from sales of our common stock in the third and final closing of the Private Placement, and \$14.2 million from the 2010 Offering.

Operating Cash Requirements

We expect to continue to incur substantial operating losses in the future. We will not receive any product revenue until a product candidate has been approved by the FDA or similar regulatory agencies in other countries, and has been successfully commercialized, if at all. We will need to raise substantial additional funding to complete the development and potential commercialization of vosaroxin. Additionally, we may evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

Our future funding requirements will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, including the VALOR trial in particular;
- the need for additional or expanded clinical trials;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs associated with building or accessing commercialization and additional manufacturing capabilities and supplies;
- the costs of acquiring or investing in businesses, product candidates and technologies, if any;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments; and
- the costs, if any, of supporting our arrangements with Biogen Idec and Millennium.

We believe that we currently have the resources to fund our operations through 2014. We will need to raise substantial additional capital to complete the development and potential commercialization of vosaroxin. Until we can generate a sufficient amount of licensing or collaboration or product revenue to finance our cash

[Table of Contents](#)

requirements, which we may never do, we expect to finance our future cash needs primarily through equity issuances, debt arrangements, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights to vosaroxin, or a combination of the above.

Our failure to raise significant additional capital in the future would force us to delay or reduce the scope of our vosaroxin development program, potentially including the VALOR trial, and/or limit or cease our operations. Any one of the foregoing would have a material adverse effect on our business, financial condition and results of operations.

Contractual Obligations

The following table summarizes our long-term contractual obligations as of December 31, 2012 (in thousands):

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3- 5 Years	After 5 Years
Long-term debt obligations, including interest(1)	\$28,579	\$9,188	\$19,391	\$ —	\$ —
Operating lease obligations(2)	\$ 135	\$ 135	\$ —	\$ —	\$ —

- (1) Upon the occurrence of an event of default, as defined in the Loan Agreement, and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.
- (2) Operating lease obligations relate solely to the lease of approximately 15,000 square feet of office space in a building at 395 Oyster Point Boulevard in South San Francisco, California, which is currently our corporate headquarters. The lease was entered into in December 2006, and was due to expire on April 30, 2013. In January 2013, we extended the lease to January 31, 2014.

The above amounts exclude potential payments under our 2003 license agreement with Dainippon, pursuant to which we are required to make certain milestone payments in the event we file new drug applications in the United States, Europe or Japan, and if we receive regulatory approvals in any of these regions, for cancer-related indications. If vosaroxin is approved for a non-cancer indication, an additional milestone payment becomes payable to Dainippon.

We also have agreements with CROs, clinical sites and other third party contractors for the conduct of our clinical trials. We generally make payments to these entities based upon the activities they perform related to the particular clinical trial. There are generally no penalty clauses for cancellation of these agreements if notice is duly given and payment is made for work performed by the third party under the related agreement.

Off-Balance Sheet Arrangements

Since our inception, we have not had any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or variable interest entities, which are typically established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

ITEM 7A: QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK**Interest Rate and Market Risk**

As of December 31, 2012 and 2011, we had \$71.2 million and \$44.1 million, respectively, in cash, cash equivalents and marketable securities. The securities in our investment portfolio are not leveraged and are classified as available-for-sale, which, due to their short-term nature, are subject to minimal interest rate risk. We currently do not hedge our interest rate risk exposure. Because of the short-term maturities of our investments, we do not believe that a change in market rates would have a significant impact on the value of our investment portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short-term and long-term investments in a variety of securities, including money market funds and U.S. and European government obligations and corporate debt securities. These securities are classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). Substantially all investments mature within approximately one year from the date of purchase. Our holdings of the securities of any one issuer, except obligations of the U.S. Treasury or U.S. Treasury guaranteed securities, do not exceed 10% of the portfolio. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We do not utilize derivative financial instruments to manage our interest rate risks.

The tables below present the original principal amounts and weighted-average interest rates by year of maturity for our investment portfolio as of December 31 of each year, by effective maturity (in thousands, except percentages):

	Expected Maturity			Fair Value as of December 31, 2012
	0-3 months	Over 3 months	Total	
Available-for-sale securities	\$30,849	\$39,835	\$70,684	\$ 70,684
Average interest rate	0.2%	0.3%		

	Expected Maturity			Fair Value as of December 31, 2011
	0-3 months	Over 3 months	Total	
Available-for-sale securities	\$22,716	\$20,718	\$43,434	\$ 43,434
Average interest rate	0.4%	0.5%		

Foreign Currency Exchange Rate Risk

We consider our direct exposure to foreign exchange rate fluctuations to be minimal. Invoices for certain services provided to us are denominated in foreign currencies, including the euro and British pound, among others. Therefore, we are exposed to adverse movements in the related foreign currency exchange rates. To manage this risk, we may purchase certain European currencies or highly-rated investments denominated in those currencies, subject to similar criteria as for other investments allowed by our investment policy. We do not make these purchases for trading or speculative purposes, and there is no guarantee that the related gains and losses will substantially offset each other. As of December 31, 2012 and 2011, we held investments denominated in Euros with an aggregate fair value of \$4.5 million and \$5.1 million, respectively. The balances are recorded at their fair value based on the current exchange rate as of each balance sheet date. The resulting exchange gains or losses and those from amounts payable for services originally denominated in foreign currencies are recorded in other income (expense) in the statements of operations and comprehensive income (loss).

[Table of Contents](#)

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	52
Consolidated Balance Sheets	53
Consolidated Statements of Operations and Comprehensive Income (Loss)	54
Consolidated Statements of Stockholders' Equity	55
Consolidated Statements of Cash Flows	56
Notes to Consolidated Financial Statements	57

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Sunesis Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Sunesis Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Sunesis Pharmaceuticals, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and comprehensive income (loss) and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Sunesis Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG, LLP

Redwood City, California
March 13, 2013

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,940	\$ 9,311
Marketable securities	56,287	34,804
Prepays and other current assets	1,705	1,550
Total current assets	<u>72,932</u>	<u>45,665</u>
Property and equipment, net	43	74
Deposits and other assets	42	130
Total assets	<u>\$ 73,017</u>	<u>\$ 45,869</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 78	\$ 658
Accrued clinical expense	5,449	2,370
Accrued compensation	1,465	1,274
Other accrued liabilities	2,113	1,805
Current portion of deferred revenue	7,956	—
Current portion of notes payable	6,610	—
Warrant liability	8,070	2,276
Total current liabilities	<u>31,741</u>	<u>8,383</u>
Non-current portion of deferred revenue	11,668	—
Non-current portion of notes payable	17,651	9,453
Non-current portion of deferred rent	—	13
Commitments		
Stockholders' equity:		
Common stock, \$0.0001 par value; 400,000 shares authorized as of December 31, 2012 and 2011; 51,565 and 46,774 shares issued and outstanding as of December 31, 2012 and 2011, respectively	5	5
Additional paid-in capital	457,011	429,142
Accumulated other comprehensive income	38	19
Accumulated deficit	<u>(445,097)</u>	<u>(401,146)</u>
Total stockholders' equity	<u>11,957</u>	<u>28,020</u>
Total liabilities and stockholders' equity	<u>\$ 73,017</u>	<u>\$ 45,869</u>

See accompanying notes to consolidated financial statements.

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

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Revenue:			
Collaboration revenue	\$ —	\$ —	\$ 27
License and other revenue	3,754	5,000	6
Total revenues	3,754	5,000	33
Operating expenses:			
Research and development	29,185	22,563	14,433
General and administrative	9,175	8,303	7,005
Total operating expenses	38,360	30,866	21,438
Loss from operations	(34,606)	(25,866)	(21,405)
Interest expense	(1,855)	(259)	—
Other income (expense), net	(7,490)	5,984	(3,182)
Net loss	(43,951)	(20,141)	(24,587)
Unrealized gain (loss) on available-for-sale securities	19	34	(15)
Comprehensive loss	\$ (43,932)	\$ (20,107)	\$ (24,602)
Basic and diluted loss per common share:			
Net loss	\$(43,951)	\$ (20,141)	\$(24,587)
Shares used in computing basic and diluted loss per common share	48,146	46,412	24,860
Basic and diluted loss per common share	\$ (0.91)	\$ (0.43)	\$ (0.99)

See accompanying notes to consolidated financial statements.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Convertible				Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2009	725	60,005	5,984	3	298,470	—	(356,418)	2,060
Issuance of \$28,500 of common stock in third closing of Private Placement, net of issuance costs of \$1,787	—	—	17,273	10	26,703	—	—	26,713
Issuance of common stock upon conversion of preferred stock	(725)	(60,005)	7,246	4	60,001	—	—	—
Issuance of \$28,820 of common stock through controlled equity offering facilities, net of issuance costs of \$1,332	—	—	5,726	3	27,485	—	—	27,488
Issuance of \$10,961 of common stock in 2010 Offering, net of issuance costs of \$1,233	—	—	7,358	5	9,723	—	—	9,728
Issuance of common stock pursuant to warrant exercises	—	—	1,764	1	(1)	—	—	—
Issuance of common stock pursuant to stock option exercises	—	—	1	—	4	—	—	4
Issuance of common stock under employee stock purchase plan	—	—	4	—	6	—	—	6
Issuance of common stock to employees	—	—	16	—	(27)	—	—	(27)
Stock-based compensation expenses—employees	—	—	—	—	870	—	—	870
Stock-based compensation expenses—non-employees	—	—	—	—	7	—	—	7
Adjustment of common stock to par value as a result of Reverse Split	—	—	—	(23)	23	—	—	—
Net loss	—	—	—	—	—	—	(24,587)	(24,587)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(15)	—	(15)
Balance as of December 31, 2010	—	—	45,372	5	423,262	(15)	(381,005)	42,247
Issuance of \$4,178 of common stock through controlled equity offering facilities, net of issuance costs of \$125	—	—	1,302	—	4,053	—	—	4,053
Issuance of common stock under employee stock purchase plans	—	—	62	—	68	—	—	68
Issuance of common stock to employees	—	—	38	—	—	—	—	—
Issuance of warrants to purchase common stock	—	—	—	—	371	—	—	371
Stock-based compensation expenses—employees	—	—	—	—	1,369	—	—	1,369
Stock-based compensation expenses—non-employees	—	—	—	—	19	—	—	19
Net loss	—	—	—	—	—	—	(20,141)	(20,141)
Unrealized gain on available-for-sale securities	—	—	—	—	—	34	—	34
Balance as of December 31, 2011	—	—	46,774	5	429,142	19	(401,146)	28,020
Issuance of \$18,124 of common stock through controlled equity offering facilities, net of issuance costs of \$504	—	—	3,714	—	17,620	—	—	17,620
Issuance of common stock pursuant to warrant exercises	—	—	801	—	3,130	—	—	3,130
Issuance of common stock pursuant to stock option exercises	—	—	146	—	330	—	—	330
Issuance of common stock under employee stock purchase plans	—	—	84	—	172	—	—	172
Issuance of common stock to employees	—	—	46	—	—	—	—	—
Issuance of warrants to purchase common stock	—	—	—	—	3,893	—	—	3,893
Stock-based compensation expenses—employees	—	—	—	—	2,402	—	—	2,402
Stock-based compensation expenses—non-employees	—	—	—	—	322	—	—	322
Net loss	—	—	—	—	—	—	(43,951)	(43,951)
Unrealized gain on available-for-sale securities	—	—	—	—	—	19	—	19
Balance as of December 31, 2012	—	\$ —	\$ 51,565	\$ 5	\$ 457,011	\$ 38	\$ (445,097)	\$ 11,957

See accompanying notes to consolidated financial statements.

SUNESIS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2012	2011	2010
Cash flows from operating activities			
Net loss	\$ (43,951)	\$ (20,141)	\$ (24,587)
Adjustments to reconcile loss to net cash used in operating activities:			
Stock-based compensation expense	2,724	1,388	877
Depreciation and amortization	31	56	150
Amortization of debt discount and debt issuance costs	400	56	—
Increase (decrease) in fair value of warrant liability	7,509	(5,878)	3,664
Foreign exchange (gain) loss on marketable securities	(82)	244	(63)
Gain on sale of property and equipment	(11)	(33)	(82)
Other non-cash items	—	—	(27)
Changes in operating assets and liabilities:			
Prepays and other assets	(98)	(343)	(659)
Accounts payable	(580)	242	55
Accrued clinical expense	3,079	796	444
Accrued compensation	191	261	284
Other accrued liabilities	522	516	564
Deferred revenue	19,624	—	—
Net cash used in operating activities	<u>(10,642)</u>	<u>(22,836)</u>	<u>(19,380)</u>
Cash flows from investing activities			
Purchases of property and equipment	—	(15)	(64)
Proceeds from sale of property and equipment	11	34	104
Purchases of marketable securities	(67,608)	(52,082)	(46,637)
Proceeds from maturities of marketable securities	46,226	56,241	7,513
Net cash (used in) provided by investing activities	<u>(21,371)</u>	<u>4,178</u>	<u>(39,084)</u>
Cash flows from financing activities			
Proceeds from notes payable, net	14,982	9,625	—
Proceeds from issuance of common stock through controlled equity offering facilities, net	17,620	4,053	27,488
Fair value of warrants issued in connection with royalty agreement	3,122	—	—
Proceeds from issuance of common stock in third closing of Private Placement, net	—	—	26,713
Proceeds from issuance of common stock and warrants in 2010 Offering, net	—	—	14,218
Proceeds from exercise of warrants, stock options and stock purchase rights	1,918	68	9
Net cash provided by financing activities	<u>37,642</u>	<u>13,746</u>	<u>68,428</u>
Net increase (decrease) in cash and cash equivalents	5,629	(4,912)	9,964
Cash and cash equivalents at beginning of period	9,311	14,223	4,259
Cash and cash equivalents at end of period	<u>\$ 14,940</u>	<u>\$ 9,311</u>	<u>\$ 14,223</u>
Supplemental disclosure of cash flow information			
Interest paid	<u>\$ 1,165</u>	<u>\$ 109</u>	<u>\$ —</u>
Supplemental disclosure of non-cash activities			
Fair value of warrants issued in connection with notes payable	<u>\$ 770</u>	<u>\$ 371</u>	<u>\$ —</u>
Transfer of intrinsic value of exercised warrants to additional paid-in capital	<u>\$ 1,715</u>	<u>\$ —</u>	<u>\$ —</u>
Cashless exercise of warrants	<u>\$ 402</u>	<u>\$ —</u>	<u>\$ 3,064</u>
Conversion of preferred stock to common stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 60,005</u>

See accompanying notes to consolidated financial statements.

SUNESIS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Company Overview

Description of Business

Sunesis Pharmaceuticals, Inc. (the “Company” or “Sunesis”) was incorporated in the state of Delaware on February 10, 1998, and its facilities are located in South San Francisco, California. Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. The Company’s primary activities since incorporation have been conducting research and development internally and through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, conducting clinical trials and raising capital.

In December 2010, the Company commenced enrollment of a Phase 3, multi-national, randomized, double-blind, placebo-controlled, pivotal clinical trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory acute myeloid leukemia (the “VALOR trial”).

Significant Risks and Uncertainties

The Company has incurred significant losses and negative cash flows from operations since its inception, and as of December 31, 2012, had cash, cash equivalents and marketable securities totaling \$71.2 million and an accumulated deficit of \$445.1 million.

The Company will need to raise substantial additional capital to complete the development and potential commercialization of vosaroxin, and expects to finance its future cash needs primarily through equity issuances, debt arrangements, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights to vosaroxin, or a combination of the above.

Concentrations of Credit Risk

In accordance with its investment policy, the Company invests cash that is not currently being used for operational purposes. The policy allows for the purchase of low risk debt securities issued by: (a) the United States and certain European governments and government agencies, and (b) highly rated banks and corporations, denominated in U.S. dollars, Euros or British pounds, subject to certain concentration limits. The policy limits maturities of securities purchased to no longer than 18 months and the weighted average maturity of the portfolio to nine months. Management believes these guidelines ensure both the safety and liquidity of any investment portfolio the Company may hold.

Financial instruments that potentially subject the Company to concentrations of credit risk generally consist of cash, cash equivalents and marketable securities. The Company is exposed to credit risk in the event of default by the institutions holding its cash, cash equivalents and any marketable securities to the extent of the amounts recorded in the balance sheets.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The financial statements include a wholly owned subsidiary, Sunesis Europe Limited, a United Kingdom corporation. Management has determined that the Company operates as a single reportable segment.

Reverse Stock Split

On February 14, 2011, the Company effected a one-for-six reverse split of its capital stock (the “Reverse Split”), as previously authorized and approved at the annual meeting of stockholders on June 2, 2010. As a result of the Reverse Split, every six shares of capital stock were combined into one share of capital stock. The Reverse Split affected the shares of Company’s common stock: (a) outstanding immediately prior to the effective time of the Reverse Split, (b) available for issuance under the Company’s equity incentive plans, and (c) issuable upon the exercise of outstanding stock options and warrants. The accompanying financial statements and notes thereto give retroactive effect to the Reverse Split for all periods presented.

Significant Estimates and Judgments

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the Company’s financial statements and notes thereto. Actual results could differ materially from these estimates. Significant estimates, assumptions and judgments made by management include those related to the valuation of equity and related instruments, revenue recognition, stock-based compensation and clinical trial accrued liabilities.

Cash Equivalents and Marketable Securities

The Company considers all highly liquid securities with original maturities of three months or less from the date of purchase to be cash equivalents, which generally consist of money market funds and corporate debt securities. Marketable securities consist of securities with original maturities of greater than three months, which may include U.S. and European government obligations and corporate debt securities.

Management determines the appropriate classification of securities at the time of purchase. The Company generally classifies its entire investment portfolio as available-for-sale. The Company views its available-for-sale portfolio as available for use in current operations. Accordingly, the Company classifies all investments as short-term, even though the stated maturity may be more than one year from the current balance sheet date. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders’ equity.

The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in other income (expense) in the statements of operations and comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are also recorded to other income (expense). The cost of securities sold is based on the specific-identification method.

Invoices for certain services provided to the Company are denominated in foreign currencies. To manage the risk of future movements in foreign exchange rates that would affect such amounts, the Company may purchase certain European currencies or highly-rated investments denominated in those currencies, subject to similar criteria as for other investments allowed by the Company’s investment policy. There is no guarantee that the related gains and losses will substantially offset each other, and the Company may be subject to significant exchange gains or losses as currencies fluctuate from quarter to quarter. To date, the Company has purchased Euros and Euro-denominated obligations of foreign governments and corporate debt, and as of December 31, 2012, held investments denominated in Euros with an aggregate fair value of \$4.5 million. These cash, cash equivalent and short-term investment balances are recorded at their fair value based on the current exchange rate as of each balance sheet date. The resulting exchange gains or losses and those from amounts payable for services originally denominated in foreign currencies are recorded in other income (expense) in the statements of operations and comprehensive income (loss).

[Table of Contents](#)

Fair Value Measurements

The Company measures cash equivalents, marketable securities and warrant liabilities at fair value on a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable GAAP:

Level 1 -	quoted prices (unadjusted) in active markets for identical assets and liabilities that can be accessed at the measurement date
Level 2 -	inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly
Level 3 -	unobservable inputs

The Company's Level 2 valuations of marketable securities are generally based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity.

The fair value of the Company's liability for warrants issued in connection with the 2010 Offering (see Note 10) is determined using the Black-Scholes model, which requires inputs such as the expected term of the warrants, share price volatility, expected dividend yield and risk-free interest rate. As some of these inputs are unobservable, and require significant analysis and judgment to measure, these variables are classified as Level 3.

The Company does not measure cash, prepayments, accounts payable, accrued liabilities, deferred revenue and notes payable at fair value, as their carrying amounts approximated the fair value as of December 31, 2012 and 2011.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease.

Accounting for Notes Payable

The accounting for certain fees and expenses related to the Loan Agreement (see Note 8) is as follows. The facility fee is being accounted for as a debt discount and classified within notes payable on the Company's balance sheet. The fair value of the warrants issued in connection with the Loan Agreement have been recorded as a debt discount within notes payable and an increase to additional paid-in capital on the Company's balance sheet. The debt discount is being amortized as interest expense over the term of the loan using the effective interest method. The final payment is being accreted as interest expense over the term of the loans using the effective interest method. The legal fees are being accounted for as deferred debt issuance costs within assets on the Company's balance sheet and are being amortized as other income (expense) over the term of the loans using the effective interest method.

Accounting for Equity Financing

In October 2010, the Company completed the 2010 Offering (see Note 10), in which the Company sold its common stock and warrants to purchase its common stock for aggregate gross proceeds of \$15.5 million. Due to the potential for the warrants to be settled in cash upon the occurrence of certain transactions specified in the warrant agreements, the warrants are being accounted for as a derivative liability as opposed to permanent equity. Outstanding warrants under this arrangement are revalued to their fair value each period end, with the change in fair value recorded to other income (expense) in the statements of operations and comprehensive income (loss).

Revenue Recognition

Revenue arrangements with multiple deliverables are accounted for in accordance with the Financial Accounting Standards Board Accounting Standards Codification, Subtopic 605-25, *Multiple-Element Arrangements* (“ASC 605-25”). Under ASC 605-25, revenue arrangements with multiple deliverables are divided into separate units of accounting based on whether certain criteria are met, including whether the delivered item has stand-alone value to the customer. Consideration is allocated among the separate units of accounting based on their respective fair value, and the applicable revenue recognition is applied to each of the separate units.

Non-refundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where continuing performance obligations exist, non-refundable fees are deferred and recognized ratably over the projected performance period.

Milestone payments from license or collaboration agreements which are substantive and at risk at the time the agreement is executed are recognized upon completion of the applicable milestone event. Royalty revenues, if any, will be recognized based on reported product sales by third-party licensees. Research funding from any future agreement will be recognized as the related research services are performed.

Research and Development

Research and development expense consists primarily of: (a) clinical trial costs, which include payments for work performed by contract research organizations (“CROs”), clinical trial sites, labs and other clinical service providers, and for drug packaging, storage and distribution; (b) drug manufacturing costs, which include costs for producing drug substance and drug product, and for stability and other testing; (c) personnel costs for related permanent and temporary employees; (d) other outside services and consulting costs; and (e) payments under license agreements. All research and development costs are expensed as they are incurred.

Clinical Trial Accounting

The Company records accruals for estimated clinical trial costs, which include payments for work performed by CROs and participating clinical trial sites. These costs are generally a significant component of research and development expense. Costs incurred for setting up clinical trial sites for participation in trials are generally non-refundable, and are expensed as incurred, with any refundable advances related to enrollment of the first patient recorded as prepayments and assessed for recoverability on a quarterly basis. Costs related to patient enrollment are accrued as patients progress through the clinical trial, including amortization of any first-patient prepayments. This amortization generally matches when the related services are rendered, however, these cost estimates may or may not match the actual costs incurred by the CROs or clinical trial sites, and if the Company has incomplete or inaccurate information, the clinical trial accruals may not be accurate. The difference between accrued expenses based on the Company’s estimates and actual expenses have not been significant to date.

Stock-Based Compensation

The Company grants options to purchase common stock to its employees, directors and consultants under its stock option plans. Under the Company’s Employee Stock Purchase Plan, eligible employees can also purchase shares of common stock at 85% of the lower of the fair market value of the Company’s common stock at the beginning of a 12-month offering period or at the end of one of the two related six-month purchase periods.

The Company values these share-based awards using the Black-Scholes option valuation model (the “Black-Scholes model”). The determination of fair value of share-based payment awards on the date of grant using the Black-Scholes model is affected by the Company’s stock price as well as assumptions regarding a

[Table of Contents](#)

number of highly complex and subjective variables. These variables include, but are not limited to, the expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors and related estimated forfeitures.

Foreign Currency

Transactions that are denominated in a foreign currency are translated into U.S. dollars at the current exchange rate on the transaction date. Any foreign currency-denominated monetary assets and liabilities are subsequently remeasured at current exchange rates as of each balance sheet date, with gains or losses on foreign exchange recognized in other income (expense) in the statements of operations and comprehensive income (loss).

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the tax basis of assets and liabilities and their basis for financial reporting. Deferred tax assets or liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's policy is to recognize interest charges and penalties as other expense.

3. Loss per Common Share

Basic loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is computed by dividing (a) net loss, less any anti-dilutive amounts recorded during the period for the change in the fair value of warrant liabilities, by (b) the weighted-average number of common shares outstanding for the period plus dilutive potential common shares as determined using the treasury stock method for options and warrants to purchase common stock. The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted loss per common share because their inclusion would have had an anti-dilutive effect (in thousands):

	As of December 31,		
	2012	2011	2010
Warrants to purchase shares of common stock	10,359	9,034	8,648
Options to purchase shares of common stock	6,288	5,099	1,065
Outstanding securities not included in calculations	16,647	14,133	9,713

4. Royalty Agreement

On March 29, 2012, the Company entered into a Revenue Participation Agreement (the "Royalty Agreement"), with RPI Finance Trust ("RPI"), an entity related to Royalty Pharma. On September 18, 2012, pursuant to the provisions of the Royalty Agreement, RPI made a \$25.0 million cash payment to the Company in exchange for a revenue participation right (the "Revenue Participation Right"). The payment was triggered following the results of the interim efficacy analysis of data from the VALOR trial, where the independent Data and Safety Monitoring Board (the "DSMB") recommended that the Company undertake a one-time increase in patient sample size for the VALOR trial. The Company is obliged to use its commercially reasonable efforts to complete the VALOR trial and to commercialize vosaroxin. Such efforts are expected to take several years to complete, and the cash payment received from RPI will be used to fund these efforts. Under no circumstances is the payment refundable, even if the drug is never commercialized.

[Table of Contents](#)

Revenue Participation Right payments will be made to RPI when and if vosaroxin is commercialized, at a rate of 6.75% of net sales of vosaroxin, on a product-by-product and country-by-country basis world-wide through the later of: (a) the expiration of the last to expire of certain specifically identified patents; (b) 10 years from the date of first commercial sale of such product in such country; or (c) the expiration of all applicable periods of data, market or other regulatory exclusivity in such country with respect to such product.

In conjunction with entering into the Royalty Agreement, the Company issued two five-year warrants to RPI, each to purchase 1,000,000 shares of the Company's common stock, at exercise prices of \$3.48 and \$4.64 per share, respectively. The warrants became exercisable following the DSMB's recommendation to increase the patient sample size for the VALOR trial, and will expire on September 18, 2017. The aggregate fair value of the two warrants as of March 29, 2012 was \$3.1 million, and was estimated using the Black-Scholes valuation model with the following assumptions: (a) fair value of common stock at issuance of \$2.48; (b) risk-free interest rate of 1.15% (based upon observed risk-free interest rates at the time appropriate for the expected term of the warrants); (c) expected volatility of 87.8% (based on the average historical volatilities of a peer group of publicly-traded companies within the Company's industry); (d) expected term of 5.5 years (based on the period from the grant date to the expiration date of the warrants); and (e) a dividend yield of 0% (based on the Company's anticipation of not paying any cash dividends in the foreseeable future).

As noted above, the payment of \$25.0 million by RPI is non-refundable, and no Revenue Participation Right payments will be made unless vosaroxin successfully completes the VALOR trial and is subsequently commercialized. Accordingly, the payment received from RPI is being accounted for as a payment for the Company to use commercially reasonable efforts to complete the VALOR trial and to commercialize vosaroxin. Therefore, the amount will be initially deferred and recognized as revenue over the projected performance period under the agreement. However, the amount deferred has been reduced by a portion of the payment representing the fair value of the warrants granted under the arrangement of \$3.1 million, which has been recorded to additional paid-in capital. The remaining \$21.9 million was classified as deferred revenue and is being amortized to revenue over the related performance period.

If upon commercialization of vosaroxin, the Company fails to make Revenue Participation Right payments due to RPI in a timely manner, RPI may require the Company to repurchase the Revenue Participation Right. As collateral for these payments, the Company agreed to grant RPI a security interest in certain of the Company's assets, including the Company's intellectual property related to vosaroxin. The security interest was granted at the time of the purchase of the Revenue Participation Right, but may only be perfected following first product approval in any country or territory. The security interest will be released upon the satisfaction of certain conditions specified in the Royalty Agreement.

5. License Agreements

In August 2004, the Company entered into a collaboration agreement with Biogen Idec MA, Inc. ("Biogen Idec") to discover, develop and commercialize small molecule inhibitors of Raf kinase and up to five additional targets that play a role in oncology and immunology indications or in the regulation of the human immune system (the "Original Biogen Idec Agreement"). In connection with the Company's June 2008 restructuring, the parties agreed to terminate the research term and related funding as of June 30, 2008.

On March 31, 2011, as part of a series of agreements among the Company, Biogen Idec and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, ("Millennium"), the Company entered into: (a) an amended and restated collaboration agreement with Biogen Idec (the "Restated Biogen Idec Agreement"), which amended and restated the Original Biogen Idec Agreement, to provide for the discovery, development and commercialization of small molecule inhibitors of a unique preclinical kinase inhibitor program involved in immunology; (b) a license agreement with Millennium (the "Millennium Agreement") under which the Company granted exclusive licenses to products against two oncology targets under the Original Biogen Idec Agreement, consisting of Raf kinase and one other identified target, under

[Table of Contents](#)

substantially the same terms as under the Original Biogen Idec Agreement; and (c) a termination and transition agreement among the Company, Biogen Idec and Millennium (the "Termination and Transition Agreement"), which provided, among other matters, for a \$4.0 million, non-refundable, upfront payment from Millennium to the Company for the Millennium Agreement and termination of the Original Biogen Idec Agreement.

Under the Restated Biogen Idec Agreement, the Company no longer has research obligations, but licenses granted to Biogen Idec with respect to the research collaboration under the Original Biogen Idec Agreement (other than the licenses transferred to Millennium under the Millennium Agreement) remain in effect. In June 2012, the Company received an event-based payment of \$1.5 million from Biogen Idec for the advancement of pre-clinical work under this agreement. The Company is eligible to receive up to an additional \$58.5 million in pre-commercialization event-based payments related to the development of the first two indications for licensed products against the specified immunology target, of which \$7.7 million is related to development events and \$50.8 million is related to regulatory events. The Company is also eligible to receive royalty payments depending on product sales, which may be increased if the Company exercises its option to co-fund product candidates worldwide, but is subject to reduction if Biogen Idec is required to in-license third party intellectual property related to certain technology jointly developed under the collaboration agreement in order to commercialize a licensed product.

Under the Millennium Agreement, the Company exclusively licensed to Millennium products against the Raf kinase target and one other identified target, under substantially the same terms as under the Original Biogen Idec Agreement. The Company is eligible to receive up to \$59.3 million in pre-commercialization event-based payments related to the development of the first two indications for each of the licensed products directed against the two exclusively licensed targets. For each of the two targets, \$8.5 million of potential payments are related to development events, and \$50.8 million of potential payments are related to regulatory events. The Company is also eligible to receive royalty payments depending on product sales, which may be increased if the Company exercises its option to co-fund product candidates worldwide, but is subject to reduction if Millennium is required to in-license third party intellectual property related to certain technology jointly developed under the collaboration agreement in order to commercialize a licensed product.

The Termination and Transition Agreement provided for: (a) termination of Biogen Idec's exclusive rights under the Original Biogen Idec Agreement to all discovery programs under such agreement other than a preclinical kinase inhibitor program involved in immunology; (b) the permitted assignment to Millennium of all related Company collaboration assets and rights to Raf kinase and one additional undisclosed kinase inhibitor program in oncology; and (c) the payment of \$4.0 million upfront from Millennium to the Company. As the upfront amount is non-refundable and the Company has no continuing performance obligations under this agreement, or either of the related agreements entered into on the same date, the \$4.0 million was recorded as revenue in March 2011.

[Table of Contents](#)

6. Financial Instruments

Financial Assets

The following tables summarize the estimated fair value of the Company's financial assets measured on a recurring basis as of the dates indicated, which were comprised solely of available-for-sale marketable securities with remaining contractual maturities of one year or less (in thousands):

<u>December 31, 2012</u>	<u>Valuation Input Level</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Money market funds	Level 1	\$ 14,397	\$ —	\$ —	\$ 14,397
U.S. corporate debt obligations	Level 2	7,156	—	(2)	7,154
U.S. commercial paper	Level 2	44,592	44	—	44,636
Foreign corporate debt obligations	Level 2	4,501	—	(4)	4,497
Total available-for-sale securities		70,646	44	(6)	70,684
Less amounts classified as cash equivalents		(14,397)	—	—	(14,397)
Amounts classified as marketable securities		<u>\$ 56,249</u>	<u>\$ 44</u>	<u>\$ (6)</u>	<u>\$ 56,287</u>

<u>December 31, 2011</u>	<u>Valuation Input Level</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Money market funds	Level 1	\$ 7,156	\$ —	\$ —	\$ 7,156
U.S. corporate debt obligations	Level 2	16,619	5	(1)	16,623
U.S. commercial paper	Level 2	14,556	18	—	14,574
Foreign government obligations	Level 2	3,607	1	—	3,608
Foreign corporate debt obligations	Level 2	1,476	—	(3)	1,473
Total available-for-sale securities		43,414	24	(4)	43,434
Less amounts classified as cash equivalents		(8,632)	—	2	(8,630)
Amounts classified as marketable securities		<u>\$ 34,782</u>	<u>\$ 24</u>	<u>\$ (2)</u>	<u>\$ 34,804</u>

The following table summarizes the available-for-sale securities that were in an unrealized loss position as of December 31, 2012, each having been in such a position for less than 12 months, and none deemed to be other-than-temporarily impaired (in thousands):

<u>December 31, 2012</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
U.S. corporate debt obligations	\$ 2	\$ 7,154
Foreign corporate debt obligations	4	2,044
Total available-for-sale securities in an unrealized loss position	<u>\$ 6</u>	<u>\$ 9,198</u>

No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of these securities. The gross unrealized losses are not considered to be significant and have been for relatively short durations of less than six months. The Company does not intend to sell these securities before maturity and it is not likely that they will need to be sold prior to the recovery of their amortized cost basis. There were no sales of available-for-sale debt securities in the years ended December 31, 2012, 2011 and 2010.

[Table of Contents](#)**Financial Liabilities**

The following table summarizes the inputs and assumptions and estimated fair value of the Company's financial liabilities measured on a recurring basis as of the dates indicated, which were comprised solely of a liability for warrants issued in connection with an underwritten equity offering completed in 2010 (see Note 10):

	<u>December 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Inputs and assumptions:		
Fair market value of Company's common stock	\$ 4.20	\$ 1.17
Exercise price	\$ 2.52	\$ 2.52
Expected term (years)	2.8	3.8
Expected volatility	78.7%	98.9%
Risk-free interest rate	0.3%	0.5%
Expected dividend yield	0.0%	0.0%
Fair value:		
Estimated fair value per warrant share	\$ 2.59	\$ 0.62
Shares underlying outstanding warrants classified as liabilities (in thousands)	<u>3,118</u>	<u>3,679</u>
Total estimated fair value of outstanding warrants (in thousands)	<u>\$ 8,070</u>	<u>\$ 2,276</u>

The warrants have been classified as a derivative liability on the Company's balance sheet due to the potential for the warrants to be settled in cash upon the occurrence of certain transactions specified in the warrant agreements. The warrants were initially recorded at their fair value of \$4.5 million. At each subsequent balance sheet date, the estimated fair value of the outstanding warrants is determined using the Black-Scholes model and recorded to the balance sheet, with the change in fair value recorded to other income (expense) in the statements of operations and comprehensive income (loss).

The Black-Scholes model requires Level 3 inputs such as the expected term of the warrants and share price volatility. These inputs are subjective and generally require significant analysis and judgment to develop. Any changes in these inputs could result in a significantly higher or lower fair value measurement. The following table summarizes the changes in the fair value of the Company's Level 3 financial liabilities for the periods indicated (in thousands):

	<u>Warrant</u> <u>Liability</u>
Balance as of December 31, 2010	\$ 8,154
Change in fair value of warrant liability	(5,878)
Balance as of December 31, 2011	2,276
Change in fair value of warrant liability	7,509
Exercise of warrants	(1,715)
Balance as of December 31, 2012	<u>\$ 8,070</u>

7. Other Accrued Liabilities

Other accrued liabilities as of December 31 were as follows (in thousands):

	<u>2012</u>	<u>2011</u>
Accrued outside services	\$1,595	\$1,209
Accrued professional services	243	358
Other accruals	275	238
Total other accrued liabilities	<u>\$ 2,113</u>	<u>\$1,805</u>

[Table of Contents](#)

8. Notes Payable

On October 18, 2011, the Company entered into a Loan and Security Agreement (the “Loan Agreement”) with Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation (collectively, the “Lenders”), under which the Company could borrow up to \$25.0 million in two tranches (the “Loan Facility”). The first tranche of \$10.0 million was funded upon closing of the transaction on October 18, 2011, and the second tranche of \$15.0 million was drawn by the Company on September 19, 2012 following the DSMB’s interim efficacy analysis of the VALOR trial.

The interest rates for the first and second tranche are 8.95% and 9.00% per annum, respectively. Payments under the Loan Agreement are monthly in arrears and interest-only until February 1, 2013, followed by 32 equal monthly payments of principal and interest from March 1, 2013 to the scheduled maturity date of October 1, 2015. In addition, a final payment equal to 3.75% of the aggregate amount drawn will be due on October 1, 2015, or such earlier date as specified in the Loan Agreement. If the Company prepays all or a portion of the loan prior to maturity, it will pay the Lenders a prepayment fee of between 1-2% of the principal amount prepaid.

In accordance with the terms of the Loan Agreement, upon each drawdown, the Company issued warrants to purchase shares of common stock to the Lenders, each with a five-year term. In conjunction with the drawdown of the first tranche of \$10.0 million, the Company issued warrants to purchase 386,100 shares of its common stock at an exercise price of \$1.30 per share, which will expire on October 18, 2016, of which 77,220 remained outstanding as of December 31, 2012. In conjunction with the drawdown of the second tranche of \$15.0 million, the Company issued warrants to purchase 194,915 shares of its common stock at an exercise price of \$3.85 per share, which will expire on September 19, 2017, of which all remained outstanding as of December 31, 2012.

The fair values of the warrants issued at the first and second tranche closings were \$0.4 million and \$0.8 million, respectively, and were estimated using the Black-Scholes valuation model with the following assumptions: (a) fair value of common stock at issuance of \$1.38 and \$5.18, respectively; (b) risk-free interest rate of 1.07% and 0.70%, respectively (based upon observed risk-free interest rates appropriate for the expected term of the warrants); (c) expected volatility of 88.9% and 96.3%, respectively (based on the average historical volatilities of a peer group of publicly-traded companies within the Company’s industry); (d) expected term of five years (the contractual life of each warrant); and (e) a dividend yield of 0%. The fair value of each warrant was recorded at issuance as a debt discount within notes payable and an increase to additional paid-in capital on the Company’s balance sheet. The debt discounts are being amortized as interest expense over the term of each loan using the effective interest method.

Aggregate future minimum payments due under the Loan Agreement as of December 31, 2012 were as follows (in thousands):

<u>Year ending December 31,</u>	
2013	\$ 9,188
2014	10,577
2015	8,814
Total minimum payments	28,579
Less amount representing interest	(3,579)
Notes payable, gross	25,000
Unamortized discount on notes payable	(994)
Accretion of final payment	255
Notes payable, balance	24,261
Current portion of notes payable	(6,610)
Non-current portion of notes payable	<u>\$17,651</u>

[Table of Contents](#)

In connection with entering into the Royalty Agreement (see Note 4), the Company amended the Loan Agreement to permit the grant of the security interest to RPI, and to concurrently grant to the Lenders a security interest in the same assets, which may also be perfected following the first product approval in any country or territory. The Lenders will retain a senior position to the RPI security interest for so long as any indebtedness under the Loan Agreement remains outstanding.

The Company recorded interest expense related to the loan of \$1.9 million, \$0.3 million and zero for the years ended December 31, 2012, 2011 and 2010, respectively. The weighted average annual effective interest rate for the notes payable, including the amortization of the debt discounts and accretion of the final payments, is 13.9%.

9. Commitments and Contingencies

Commitments

The Company's operating lease obligations as of December 31, 2012 relate to the lease of approximately 15,000 square feet of office space in a building at 395 Oyster Point Boulevard in South San Francisco, California, which is currently the Company's headquarters. The lease was entered into in December 2006 and was originally due to expire on April 30, 2013, and provided for increasing monthly rent payments over this period. In January 2013, the term of the lease was extended until January 31, 2014 at a lower rate.

Aggregate non-cancelable future minimum rental payments under operating leases as of December 31, 2012 were as follows (in thousands):

<u>Year Ending December 31:</u>	<u>Payments</u>
2013	\$ 135
Total rental payments	<u>\$ 135</u>

Aggregate non-cancelable future minimum rental payments under operating leases as of December 31, 2012, including the effect of the lease extension executed in January 2013, were as follows (in thousands):

<u>Year Ending December 31:</u>	<u>Payments</u>
2013	\$ 326
2014	24
Total rental payments	<u>\$ 350</u>

The Company recognizes rent expense on a straight-line basis. The Company recorded rent expense of \$0.4 million, \$0.4 million and \$0.5 million for the years ended December 31, 2012, 2011 and 2010, respectively. Deferred rent balances in the Company's balance sheet represent the difference between actual rent payments and straight-line rent expense.

Contingencies

From time to time, the Company may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of its business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on the Company's results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on the Company because of the defense costs, diversion of management resources and other factors. The Company is not currently involved in any material legal proceedings.

10. Stockholders' Equity

Preferred Stock

The Company has 10,000,000 shares of authorized preferred stock available for issuance in one or more series. Upon issuance, the Company can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. There were no shares of preferred stock outstanding as of December 31, 2012 and 2011.

Common Stock

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors.

Controlled Equity Offerings

In April 2010 and August 2011, the Company entered into two controlled equity offering sales agreements with Cantor Fitzgerald & Co. ("Cantor"). Pursuant to each of these agreements, the Company could issue and sell shares of its common stock having an aggregate offering price of up to \$20.0 million per agreement from time to time through Cantor acting as agent and/or principal (the "2010 Cantor Facility" and the "2011 Cantor Facility", respectively, and collectively the "Cantor Facilities"). The Company agreed to pay Cantor a commission of 3.0% of the gross proceeds from sales under each facility.

During the year ended December 31, 2012, the Company sold an aggregate of 3,713,813 shares of common stock under the Cantor Facilities at an average price of approximately \$4.88 per share for gross proceeds of \$18.1 million and net proceeds of \$17.6 million, after deducting Cantor's commission. As of December 31, 2012, the 2010 Cantor Facility had been fully utilized and \$3.9 million of common stock remained available to be sold under the 2011 Cantor Facility, subject to certain conditions as specified in the agreement.

2010 Offering

In October 2010, the Company completed an underwritten offering, pursuant to which the Company issued an aggregate of 7,357,610 shares of common stock and warrants to purchase 3,678,798 shares of common stock, for aggregate gross proceeds of \$15.5 million (the "2010 Offering"). Net proceeds from the sale were \$14.2 million, after deducting underwriting discounts and offering expenses. The warrants have an exercise price of \$2.52 per share, and expire five years from the date of issuance.

The warrants have been classified as a derivative liability on the Company's balance sheet due to potential cash settlement of the warrants on terms, which do not include a cash limit, and upon the occurrence of certain transactions, as specified in the warrant agreements. At each balance sheet date, the estimated fair value of the outstanding warrants is determined using the Black-Scholes model and recorded to the balance sheet, with the change in fair value recorded to other income (expense) in the statements of operations and comprehensive income (loss). During the year ended December 31, 2012, warrants to purchase an aggregate of 561,166 shares of common stock that were issued in connection with the 2010 Offering were exercised, resulting in cash proceeds to the Company of \$1.4 million. As of December 31, 2012, warrants to purchase an aggregate of 3,117,632 shares of common stock issued in connection with the 2010 Offering remained outstanding, with a fair value of \$8.1 million.

Private Placement

In June 2010, the Company completed the third and final closing under a securities purchase agreement entered into in April 2009 with accredited investors, including certain members of management (the "Private Placement"). In the third closing, the Company issued 17,272,716 shares of common stock to the investors at a purchase price of \$1.65 per share, for gross proceeds of \$28.5 million and net proceeds of \$26.7 million. In conjunction with this closing, each outstanding share of Series A convertible preferred stock issued in the initial and second closings of the Private Placement was converted into 10 shares of common stock, and as a result, an additional 7,246,339 shares of common stock were issued on June 30, 2010. The remaining rights of investors in the Private Placement include the right of certain of the investors to designate members of the Company's board of directors.

Equity Incentive Plans

The Company grants options to purchase shares of its common stock primarily to: (i) new employees, of which 25% of the shares subject to such options become exercisable on the first anniversary of the vesting commencement date, and 1/48th of the shares subject to such options become exercisable each month over the remainder of the four-year vesting period, (ii) existing employees, of which 1/48th of the shares subject to such options become exercisable each month following the date of grant over a four-year vesting period, (iii) new non-employee members of the board of directors, of which 50% of the shares subject to such options become exercisable on each of the first and second anniversary of the vesting commencement date, and (iv) continuing non-employee members of the board of directors, of which, commencing in 2011, 1/24th of the shares subject to such options become exercisable each month following the date of grant over a two-year vesting period.

On March 15, 2011, the Company's Board of Directors adopted, and on June 3, 2011, the Company's stockholders approved, the 2011 Equity Incentive Plan (the "2011 Plan"). The 2011 Plan is intended as the successor to and continuation of the Company's 1998 Stock Plan, 2001 Stock Plan, 2005 Equity Incentive Award Plan and 2006 Employment Commencement Incentive Plan (collectively, the "Prior Plans"). Following stockholder approval on June 3, 2011 (the "Effective Date"), no additional stock awards shall be granted under Prior Plans.

The Company initially reserved a total of 6,041,856 shares of common stock for issuance under the 2011 Plan, which is the sum of (i) the 539,803 shares remaining available as of the Effective Date under the Prior Plans, (ii) an additional 4,400,000 new shares, and (iii) that portion of the 1,102,053 shares underlying stock options granted and currently outstanding under the Prior Plans that expire or terminate for any reason prior to exercise or settlement or that are forfeited because of the failure to meet a contingency or condition required to vest such shares.

The number of shares of common stock available for issuance under the 2011 Plan automatically increases on January 1st of each year for a period of 10 years commencing on January 1, 2012 by an amount equal to: (i) 4.0% of the Company's outstanding shares of common stock on December 31st of the preceding calendar year, or (ii) a lesser amount determined by the Board of Directors. On January 1, 2012 and 2013, the number of shares of common stock available for issuance under the 2011 Plan was increased by 1,870,968 and 2,062,609 shares, respectively, which represented 4.0% of the Company's outstanding shares of common stock on December 31, 2011 and 2012, respectively.

During the year ended December 31, 2012, options to purchase 2,454,500 shares of the Company's common stock were granted under the 2011 Plan. As of December 31, 2012, there were 1,432,278 shares available for future grants under the 2011 Plan.

[Table of Contents](#)

Employee Stock Purchase Plans

On March 15, 2011, the Company's Board of Directors adopted, and on June 3, 2011, the Company's stockholders approved, the 2011 Employee Stock Purchase Plan (the "2011 ESPP"). The 2011 ESPP is intended as the successor to the Company's 2005 Employee Stock Purchase Plan, which was terminated on June 3, 2011.

The 2011 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of a 12-month offering period, or (ii) at the end of one of the two related 6-month purchase periods. No participant in the 2011 ESPP may be issued or transferred shares of common stock valued at more than \$25,000 per calendar year. The initial offering under the 2011 ESPP commenced on June 13, 2011 and ended on May 31, 2012. Additional 12-month offerings will commence on June 1st of each year. The first such subsequent offering began on June 1, 2012.

The Company initially reserved a total of 500,000 shares of common stock for issuance under the 2011 ESPP. The number of shares of common stock available for issuance under the 2011 ESPP automatically increases on January 1st of each year for a period of 10 years commencing on January 1, 2012 by an amount equal to: (i) 1.0% of the Company's outstanding shares of common stock on December 31st of the preceding calendar year, or (ii) a lesser amount determined by the Board of Directors. No shares were added to the 2011 ESPP on January 1, 2012 and 2013.

A total of 83,920 shares were issued under the 2011 ESPP during the year ended December 31, 2012. As of December 31, 2012, there were 355,610 shares available for future issuance under the ESPP.

Warrants

As of December 31, 2012, the following warrants to purchase shares of the Company's common stock were outstanding (in thousands, except per share amounts):

<u>Date Issued</u>	<u>Shares</u>	<u>Exercise Price Per Share</u>	<u>Expiration</u>
March 2006	363	\$ 37.26	March 2013
August 2005	14	\$ 54.60	August 2015
October 2010 (see Note 10)	3,118	\$ 2.52	October 2015
April 2009	2,876	\$ 1.32	April 2016
October 2009	1,716	\$ 1.32	October 2016
October 2011 (see Note 8)	77	\$ 1.30	October 2016
September 2012 (see Note 8)	195	\$ 3.85	September 2017
March 2012 (see Note 4)	1,000	\$ 3.48	September 2017
March 2012 (see Note 4)	1,000	\$ 4.64	September 2017
Total warrants outstanding	<u>10,359</u>		

Reserved Shares

As of December 31, 2012, the Company's shares of common stock reserved for future issuance were as follows (in thousands):

	Shares Available for Future Grant	Outstanding Securities	Total Shares Reserved
Warrants	—	10,359	10,359
Stock option plans	1,432	6,288	7,720
Employee stock purchase plan	356	—	356
Total reserved shares of common stock	<u>1,788</u>	<u>16,647</u>	<u>18,435</u>

11. Stock-Based Compensation

Overview

Employee stock-based compensation expense is calculated based on the grant-date fair value of awards ultimately expected to vest, reduced for estimated forfeitures, and is recorded on a straight-line basis over the vesting period of the awards. Forfeitures are estimated at the time of grant, based on historical option cancellation information, and revised in subsequent periods if actual forfeitures differ from those estimates. The following table summarizes stock-based compensation expense related to the Company's stock-based awards for the periods indicated (in thousands):

	Year ended December 31,		
	2012	2011	2010
Research and development	\$ 1,030	\$ 630	\$ 300
General and administrative	1,372	739	570
Employee stock-based compensation expense	2,402	1,369	870
Non-employee stock-based compensation expense	322	19	7
Total stock-based compensation expense	<u>\$2,724</u>	<u>\$ 1,388</u>	<u>\$877</u>

[Table of Contents](#)

Fair Value of Awards

The Company determines the fair value of stock-based awards on the grant date using the Black-Scholes model, which is impacted by the Company's stock price, as well as assumptions regarding a number of highly subjective variables. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model, and resulting weighted-average and total estimated grant date fair values of employee stock options granted during the periods indicated:

	Year Ended December 31,		
	2012	2011	2010
Stock Option Plans			
Assumptions:			
Expected term (years)	5.4	5.5	4.5
Expected volatility	88.7%	85.0%	90.4%
Risk-free interest rate	1.1%	1.9%	1.7%
Expected dividend yield	0.0%	0.0%	0.0%
Fair value:			
Weighted-average estimated grant date fair value per share	\$ 1.46	\$ 1.42	\$ 2.10
Options granted to employees (in thousands)	2,310	4,179	58
Total estimated grant date fair value (in thousands)	<u>\$3,377</u>	<u>\$5,915</u>	<u>\$ 121</u>

The estimated fair value of stock options that vested in the years ended December 31, 2012, 2011 and 2010, was \$2.1 million, \$1.4 million and \$0.8 million, respectively. The Company based its assumptions for the expected term on historical cancellation and exercise data, and the contractual term and vesting terms of the awards. Expected volatility is based on historical volatility of the Company's common stock, as well as that for a mature peer group of companies in the same industry. The Company does not anticipate paying any cash dividends in the foreseeable future, and therefore uses an expected dividend yield of zero.

Option Plan Activity

The following table summarizes stock option activity for the Company's stock option plans in the periods presented (in thousands, except per share amounts):

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2011	5,099	\$ 3.51		
Options granted	2,455	\$ 2.13		
Options exercised	(147)	\$ 2.26		
Options forfeited or expired	(1,119)	\$ 2.72		
Outstanding as of December 31, 2012	<u>6,288</u>	<u>\$ 3.14</u>	<u>8.40</u>	<u>\$ 12,306</u>
Vested and expected to vest as of December 31, 2012	5,932	\$ 3.20	8.36	\$ 11,560
Exercisable as of December 31, 2012	2,477	\$ 4.69	7.65	\$ 4,288

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (i.e., the difference between the Company's closing stock price on the last trading day of the period and the exercise price, multiplied by the number of in-the-money options) that would have been received by option holders if they had exercised all their options on December 31, 2012.

[Table of Contents](#)

The intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$0.2 million, zero and \$3,000, respectively. As the Company believes it is more likely than not that no stock option related tax benefits will be realized, the Company does not record any net tax benefits related to exercised options.

Total estimated unrecognized stock-based compensation cost related to unvested stock options was \$5.4 million as of December 31, 2012, which is expected to be recognized over the respective vesting terms of each award. The weighted average term of the unrecognized stock-based compensation expense is 2.6 years.

12. Income Taxes

No provision for income taxes was recorded in the periods presented due to tax losses incurred in each period. The income tax provision differs from the amount computed by applying the statutory income tax rate of 34% to pre-tax loss as follows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Tax at statutory rate	\$(14,943)	\$ (6,848)	\$(8,359)
Current year net operating losses and temporary differences for which no tax benefit is recognized	12,023	8,549	6,973
Non-cash expense (credit) related to financings	2,570	(1,995)	1,246
Other permanent differences	350	294	140
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the net tax effects of loss and credit carry-forwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31,	
	2012	2011
Deferred tax assets:		
Federal and state net operating loss carry-forwards	\$ 110,791	\$ 104,757
Federal and state research credit carry-forwards	10,586	10,515
Capitalized research costs	4,535	5,177
Deferred revenue	7,850	—
Stock-based compensation	2,281	1,920
Property and equipment	146	162
Accrued liabilities	194	98
Gross deferred tax assets	136,383	122,629
Valuation allowance	(136,383)	(122,629)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately \$13.7 million, \$10.3 million and \$8.9 million during the years ended December 31, 2012, 2011 and 2010, respectively.

As of December 31, 2012, the Company had federal net operating loss carry-forwards of \$292.3 million and federal research and development tax credit carry-forwards of \$6.5 million. If not utilized, the federal net

[Table of Contents](#)

operating loss and tax credit carry-forwards will expire at various dates beginning in 2018. As of December 31, 2012, the Company had state net operating loss carry-forwards of \$190.3 million, which begin to expire in 2013, and state research and development tax credit carry-forwards of \$6.0 million, which do not expire.

Utilization of these net operating loss and tax credits carry-forwards may be subject to a substantial annual limitation due to the ownership change rules under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). The limitations are applicable if an "ownership change," as defined in the Code, is deemed to have occurred or occurs in the future. The annual limitation may result in the expiration of net operating loss and credit carry-forwards before they can be utilized.

The Company recognizes the financial statement effect of tax positions when it is more likely than not that the tax positions will be sustained upon examination by the appropriate taxing authorities. As of December 31, 2012 and 2011, the Company had no unrecognized tax positions.

The Company files U.S. federal and California tax returns. The Company's wholly owned subsidiary files tax returns in the United Kingdom. To date, neither the Company nor its wholly owned subsidiary has been audited by the Internal Revenue Service, any state income tax authority or tax authority in the United Kingdom. Due to net operating loss carry-forwards, substantially all of the Company's tax years remain open to federal tax examination.

13. Guarantees and Indemnification

As permitted under Delaware law and in accordance with the Company's Bylaws, the Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The indemnification agreements with the Company's officers and directors terminate upon termination of their employment, but the termination does not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company's officer and director insurance policy reduces the Company's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification agreements is minimal. In addition, in the ordinary course of business the Company enters into agreements, such as licensing agreements, clinical trial agreements and certain services agreements, containing standard indemnifications provisions. The Company believes that the likelihood of an adverse judgment related to such indemnification provisions is remote. Accordingly, the Company has not recorded any liabilities for any of these agreements as of December 31, 2012.

14. Selected Quarterly Financial Data (unaudited, and in thousands, except per share amounts)

The following table sets forth our unaudited consolidated financial results for the last eight fiscal quarters.

	Three Months Ended							
	Mar. 31, 2012	June 30, 2012	Sep. 30, 2012	Dec. 31, 2012	Mar. 31, 2011	June 30, 2011	Sep. 30, 2011	Dec. 31, 2011
Revenue	\$ —	\$ 1,500	\$ 265	\$ 1,989	\$ 4,000	\$ —	\$ 1,000	\$ —
Net income (loss):								
Basic	\$ (13,924)	\$ (8,579)	\$ (17,396)	\$ (4,052)	\$ 1,840	\$ (8,227)	\$ (5,014)	\$ (8,740)
Diluted	\$ (13,924)	\$ (9,332)	\$ (17,396)	\$ (10,352)	\$ 1,840	\$ (8,227)	\$ (5,014)	\$ (8,740)
Shares used in computing net income (loss) per common share:								
Basic	46,793	46,953	47,398	51,412	45,894	46,295	46,714	46,733
Diluted	46,793	47,286	47,398	52,848	47,866	46,295	46,714	46,733
Net income (loss) per common share:								
Basic	\$ (0.30)	\$ (0.18)	\$ (0.37)	\$ (0.08)	\$ 0.04	\$ (0.18)	\$ (0.11)	\$ (0.19)
Diluted	\$ (0.30)	\$ (0.20)	\$ (0.37)	\$ (0.20)	\$ 0.04	\$ (0.18)	\$ (0.11)	\$ (0.19)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Based on their evaluation as of December 31, 2012, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that, subject to the limitations described below, our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act) were effective at the reasonable assurance level to ensure the information required to be disclosed by us in reports that we file or submit under the Exchange is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012. Management based its assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2012, our internal control over financial reporting was effective at the reasonable assurance level.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their attestation report, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures provide our Chief Executive Officer and Chief Financial Officer with only reasonable assurances that our disclosure controls and procedures will achieve their objectives. However, our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting can or will prevent all human error. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are internal resource constraints, and the benefit of controls must be weighed relative to their corresponding costs. Because of the limitations in all control systems, no evaluation of controls can provide

[Table of Contents](#)

complete assurance that all control issues and instances of error, if any, within our company are detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur due to human error or mistake. Additionally, controls, no matter how well designed, could be circumvented by the individual acts of specific persons within the organization. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated objectives under all potential future conditions.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Sunesis Pharmaceuticals, Inc.

We have audited Sunesis Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Sunesis Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Sunesis Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Sunesis Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of Sunesis Pharmaceuticals, Inc. and our report dated March 13, 2013 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Redwood City, California
March 13, 2013

[Table of Contents](#)

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this report because we will file with the SEC a definitive proxy statement pursuant to Regulation 14A, or the Proxy Statement, not later than 120 days after the year ended December 31, 2012, and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information responsive to this item regarding directors and director nominees, executive officers, the board of directors and its committees, and certain corporate governance matters is incorporated herein by reference to the information set forth under the captions “Election of Nominees to the Board of Directors,” “Information About the Board of Directors and Corporate Governance” and “Certain Information with Respect to Executive Officers” in our definitive Proxy Statement.

Code of Business Conduct & Ethics

We have adopted a Code of Business Conduct & Ethics which applies to all of our directors, officers and employees. A copy of our Code of Business Conduct & Ethics can be found on our website, www.sunesis.com, in the section titled “*Investors & Media*” under the subsection titled “*Corporate Governance*.” Information found on our website is not incorporated by reference into this report. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct & Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our Code of Business Conduct & Ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

All additional information required by this Item 10 will be set forth in our definitive Proxy Statement and is incorporated in this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information responsive to this item is incorporated herein by reference to the information set forth under the captions “Executive Compensation and Related Information” and “Information About the Board of Directors and Corporate Governance” in our definitive Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Ownership of Sunesis Securities

Information responsive to this item is incorporated herein by reference to the information set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” in our definitive Proxy Statement.

[Table of Contents](#)

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2012:

<u>Plan Category</u>	<u>(A)</u> Number of Securities to be Issued upon Exercise of Outstanding Options	<u>(B)</u> Weighted Average Exercise Price of Outstanding Options	<u>(C)</u> Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A)
Equity Compensation Plans Approved by Stockholders(1)	6,288,114(2)	\$ 3.14	1,787,888(3)
Equity Compensation Plans Not Approved by Stockholders	—	\$ —	—
Total	6,288,114	\$ 3.14	1,787,888

- (1) Includes securities issuable under our 2011 Equity Incentive Plan, or 2011 Plan, and 2011 Employee Stock Purchase Plan, or ESPP.
- (2) Excludes purchase rights currently accruing under the ESPP. Offering periods under the ESPP are 12-month periods, which are comprised of two six-month purchase periods. Eligible employees may purchase shares of common stock at a price equal to 85% of the lower of the fair market value of the common stock at the beginning of each offering period or the end of each semi-annual purchase period. No participant in the ESPP may be issued or transferred shares of common stock valued at more than \$25,000 per calendar year.
- (3) Includes (i) 1,432,278 shares of common stock available for issuance under our 2011 Plan and (ii) 355,610 shares of common stock available for issuance under our ESPP. Beginning in 2012, the number of shares of common stock reserved under the 2011 Plan automatically increases on January 1st of each year by an amount equal to: (i) 4.0% of our shares of common stock outstanding on December 31st of the preceding calendar year, or (ii) a lesser amount determined by our Board of Directors. The number of shares of common stock reserved under our ESPP automatically increases on January 1st of each year by an amount equal to: (i) 1.0% of our shares of common stock outstanding on December 31st of the preceding calendar year, or (ii) a lesser amount determined by our Board of Directors.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information responsive to this item is incorporated herein by reference to the information set forth under the captions “Certain Relationships and Related Party Transactions” and “Information About the Board of Directors and Corporate Governance” in our definitive Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information responsive to this item is incorporated herein by reference to the information set forth under the caption “Independent Registered Public Accounting Firm” in our definitive Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibits and Financial Statement Schedules:

(a)(1) Financial Statements

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	52
Consolidated Balance Sheets	53
Consolidated Statements of Operations and Comprehensive Income (Loss)	54
Consolidated Statements of Stockholders' Equity	55
Consolidated Statements of Cash Flows	56
Notes to Consolidated Financial Statements	57

(a)(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable, or the information is included in the financial statements or notes thereto.

(a)(3) Exhibits

A list of exhibits filed with this report or incorporated herein by reference is found in the Exhibit Index immediately following the signature page of this report.

[Table of Contents](#)

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ HELEN S. KIM</u> Helen S. Kim	Director	March 13, 2013
<u>/S/ DAYTON MISFELDT</u> Dayton Misfeldt	Director	March 13, 2013
<u>/S/ HOMER L. PEARCE, PH.D.</u> Homer L. Pearce, Ph.D.	Director	March 13, 2013
<u>/S/ DAVID C. STUMP, M.D.</u> David C. Stump, M.D.	Director	March 13, 2013

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
3.1	Amended and Restated Certificate of Incorporation of the Registrant	10-K/A	000-51531	3.1	5/23/2007	
3.2	Amended and Restated Bylaws of the Registrant	8-K	000-51531	3.2	12/11/2007	
3.3	Certificate of Designation of the Series A Preferred Stock of the Registrant	8-K	000-51531	3.3	4/3/2009	
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant	S-8	333-160528	3.4	7/10/2009	
3.5	Certificate of Amendment to the Certificate of Designation of the Series A Preferred Stock of the Registrant	8-K	000-51531	3.4	11/2/2009	
3.6	Certificate of Amendment to the Certificate of Designation of the Series A Preferred stock of the Registrant	8-K	000-51531	3.5	1/21/2010	
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant	8-K	000-51531	3.1	2/14/2011	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7 above.					
4.2	Specimen Common Stock certificate of the Registrant	10-K	000-51531	4.2	3/29/2011	
4.3	Investor Rights Agreement, dated April 3, 2009, by and among the Registrant and the purchasers identified on the signature pages thereto	8-K	000-51531	4.1	4/3/2009	
10.1*	1998 Stock Plan and Form of Stock Option Agreement	S-1/A	333-121646	10.1	1/27/2005	
10.2*	2001 Stock Plan and Form of Stock Option Agreement	S-1	333-121646	10.2	12/23/2004	
10.3*	2005 Equity Incentive Award Plan, as amended, and Form of Stock Option Agreement	10-K/A	000-51531	10.3	4/30/2009	
10.4*	Employee Stock Purchase Plan and Enrollment Form	10-Q	000-51531	10.4	11/9/2006	
10.5*	Form of Indemnification Agreement for directors and executive officers	S-1	333-121646	10.5	12/23/2004	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.6	Warrant, dated June 11, 2003, issued to General Electric Capital Corporation	S-1	333-121646	10.21	12/23/2004	
10.7	Warrant, dated June 21, 2004, issued to General Electric Capital Corporation and Amendment No. 1 thereto, dated December 16, 2004	S-1/A	333-121646	10.22	4/29/2005	
10.8†	License Agreement, dated October 14, 2003, by and between the Registrant and Dainippon Sumitomo Pharma Co., Ltd. (formerly known as Dainippon Pharmaceutical Co., Ltd.)	S-1/A	333-121646	10.36	4/29/2005	
10.9	Warrant, dated August 25, 2005, issued to Horizon Technology Funding Company II LLC	S-1/A	333-121646	10.40	9/1/2005	
10.10	Warrant, dated August 25, 2005, issued to Horizon Technology Funding Company III LLC	S-1/A	333-121646	10.41	9/1/2005	
10.11	Warrant, dated August 25, 2005, issued to Oxford Finance Corporation	S-1/A	333-121646	10.42	9/1/2005	
10.12	Warrant, dated September 9, 2005, issued to General Electric Capital Corporation	10-K	000-51531	10.16	3/29/2011	
10.13*	Amended and Restated 2006 Employment Commencement Incentive Plan	10-K/A	000-51531	10.32	4/30/2009	
10.14	Common Stock and Warrant Purchase Agreement, dated as of March 17, 2006, among the Registrant and the investors listed on the signature pages thereto	8-K	000-51531	10.44	3/22/2006	
10.15	Registration Rights Agreement, dated as of March 17, 2006, among the Registrant and the investors listed on the signature pages thereto	8-K	000-51531	10.45	3/22/2006	
10.16	Form of Warrant	8-K	000-51531	10.46	3/22/2006	
10.17†	Sublease, dated December 22, 2006, by and between the Registrant and Oncology Therapeutics Network Joint Venture, L.P., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-K	000-51531	10.47	3/17/2008	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.18*	Consulting Agreement, dated August 17, 2006, by and between the Registrant and Homer L. Pearce, Ph. D.	10-Q	000-51531	10.49	5/9/2007	
10.19*	Consulting Agreement, dated September 2, 2006, by and between the Registrant and David C. Stump, M. D.	10-Q	000-51531	10.50	5/9/2007	
10.20*	Forms of Stock Option Grant Notice and Stock Option Agreement under the 2005 Equity Incentive Award Plan	8-K	000-51531	10.52	9/19/2007	
10.21*	Second Amended and Restated Executive Severance Benefits Agreement, dated December 24, 2008, by and between Registrant and Daniel N. Swisher, Jr.	10-K	000-51531	10.44	4/3/2009	
10.22*	Second Amended and Restated Executive Severance Benefits Agreement, dated December 24, 2008, by and between Registrant and Eric H. Bjerkholt	10-K	000-51531	10.45	4/3/2009	
10.23*	Forms of Stock Option Grant Notice and Stock Option Agreement for Automatic Grants to Outside Directors under the 2005 Equity Incentive Award Plan	10-Q	000-51531	10.69	11/7/2008	
10.24*	Forms of Stock Option Grant Notice and Stock Option Agreement under the Amended and Restated 2006 Employment Commencement Incentive Plan	8-K	000-51531	10.71	12/23/2008	
10.25	Summary of Non-Employee Director Cash Compensation Arrangements	10-Q	000-51531	10.2	8/13/2010	
10.26	Form of Warrant to purchase shares of Common Stock	8-K	000-51531	10.2	4/3/2009	
10.27	Agreement Regarding Private Placement of Securities of Sunesis Pharmaceuticals, Inc., dated as of June 29, 2009, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.1	7/2/2009	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.28	Second Agreement Regarding Private Placement of Securities of Sunesis Pharmaceuticals, Inc., dated as of October 27, 2009, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.66	11/2/2009	
10.29	Third Agreement Regarding Private Placement of Securities of Sunesis Pharmaceuticals, Inc., dated as of January 19, 2010, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.67	1/21/2010	
10.30	Fourth Agreement Regarding Private Placement of Securities of Sunesis Pharmaceuticals, Inc., dated as of March 29, 2010, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.1	4/2/2010	
10.31	Sales Agreement, dated April 29, 2010, between the Registrant and Cantor Fitzgerald & Co.	8-K	000-51531	10.1	4/29/2010	
10.32*	Sunesis Pharmaceuticals, Inc. 2012 Bonus Program	8-K	000-51531	10.1	3/28/2012	
10.33	Underwriting Agreement, dated September 30, 2010, by and between the Registrant and Cowen and Company LLC	8-K	000-51531	1.1	10/1/2010	
10.34	Form of Warrant to Purchase Common Stock of the Registrant	8-K	000-51531	4.1	10/1/2010	
10.35	Master Services Agreement, dated November 3, 2003, by and between the Registrant and AAI Developmental Services Inc.	10-K	000-51531	10.49	3/29/2011	
10.36	First Amendment to Master Services Agreement, dated September 11, 2006, by and between the Registrant and AAIPharma Inc.	10-K	000-51531	10.50	3/29/2011	
10.37	Second Amendment to Master Services Agreement, dated May 2, 2008, by and between the Registrant and AAIPharma Inc.	10-K	000-51531	10.51	3/29/2011	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.38	Third Amendment to Master Services Agreement, dated November 3, 2009, by and between the Registrant and AAIPharma Services Corp.	10-K	000-51531	10.52	3/29/2011	
10.39	Master Services Agreement, dated January 1, 2010, by and between the Registrant and Albany Molecular Research, Inc.	10-K	000-51531	10.53	3/29/2011	
10.40	Master Services Agreement, dated June 21, 2010, by and between the Registrant and Icon Clinical Research Limited	10-K	000-51531	10.54	3/29/2011	
10.41	Master Services Agreement, dated August 26, 2004, by and between the Registrant and Quintiles, Inc.	10-Q	000-51531	10.2	5/12/2011	
10.42	First Amendment to Master Services Agreement, dated August 1, 2008, by and between the Registrant and Aptuit, Inc. (as assignee of Quintiles, Inc.)	10-Q	000-51531	10.3	5/12/2011	
10.43	Amended and Restated Collaboration Agreement, dated March 31, 2011, by and between the Registrant and Biogen Idec MA Inc.	10-Q/A	000-51531	10.4	6/30/2011	
10.44	License Agreement, dated March 31, 2011, by and between the Registrant and Millennium Pharmaceuticals, Inc.	10-Q/A	000-51531	10.5	6/30/2011	
10.45	Termination and Transition Agreement, dated March 31, 2011, by and between the Registrant, Biogen Idec MA Inc. and Millennium Pharmaceuticals, Inc.	10-Q	000-51531	10.6	5/12/2011	
10.46*	Sunesis Pharmaceuticals, Inc. 2011 Equity Incentive Plan	S-8	333-174732	99.1	6/6/2011	
10.47*	Sunesis Pharmaceuticals, Inc. 2011 Employee Stock Purchase Plan	S-8	333-174732	99.2	6/6/2011	
10.48	Sales Agreement, dated August 11, 2011, between Sunesis Pharmaceuticals, Inc. and Cantor Fitzgerald & Co.	8-K	000-51531	10.1	8/11/2011	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.49	Loan and Security Agreement among Sunesis Pharmaceuticals, Inc., Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation, dated as of October 18, 2011	8-K	000-51531	10.1	10/19/2011	
10.50	Warrant to Purchase Stock issued to Horizon Technology Finance Corporation, dated as of October 18, 2011	8-K	000-51531	10.4	10/19/2011	
10.51	Fifth Agreement Regarding Private Placement of Securities of Sunesis Pharmaceuticals, Inc., dated as of February 2, 2012, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.1	2/3/2012	
10.52*	Letter Agreement, dated February 2, 2012, by and between Sunesis Pharmaceuticals, Inc. and Steven B. Ketchum	8-K	000-51531	10.2	2/3/2012	
10.53*	Offer Letter, dated January 31, 2012, by and between Sunesis Pharmaceuticals, Inc. and Adam R. Craig	10-K	000-51531	10.55	3/14/2012	
10.54*	Executive Severance Benefits Agreement, dated January 31, 2012, by and between Sunesis Pharmaceuticals, Inc. and Adam R. Craig	10-K	000-51531	10.56	3/14/2012	
10.55*	Forms of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan	10-K	000-51531	10.57	3/14/2012	
10.56*	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2011 Equity Incentive Plan	10-K	000-51531	10.58	3/14/2012	
10.57†	Revenue Participation Agreement, dated March 29, 2012, by and between Sunesis Pharmaceuticals, Inc. and RPI Finance Trust	10-Q	000-51531	10.6	5/15/2012	

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
10.58	First Amendment to Loan and Security Agreement Among the Registrant, Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation, dated March 29, 2012	10-Q	000-51531	10.7	5/15/2012	
10.59 †	Form of Warrant, dated March 29, 2012, issued to RPI Financial Trust	10-Q	000-51531	10.8	5/15/2012	
10.60	First Amendment of Sublease, dated January 14, 2013, by and between the Registrant and McKesson Specialty Care Distribution Joint Venture, LP (as successor in interest), for office space located at 395 Oyster Point Boulevard, South San Francisco, California					X
10.61 *	Amendment to Executive Severance Benefit Agreement, dated October 24, 2012, by and between Sunesis Pharmaceuticals, Inc. and Adam R. Craig					X
21.1	Subsidiaries of the Registrant	10-K	000-51531	21.1	3/17/2008	
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney					(included on Signature page)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act					X
32.1#	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 13a-14(b) or 15d-14(b) of the Exchange Act					X
101.INS	XBRL Instance Document					(1)
101.SCH	XBRL Taxonomy Extension Schema Document					(1)

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated By Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				(1)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				(1)
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				(1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				(1)

* Management contract, compensatory plan or arrangement.

† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted information has been filed separately with the Securities and Exchange Commission.

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule; Management's Reports on Internal Control over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the Certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-K and will not be filed for purposes of Section 18 of the Exchange Act. Such certification will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

(1) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act are deemed not filed for purposes of Section 18 of the Exchange Act.

FIRST AMENDMENT OF SUBLEASE

This First Amendment of Sublease (this "*First Amendment*") is made as of January 14, 2013 by and between MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, LP, a Delaware limited partnership ("*Sublandlord*"), and SUNESIS PHARMACEUTICALS, INC., a Delaware corporation ("*Subtenant*").

WHEREAS, Kashiwa Fudosan American, Inc., a California corporation, as landlord ("*Prime Landlord*"), and Sublandlord's predecessor-in-interest, entered into that certain Office Lease, dated June 1, 2003 (as subsequently amended, the "*Prime Lease*") for certain premises (the "*Prime Lease Premises*") located at 395 Oyster Point Boulevard, Suite 400, South San Francisco, California 94080;

WHEREAS, Sublandlord's predecessor-in-interest and Subtenant entered into a Sublease, dated December 22, 2006 (the "*Sublease*") for a portion (the "*Demised Premises*") of the Prime Lease Premises consisting of 15,378 rentable square feet located at 395 Oyster Point Boulevard, South San Francisco, California 94080;

WHEREAS, the current term of the Sublease (the "*Sublease Term*") expires on April 30, 2013; and

WHEREAS, Sublandlord and Subtenant desire to extend the Sublease Term so that it shall expire on January 31, 2014.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, Sublandlord and Subtenant agree as follows:

NOW, THEREFORE, for and in consideration of the mutual covenants, promises, conditions and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, covenant and agree as follows:

1. Recitals/Definitions. The foregoing recitals are hereby incorporated into this First Amendment as if such recitals were restated in their entirety in this section. Those capitalized terms not defined herein shall have the same meanings ascribed to them in the Sublease.

2. Sublease Term. The Sublease Term is extended so that it shall expire on January 31, 2014.

3. Condition of Demised Premises. Subtenant agrees to continue to occupy the Demised Premises in its current "as is" condition

4. Base Rent. Effective as of May 1, 2013 base rent payable during the extended Sublease Term shall be Twenty Three Thousand Eight Hundred Thirty Five and ninety hundredths Dollars (\$23,835.90) per month.

5. Operating Expenses, Property Taxes and Utilities. Effective as of May 1, 2013 Subtenant shall no longer be required to pay its Pro-Rata Share of Operating Expenses, increases in Real Estate Taxes and Utilities as provided by Section 10 of the Sublease.

6. After-Hours Air-Conditioning. Notwithstanding Section 5 of this First Amendment, if Subtenant shall require air-conditioning service for the Demised Premises at any time other than during regular business hours, Subtenant shall request such service from Prime Landlord in accordance with the terms of the Prime Lease and shall reimburse Prime Landlord or Sublandlord (as directed by Sublandlord) for such service at Prime Landlord's then-current prevailing rate for such service. Subtenant agrees that if in order to provide such service to the Demised Premises, such service must also be provided to portions of the Prime Lease Premises other than the Demised Premises, Subtenant shall be obligated to pay the entire cost of such service.

7. Consent of Prime Landlord. This First Amendment is subject to and shall be effective upon the written consent of Prime Landlord. If Prime Landlord elects to exercise any termination or recapture right which it may have under the Prime Lease with respect to the Demised Premises, then this First Amendment shall become null and void, with no further obligations due on the part of either party.

8. PDF Format. This First Amendment may be executed by facsimile copies or copies in PDF format, each of which facsimile copies or copies in PDF format will be deemed an original hereof.

9. Ratification of Sublease. All other terms and conditions of the Sublease shall remain in full force and effect. In the event of any conflict between the provisions of the Sublease and the provisions of this First Amendment, the provisions of this First Amendment shall prevail.

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this First Amendment as of the date first above written.

SUBLANDLORD:

MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, LP, a Delaware limited partnership

By: Oncology Therapeutics Network Corporation, a Delaware corporation Its General Partner

By: /s/ Nicholas A. Loiacono

Nicholas A. Loiacono
Vice President and Treasurer

SUBTENANT:

SUNESIS PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Eric Bjerkholt
Print Name: Eric Bjerkholt
Title: EVP Corp Dev and Finance, CFO

CONSENT TO FIRST AMENDMENT

Kashiwa Fudosan American, Inc., a California corporation, as Prime Landlord under the Prime Lease, hereby consents to the First Amendment of Sublease, dated January 14, 2013 between McKesson Specialty Care Distribution Joint Venture, LP, a Delaware limited partnership (“***Sublandlord***”), and Sunesis Pharmaceuticals, Inc.

KASHIWA FUDOSAN AMERICAN, INC.,
a California corporation

By: /s/ Tory Iwai
Print Name: Tory Iwai
Title: Attorney-in-Fact

SUNESIS PHARMACEUTICALS, INC.
AMENDMENT TO
EXECUTIVE SEVERANCE BENEFITS AGREEMENT

THIS AMENDMENT TO EXECUTIVE SEVERANCE BENEFITS AGREEMENT (“Amendment”) is made as of October 24, 2012, by and between **SUNESIS PHARMACEUTICALS, INC.**, a Delaware corporation (the “Company”), and **ADAM R. CRAIG** (“Executive”). Capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the Severance Agreement (as defined below).

RECITALS

WHEREAS, the Company and Executive entered into that certain Executive Severance Benefits Agreement dated as of January 31, 2012 (the “Severance Agreement”);

WHEREAS, Section 6.7 of the Severance Agreement permits the parties to amend the Severance Agreement upon mutual written consent of the Company and Executive, which shall be signed by an executive officer of the Company after such amendment has been approved by the Board;

WHEREAS, the Company and Executive wish to amend the Severance Agreement in the manner provided herein; and

WHEREAS, the Board approves the amendment to the Severance Agreement in the manner provided herein.

AMENDMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the Company and Executive hereby agree as follows:

1. Section 2.1 of the Severance Agreement is hereby amended to add the following subsection:

“(c) **Acceleration.** The vesting and/or exercisability of the unvested shares subject to Executive’s then-outstanding Stock Awards shall be automatically accelerated by twelve (12) months on Executive’s Separation from Service.”

2. All other terms of the Severance Agreement shall remain in full force and effect.

3. Executive acknowledges that he is knowingly and voluntarily entering into this Amendment, and that the Company has not required Executive’s entering into this Amendment as a condition to Executive’s continued employment by the Company.

4. This Amendment does not alter the status of Executive’s at-will employment relationship with the Company and, subject to the terms of this Amendment, does not in any way

interfere with Executive's right or the Company's right to terminate Executive's employment at any time, with or without Cause or advance notice, which rights are hereby expressly reserved.

5. This Amendment shall be governed by and construed under the laws of the State of California, without regard to conflict of laws principles.

6. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned have executed this AMENDMENT as of the day and year first set forth above.

COMPANY:

SUNESIS PHARMACEUTICALS, INC.

By: /s/ Daniel N. Swisher, Jr.

Daniel N. Swisher, Jr.

Chief Executive Officer and President

EXECUTIVE:

/s/ Adam R. Craig

Adam R. Craig

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-164025, 333-166366 and 333-168191) and related Prospectuses, and the Registration Statements on Form S-8 (Nos. 333-128647, 333-132679, 333-138758, 333-145404, 333-150834, 333-160528, 333-174732 and 333-180101) pertaining to the 1998 Stock Plan, 2001 Stock Plan, 2005 Equity Incentive Award Plan, Amended and Restated 2006 Employment Commencement Incentive Plan, Employee Stock Purchase Plan, 2011 Equity Incentive Plan and 2011 Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc., of our report dated March 13, 2013, with respect to the consolidated financial statements of Sunesis Pharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of Sunesis Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/ Ernst & Young LLP

Redwood City, California
March 13, 2013

CERTIFICATION

I, Daniel N. Swisher, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunesis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2013

/s/ DANIEL N. SWISHER, JR.
Daniel N. Swisher, Jr.
President and Chief Executive Officer

CERTIFICATION

I, Eric H. Bjerkholt, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sunesis Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 13, 2013

/S/ ERIC H. BJERKHOLT
Eric H. Bjerkholt
*Executive Vice President, Corporate
Development and Finance, Chief Financial Officer*

**Certification of Chief Executive Officer and Chief Financial Officer Pursuant to
18 U.S.C. Section 1350, as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Daniel N. Swisher, Jr., Chief Executive Officer of Sunesis Pharmaceuticals, Inc. (the "Company"), and Eric H. Bjerkholt, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2012, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 13th day of March, 2013.

/s/ DANIEL N. SWISHER, JR.

Daniel N. Swisher, Jr.
Chief Executive Officer

/s/ ERIC H. BJERKHOLT

Eric H. Bjerkholt
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sunesis Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

