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**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, 2016

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

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, 2016, as reported by The NASDAQ Stock Market, was \$43,332,609. The calculation of the aggregate market value of voting and non-voting stock excludes 1,371,299 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 24, 2017, was 20,924,522.

**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 2017 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, 2016.

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SUNESIS PHARMACEUTICALS, INC.

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## 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, Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1995, 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 receiving approval of vosaroxin from the European Medicines Agency, our regulatory and clinical strategies for gaining marketing approval in the United States, our marketing plans and commercialization strategies for vosaroxin, if approved, and the commercial potential of vosaroxin in Europe and clinical development of SNS-062, 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,” “could,” “estimates,” “expects,” “intend,” “look forward,” “may,” “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 subsidiaries, except where it is made clear that the term refers only to the parent company.*

#### ITEM 1. BUSINESS

##### General

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 January 2014, we announced the expansion of our oncology pipeline through separate global licensing agreements for two preclinical kinase inhibitor programs. The first agreement, with Biogen Idec MA, Inc. (“Biogen”), is for global commercial rights to SNS-062, a selective non-covalently binding, reversible oral inhibitor of BTK. We filed a Clinical Trial Authorization application in the first quarter of 2016 in Belgium and enrolled the first subjects in a Phase 1A study of SNS-062 in healthy volunteers. In September and again in December 2016, we announced results from the Company’s Phase 1A study in healthy volunteers evaluating the oral non-covalent, reversible BTK inhibitor SNS-062. The study demonstrated a favorable safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile for SNS-062 in healthy subjects. In December 2016 we filed an Investigational New Drug (“IND”) application with the FDA to conduct a Phase 1B/2 trial in patients with various B-cell malignancies, and in January 2017 the IND was cleared to proceed.

The second agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”), is for global commercial rights to several potential first-in class, pre-clinical inhibitors of the novel target PDK1. In 2014, we selected two PDK1 inhibitors, SNS-229 and SNS-510, of which we have taken one, SNS-229, into IND-enabling pharmacology absorption, distribution, metabolism and excretion, and toxicology studies.

Both BTK and PDK1 programs were originally developed under a research collaboration agreement between Biogen and Sunesis. In 2011, Biogen exclusively licensed the PDK1 program to Takeda along with the more advanced program, TAK-580 (formerly MLN2480). We currently expect that SNS-062, and SNS-510 and SNS-229 will be developed exclusively by Sunesis for the foreseeable future.

In addition, we are in a collaboration with Takeda for the development of TAK-580 (formerly MLN2480), an oral pan-RAF inhibitor, for which Takeda is conducting a multi-arm, open-label Phase 1B study in combination with nivolumab, a PD-1 checkpoint inhibitor; TAK-228, an oral mTORC 1/2 inhibitor; alisertib, an oral aurora A kinase inhibitor; and several chemotherapeutic agents, in adult patients with advanced non-hematologic malignancies.

Our most advanced program is QINPREZO™ (vosaroxin), our product candidate for the potential treatment of acute myeloid leukemia (“AML”). Vosaroxin is an anticancer quinolone derivative (“AQD”)—a class of compounds that has not been used previously for the treatment of cancer.

In October 2014, we announced the results of a Phase 3, multi-national, randomized, double-blind, placebo-controlled trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML, or the VALOR trial. Detailed results of the VALOR trial were presented in the “Late Breaking Abstracts” session of the American Society of Hematology (“ASH”) Annual Meeting in December 2014 and additionally published in the September 2015 issue of *The Lancet Oncology*.

The VALOR trial did not meet its primary endpoint of demonstrating a statistically significant improvement in overall survival, but based upon the favorable results of other predefined analyses of the data, in November 2014, we submitted a letter of intent to the European Medicines Agency (“EMA”), describing our intention to file a marketing authorization application (“MAA”), for marketing authorization of vosaroxin plus cytarabine for the treatment of relapsed or refractory AML in the European Union. In June 2015, we met separately with our Rapporteur and Co-Rapporteur, who are two appointed members of the EMA’s Committee for Medicinal Products for Human Use (“CHMP”). Based upon feedback from these meetings, we filed an MAA with the EMA at the end of 2015. In April 2016 we received a list of questions relating to our MAA filing (the “Day 120 Questions”). We responded to these questions in October 2016 and in December 2016 we received a list of outstanding issues (the “Day 180 LOI”). We are currently in the process of preparing responses to the Day 180 LOI. In July 2015, we met with the U.S. Food and Drug Administration (the “FDA”), to discuss a potential regulatory filing in the U.S. Based upon the meeting, the FDA recommended that we provide additional clinical evidence prior to any regulatory filing in the U.S. As a result, we are evaluating regulatory and clinical strategies with the goal of gaining future marketing approval in the U.S.

In the second half of 2013, we announced the initiation of three Phase 1/2 investigator-sponsored trials of vosaroxin, either as a standalone therapy or in combination with approved compounds, in various indications of AML and high-risk myelodysplastic syndrome (“MDS”). The trials are being conducted at the University of Texas MD Anderson Cancer Center (“MDACC”), Weill Cornell Medical College and New York-Presbyterian Hospital, and the Washington University School of Medicine (“Washington University”).

In June 2016, results from the ongoing Phase 1b/2 MDACC-sponsored trial of vosaroxin in combination with decitabine in older patients with previously untreated AML and high-risk MDS were presented at the European Hematology Association (“EHA”) Annual Meeting.

We own worldwide development and commercialization rights to vosaroxin. In 2009, vosaroxin received orphan drug designation for the treatment of AML from the FDA and in 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 a product approval for this indication in Europe. In 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.

## **Our Strategy**

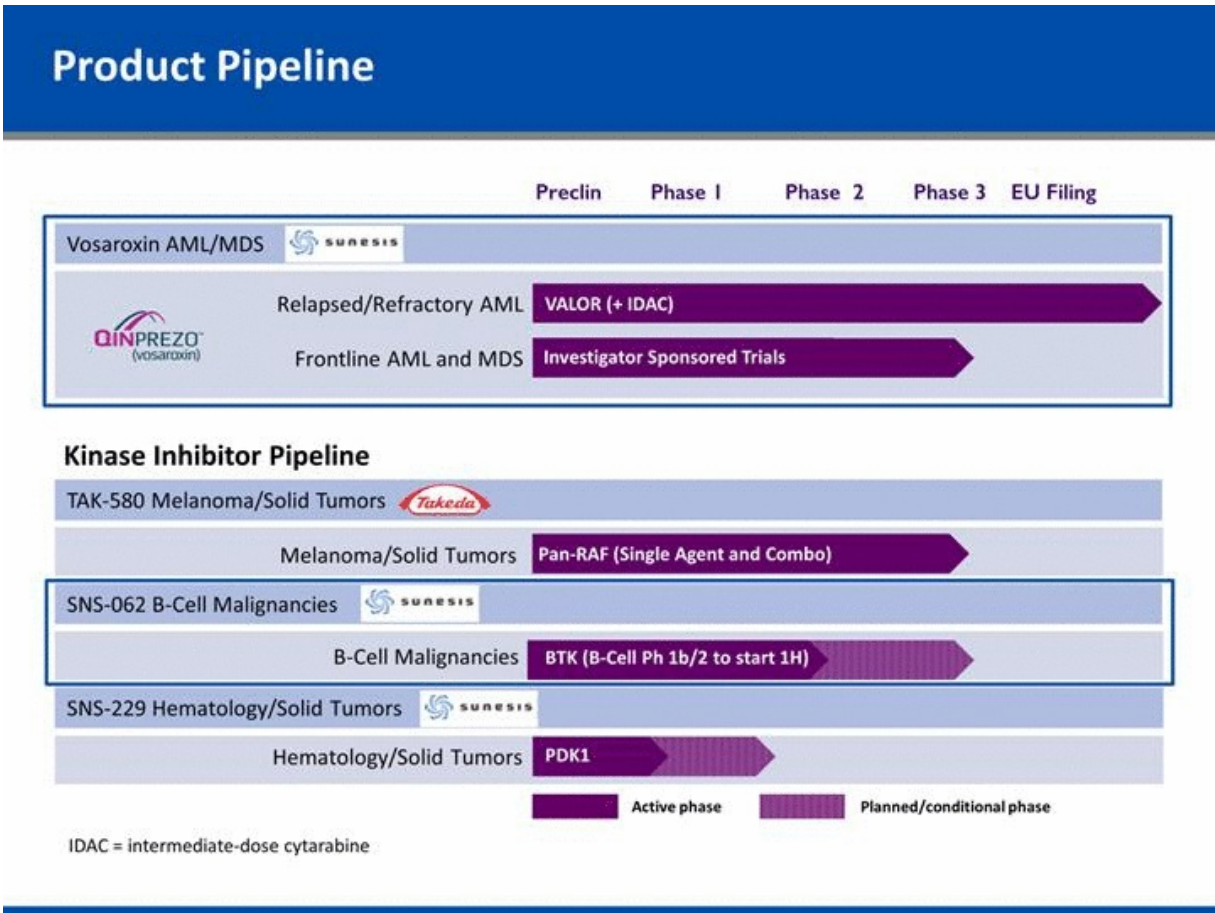
We plan to continue to build Sunesis into a leading biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers by:

- conducting a Phase 1b/2 study in patients with B-cell malignancies for our oral, non-covalent, reversible BTK inhibitor, SNS-062. In the Phase 2 portion of this study, we will explore SNS-062 as a potential treatment for Chronic Lymphocytic Leukemia (“CLL”) patients who have relapsed while being treated with a covalent BTK inhibitor primarily as a result of the C481S mutation;
- pursuing regulatory approval for vosaroxin as a potential treatment for relapsed or refractory AML in Europe, the United States, and other major markets;
- leveraging potential partners and distributors to commercialize vosaroxin in selective international markets, if approved;
- establishing vosaroxin as the new standard of care for patients with relapsed or refractory AML, if approved;

- exploring the broader potential of vosaroxin, beyond our pivotal indication, in different patient segments within AML and MDS through investigator sponsored trials;
- investing in additional clinical testing to evaluate vosaroxin for additional AML indications, MDS, other hematologic malignancies and solid tumors;
- leveraging our strong intellectual property protection over vosaroxin to capitalize on its full potential;
- supporting our multi-kinase inhibitor programs with Takeda in oncology and Biogen for immunology indications;
- conducting Absorption, Distribution, Metabolism and Excretion (“ADME”) and safety studies with our PDK1 inhibitor, SNS-510 in 2017; and
- continuing to expand and develop our oncology-focused pipeline through further licensing or collaboration arrangements and research and development.

**Development Pipeline**

The following chart summarizes our development pipeline:



## ***Vosaroxin***

**Background.** Vosaroxin is an AQD—a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that vosaroxin both intercalates DNA and inhibits topoisomerase II, an enzyme critical for cell replication, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis. We licensed worldwide development and commercialization rights to vosaroxin from Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”), in 2003.

**Mechanism of Action.** The molecular core of vosaroxin is structurally similar to quinolones and distinct from anthracyclines and anthracenediones. Vosaroxin's anticancer activity results from apoptosis caused exclusively by DNA intercalation, inhibition of topoisomerase II, and cell cycle inhibition in replicating cells.

Vosaroxin's cytotoxic activity is established in diverse human tumors and clinical activity is observed in both solid and hematologic malignancies. In preclinical studies, vosaroxin demonstrated broad antitumor activity and exhibited additive or synergistic activity when combined with several therapeutic agents currently used in the treatment of cancer, including cytarabine. Vosaroxin maintains activity in drug resistant tumor cell lines and human tumor models. Vosaroxin evades P-gp transporter-mediated resistance, and its activity is p53 independent, reducing resistance to therapy. Vosaroxin has demonstrated anticancer activity in patients who have failed other topoisomerase II inhibitor treatment.

**Development Opportunity.** Our goal is to establish vosaroxin in combination with cytarabine as the standard of care for patients with relapsed or refractory AML. Additionally, we are exploring the broader potential of vosaroxin in different patient segments within AML and MDS through investigator-sponsored trials. Based on the outcome of regulatory interactions related to our VALOR trial, the results of investigator-sponsored trials, competitive concerns, our financial resources and various other factors, we may further invest in the development and clinical testing of vosaroxin for related disease areas and indications such as other AML populations, MDS, other hematologic malignancies and solid tumors.

### ***Vosaroxin Company-Sponsored Clinical Trials in AML***

**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. The trial, which enrolled 711 adult patients, was conducted at 124 study sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. Patients were stratified for age, geographic region and disease status and randomized one to one to receive either vosaroxin and cytarabine or placebo and cytarabine. In October 2014, we announced the results from the VALOR trial, and further detail was presented in the "Late Breaking Abstracts" session of the ASH Annual Meeting in December 2014 and additionally published in the September 2015 issue of *The Lancet Oncology*.

Patients treated with vosaroxin achieved increased overall survival compared to those treated with placebo (7.5 months vs 6.1 months, HR=0.87), the primary endpoint, but this difference did not achieve statistical significance (p=0.06). The complete remission (CR) rate, the sole secondary efficacy endpoint in the trial, did demonstrate a significant difference for the vosaroxin combination arm (30.1% vs 16.3%, p < 0.0001).

In a pre-planned analysis accounting for the stratification factors at randomization, a significant improvement in overall survival was demonstrated (HR=0.83, p=0.02). The pre-planned analysis of all treatment strata included the following poor-prognosis patient categories: over 60 years old (7.1 months vs 5.0 months, HR=0.75, p=0.003, n=451), refractory disease (6.7 months vs 5.0 months, HR=0.87, p=0.23, n=301), and early relapsed disease (6.7 months vs 5.2 months, HR=0.77, p=0.04, n=256). Outcomes in patients under 60 years old or with late relapsed disease were comparable between treatment arms, with no improvement in overall survival. Across all strata, the CR and Composite CR (CR+CRp+CRi) rates were higher in the vosaroxin combination arm.

Given the complexity of interpreting the impact of transplantation therapy, a predefined analysis of overall survival censoring for hematopoietic stem cell transplantation was planned. In this analysis, patients receiving the vosaroxin combination had a median overall survival of 6.7 months versus 5.3 months for patients receiving placebo and cytarabine (HR=0.81, p=0.02).

Regarding drug safety, Grade 3 or higher non-hematologic adverse events that were more common in the vosaroxin combination arm were gastrointestinal and infection-related toxicities, consistent with those observed in our previous clinical trials. The rate of serious adverse events was 55.5% in the vosaroxin combination arm compared to 35.7% in the placebo and cytarabine arm. 30-day and 60-day all-cause mortality were comparable between the trial arms (7.9% versus 6.6% and 19.7% versus 19.4%, for the vosaroxin combination versus placebo and cytarabine, respectively).

**Phase 2 Combination.** The results from our completed Phase 1b/2 clinical trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML were published in the November 7, 2014 Ahead of Print issue of *Haematologica*. The article, titled "A Phase 1b/2 study of vosaroxin in combination with cytarabine in patients with relapsed or refractory acute myeloid leukemia," is available online at: <http://www.haematologica.org/content/100/2/231>.

The Phase 1b/2 study assessed the safety and tolerability of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML. Escalating vosaroxin doses (10-minute infusion; 10-90 mg/m<sup>2</sup> on days 1, 4) were given in combination with cytarabine on one of two schedules: schedule A (24-hour continuous intravenous infusion, 400 mg/m<sup>2</sup> per day on days 1-5) or schedule B (2-hour intravenous infusion, 1 g/m<sup>2</sup> per day on days 1-5). Following dose escalation, enrollment was expanded at the maximum tolerated dose. The maximum tolerated dose for schedule A was vosaroxin 80 mg/m<sup>2</sup> (dose-limiting toxicities: grade 3 bowel obstruction and stomatitis); the maximum tolerated dose was not reached for schedule B (recommended phase 2 dose: 90 mg/m<sup>2</sup>).

The median age in the study was 60 years, and patients had received as many as six prior cycles of therapy. Furthermore, most patients (89%) had intermediate or unfavorable cytogenetic risk status. The most common treatment-emergent non-hematologic adverse events of any grade were diarrhea, hypokalemia, nausea, and stomatitis. In the efficacy population, (all first relapsed or primary refractory patients treated with vosaroxin 80-90 mg/m<sup>2</sup>; n=69), the CR and combined CR rates (CR or CR with incomplete blood count recovery) were 25% and 28%, respectively. Thirty-day all-cause mortality was 2.5% among all patients treated at 80-90 mg/m<sup>2</sup>.

**Phase 2 Single-Agent.** The results from our completed Response Evaluation of Vosaroxin in Elderly AmL (REVEAL-1) trial, a Phase 2 trial of single agent vosaroxin in previously untreated, poor-risk elderly AML patients who are unlikely to benefit from standard induction chemotherapy, were published in the November 17, 2014 Online Version of Record of the *British Journal of Haematology*. The article, titled "REVEAL-1, a phase 2 dose regimen optimization study of vosaroxin in older poor-risk patients with previously untreated acute myeloid leukemia," is available online at: <http://onlinelibrary.wiley.com/doi/10.1111/bjh.13214/abstract>.

The REVEAL-1 trial evaluated single-agent vosaroxin in patients ≥60 years of age (n=113) with previously untreated unfavorable prognosis AML. Dose regimen optimization was explored in sequential cohorts (A: 72 mg/m<sup>2</sup> on days 1, 8, 15; B: 72 mg/m<sup>2</sup> on days 1, 8; C: 72 mg/m<sup>2</sup> or 90 mg/m<sup>2</sup> on days 1, 4). The primary efficacy endpoint was combined complete remission rate (CR plus CR with incomplete platelet recovery, or CRp). The median age in the study was 75 years and most patients (82%) had 2 or more risk factors (age ≥ 70, antecedent hematologic disease, ECOG PS=2, or intermediate/unfavorable cytogenetics).

Common (>20%) grade ≥3 adverse events were thrombocytopenia, febrile neutropenia, anemia, neutropenia, sepsis, pneumonia, stomatitis, and hypokalemia. Overall CR and CR/CRp rates were 29% and 32%; median overall survival was 7.0 months; 1-year overall survival was 34%. Schedule C (72 mg/m<sup>2</sup>) had the most favorable balance of safety and efficacy, with faster hematologic recovery (median 27 days) and lowest incidence of aggregate sepsis (24%) and 30-day (7%) and 60-day (17%) all-cause mortality. At this dose and schedule, CR and CR/CRp rates were 31% and 35%, median overall survival was 7.7 months, and 1-year overall survival was 38%.

**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/m<sup>2</sup> for a once weekly for three weeks schedule and 40 mg/m<sup>2</sup> for a twice weekly for two weeks schedule.

#### ***Vosaroxin Company-Sponsored Clinical Trials in Ovarian Cancer and Other Solid Tumors***

In 2010, we completed a Phase 2 single-agent trial of vosaroxin in platinum-resistant ovarian cancer. Three dosing levels in two treatment schedules were studied, and encouraging, durable anti-tumor activity was observed across all doses. For patients on dosing levels of 48, 60 and 75 mg/m<sup>2</sup>, the overall response rate 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/m<sup>2</sup> 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.

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 trials in non-small cell lung cancer and small cell lung cancer. Although objective responses were observed in both lung cancer trials, it was determined that vosaroxin could be administered with greater dose intensity given the low incidence of severe neutropenia and the trials were halted.

### ***Vosaroxin Investigator Sponsored Clinical Trials***

***MD Anderson.*** In July 2013, we announced the initiation of an investigator-sponsored trial of vosaroxin in combination with decitabine in older patients with previously untreated AML and high-risk MDS. The Phase 1/2 trial is being conducted at the University of Texas MD Anderson Cancer Center under the direction of Naval Daver, M.D., Assistant Professor, and Farhad Ravandi, M.D., Professor of Medicine and a principal investigator in the VALOR trial. The primary endpoints of the Phase 1 cohort of the study are to determine the safety, maximum tolerated dose (“MTD”), and dose limiting toxicity (“DLT”), of vosaroxin in combination with decitabine in patients with high-risk MDS or AML who are elderly and/or unable or unwilling to receive standard cytarabine plus anthracycline based chemotherapy. The primary endpoint of the Phase 2 cohort of the study is to determine the efficacy of the combination based on achievement of CR, and CR with incomplete blood count recovery (“Cri”). Secondary endpoints include safety, CR duration, leukemia-free survival, and overall survival. In October 2013, we announced the commencement of the Phase 2 portion of the study. In June 2016, results from this study were presented at the EHA Annual Meeting.

***Weill Cornell.*** In October 2013, we announced the initiation of a second investigator-sponsored trial of vosaroxin in adult patients with previously treated intermediate-2 or high-risk MDS. The trial is being conducted at Weill Cornell Medical College and New York-Presbyterian Hospital under the direction of Gail J. Roboz, M.D., Associate Professor of Medicine and Director of the Leukemia Program. The Phase 1/2, open-label, dose escalating trial is expected to enroll up to 40 patients with MDS who have previously failed treatment with hypomethylating agent-based therapy. Patient cohorts will initially receive escalating doses of vosaroxin over each 28 day treatment cycle. Once the MTD is determined, an expanded evaluation of safety and hematologic response or improvement rate at this dose level will be conducted in additional subjects, so that the total number of subjects exposed to this dose level increases to up to 15 subjects. In addition to MTD and DLT, study endpoints include the rate of complete remission, partial remission, hematologic improvement and blood transfusion requirements.

***Washington University.*** In December 2013, we announced the initiation of a third investigator-sponsored trial of vosaroxin in combination with azacitidine in patients with MDS. The trial is being conducted at the Washington University School of Medicine under the direction of Meagan A. Jacoby, M.D., Ph.D., Instructor of Medicine, Division of Oncology. The Phase 1/2, open label, dose-escalation trial will enroll up to approximately 40 patients with MDS who may have received up to three prior cycles of hypomethylating agent-based therapy. Patients will receive vosaroxin (days one and four) and azacitidine (days one through seven) for a maximum of six cycles. This dose escalation study is designed to enroll six patients per cohort in order to determine the MTD and DLT of the combination. Other endpoints include best response, safety, tolerability, and event-free, progression-free, disease-free and overall survival. Once the MTD is determined, up to an additional 20 patients will be enrolled, treated and evaluated at that dose level. In December 2015, we announced the preliminary results from the first 16 patients enrolled in this study at the ASH annual meeting.

***Vanderbilt University.*** In March 2016, we announced that the first patients have been treated in the investigator-sponsored VITAL (Vosaroxin and Infusional Cytarabine for Frontline Treatment of Acute Myeloid Leukemia) Phase 2 study of vosaroxin in combination with cytarabine in patients with previously untreated AML.

***Cardiff University School of Medicine.*** In December 2011, we announced our participation in the randomized Phase 2/3 Less Intensive 1 (LI-1) Study being conducted by the United Kingdom's National Cancer Research Institute (NCRI) Haematological Oncology Study Group under the direction of Professor Alan K. Burnett, Head of Haematology, Department of Medical Genetics, Haematology & Pathology at Cardiff University School of Medicine. The trial enrolled patients over the age of 60 with AML or high-risk MDS and randomized them to one of a number of treatment regimens: Low Dose Ara-C (control); single-agent vosaroxin; vosaroxin combined with Low Dose Ara-C; or to other experimental therapies considered for inclusion in the comparison. In 2013, at the first interim analyses, the Data Monitoring and Ethics Committee recommended closure of the vosaroxin-containing trial arms as a clinically relevant benefit was unlikely.

### ***SNS-062***

***Background.*** SNS-062 is a non-covalently binding inhibitor of BTK. BTK mediates signaling through the B-cell receptor (“BCR”), and is critical for adhesion, migration, proliferation and survival of normal and malignant B-lineage lymphoid cells. BTK has been well validated as a target for treatment of B-cell malignancies, with a BTK inhibitor approved for relapsed/refractory mantle cell lymphoma, newly diagnosed and relapsed/refractory chronic lymphocytic leukemia (“CLL”), CLL with 17p deletion, Waldenström’s macroglobulinemia and marginal zone lymphoma. This BTK inhibitor is covalent and forms an irreversible bond with cysteine residue 481 (C481) in the BTK kinase domain. This cysteine may mutate over time to a serine (“C481S”) and is associated with disease progression and resistance to further treatment with the approved covalent BTK inhibitor.

In 2015, we conducted IND-enabling studies for SNS-062, and in 2016 we conducted a Phase 1a healthy volunteer study in Belgium. The results of this study supported further development of SNS-062. In December 2016, we filed an IND with the FDA and



in January 2017, the IND was cleared to proceed by the FDA. The rights to develop SNS-062 for oncology indications were in-licensed from Biogen in December 2013, as described below.

*Mechanism of Action.* SNS-062 has inhibitory activity in vitro in BTK kinase assays and in B-cell signaling assays, as well as in vivo models of B-cell mediated diseases. The mechanism by which SNS-062 inhibits BTK is distinct from the mechanism of BTK inhibitor compounds, as SNS-062 binds BTK non-covalently, and does not interact with C481 of BTK. In addition, SNS-062 has a unique kinase selectivity profile and a favorable pharmacokinetics compared to covalently binding BTK inhibitors and this may translate to clinical benefit for patients.

*Development Opportunity.* SNS-062 has demonstrated distinct binding interaction and kinase selectivity profile, and favorable pharmacokinetic profile in preclinical studies, and may provide differentiated opportunities for treatment of B-cell malignancies and other blood cancers. Specifically, SNS-062 may have utility to treat CLL patients who have relapsed while being treated with a covalent BTK inhibitor primarily as a result of the C481S mutation.

#### **TAK-280 (formerly MLN2480)**

*Background.* A pan-Raf inhibitor program was originally developed through a collaboration agreement between Sunesis and Biogen. In March 2011, Biogen's rights to this program were purchased by and exclusively licensed to Takeda. In September 2011, Takeda initiated a Phase 1 clinical study of TAK-580, an oral, investigative drug selective for pan-Raf kinase inhibition, in patients with relapsed or refractory solid tumors. The Phase 1, multicenter, open-label, dose escalation study was designed to evaluate the safety, tolerability and MTD of TAK-580, and to be conducted in two stages: dose escalation and cohort expansion. The dose escalation stage is complete and MTD was established, and TAK-580 is now in the cohort expansion stage of this multicenter study. Four abstracts of preclinical and clinical data of TAK-580 were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in November 2014.

Under the license agreement, we may in the future receive up to \$57.5 million in pre-commercialization, event-based payments related to the development by Takeda of the first two indications for each of the licensed products directed against the Raf target, and royalty payments depending on related product sales, as further described below.

*Mechanism of Action.* The Raf kinases (A-Raf, B-Raf and C-Raf) are key regulators of cell proliferation and survival within the mitogen-activated protein kinase (MAPK) pathway.

*Development Opportunity.* TAK-580 is a pan-Raf kinase inhibitor with a distinct molecular signature that has exhibited a promising profile.

#### **SNS-229 and SNS-510**

*Background.* In January 2014, we in-licensed a series of selective PDK1 inhibitors from Takeda that were discovered under a research collaboration agreement between Biogen and Sunesis, as described below. PDK1 is a key kinase and mediator of PI3K/AKT signaling, a pathway involved in cell growth, differentiation, survival and migration. PDK1 inhibitors are expected to have unique effects on survival and invasion signaling and to be broadly active in both hematologic and solid tumor malignancies. We have taken a series of PDK1 inhibitors with confirmed antitumor activity in vitro and in vivo into preclinical development, and in 2014, we selected two PDK1 inhibitors, SNS-229 and SNS-510, of which are in pre-clinical ADME and safety studies.

*Mechanism of Action.* There are multiple PI3K pathway inhibitors in late stage development for use in CLL and solid tumor indications, including breast cancer and pancreatic cancer. Because PDK1-dependent activation of AKT is critical for PI3K pathway activation, we believe that PDK1 represents a key oncology target within the PI3K pathway. We believe Sunesis' PDK1 inhibitors are potential first-in-class compounds with demonstrated inhibition of AKT activity and a compelling in vitro and in vivo profile, that have potential for single agent and broad-spectrum combination activity, thus providing a novel therapeutic opportunity for targeting the PI3K signaling pathway in both solid and hematologic malignancies.

*Development Opportunity.* Inhibitors of PDK1 are expected to be able to provide similar clinical benefits to those observed with PI3K inhibitors and have the potential to provide additional benefits through inhibition of PI3K independent cancer signaling pathways, especially in cancer types in which PDK1 is overexpressed such as breast cancer and AML. We believe that Sunesis' PDK1 inhibitors can be differentiated from PI3K and PDK1 inhibitors currently in research and development and that may provide novel opportunities for treatment of solid and hematological malignancies.

## License, Collaboration and Royalty Agreements

### *In-license Agreement with Sumitomo*

In October 2003, we entered into an agreement with Sumitomo to acquire exclusive worldwide development and marketing rights for vosaroxin. In January 2011, we made a \$0.5 million milestone payment to Sumitomo as a result of the initiation of our VALOR trial in December 2010. In January 2016, we made an additional \$0.5 million milestone payment to Sumitomo as a result of the filing of our MAA. In the future we may be required to make additional milestone payments of up to \$6.5 million in aggregate to Sumitomo for (a) filing New Drug Applications (“NDA”), in the U.S. and Japan, and (b) for receiving regulatory approvals in these regions and the EU, for cancer-related indications. If vosaroxin is approved for a non-cancer indication, an additional milestone payment will become payable to Sumitomo.

The agreement also provides for royalty payments to Sumitomo at rates based on total annual net sales. Under the agreement, we may reduce our royalty payments to Sumitomo 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 Sumitomo. The agreement may be terminated by either party for the other party’s uncured breach or bankruptcy.

### *Licensing and Collaboration Agreements with Biogen and Takeda*

#### Overview

In August 2004, we entered into the original collaboration agreement with Biogen (the “Biogen OCA”) to discover, develop and commercialize small molecule inhibitors of the human protein Raf kinase, including family members Raf-1, A-Raf, B-Raf and C-Raf, (collectively “Raf”), and up to five additional targets that play a role in oncology and immunology indications such as BTK and PDK1.

In June 2008, 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 that date. We received a total of \$3.0 million in milestone payments for meeting certain preclinical milestones through the Biogen 1st ARCA date, as described below, including a \$1.5 million event-based payment received in cash in July 2009 for Biogen’s selection of a Raf kinase inhibitor development candidate for the treatment of cancer.

In March 2011, as part of a series of agreements among Sunesis, Biogen and Takeda, we entered into: (a) an amended and restated collaboration agreement with Biogen (“the Biogen Idec 1st ARCA”); (b) a license agreement with Millennium (“the Takeda Agreement”); and (c) a termination and transition agreement among the Sunesis, Biogen and Takeda (“the Termination and Transition Agreement”).

The Termination and Transition Agreement provided for (a) the termination of Biogen’s exclusive rights under the Biogen OCA to all discovery programs under such agreement other than for small molecule inhibitors of the human protein BTK; (b) the permitted assignment to Takeda of all related Sunesis collaboration assets and rights to Raf kinase and the human protein PDK1; and (c) the payment of \$4.0 million to us from Takeda, which was recorded as revenue in March 2011.

#### Biogen

The Biogen 1st ARCA amended and restated the Biogen OCA, to provide for the discovery, development and commercialization of small molecule BTK inhibitors. Under this agreement, we no longer have research obligations, but licenses granted to Biogen with respect to the research collaboration under the Biogen OCA (other than the licenses transferred to Takeda under the Takeda Agreement) remain in effect.

In June 2012, we received an event-based payment of \$1.5 million from Biogen for its advancement of pre-clinical work in connection with the Biogen 1st ARCA. 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 by Biogen of the first two indications for licensed products against the BTK target. We are also eligible to receive royalty payments depending on related product sales, which may be increased if we exercise our option to co-fund product candidates worldwide.

In December 2013, we entered into a second amended and restated collaboration agreement with Biogen (the “Biogen 2nd ARCA”), which amended and restated the Biogen 1st ARCA, to provide us with an exclusive worldwide license to develop, manufacture and commercialize SNS-062, a BTK inhibitor synthesized under the Biogen 1st ARCA, solely for oncology indications. Under the Biogen 2nd ARCA, we may be required to make a \$2.5 million milestone payment depending on our development of SNS-062 and royalty payments depending on related product sales of SNS-062. Additionally, potential future royalty payments to Sunesis were reduced to equal those amounts due to Biogen for potential future sales of SNS-062. All other of Sunesis’ rights contained in the Biogen 1st ARCA remain unchanged.

#### *Takeda*

Under the Takeda Agreement, we granted exclusive licenses to products against two oncology targets originally developed under the Biogen OCA, Raf and PDK1, under substantially the same terms as under the Biogen OCA.

In January 2014, we entered into an amended and restated license agreement with Takeda (“the Amended Takeda Agreement”), to provide us with an exclusive worldwide license to develop and commercialize preclinical inhibitors of PDK1. In connection with execution of the Amended Takeda Agreement, we paid an upfront fee and may in the future be required to make up to \$9.2 million in pre-commercialization milestone payments depending on our development of PDK1 inhibitors and royalty payments depending on related product sales.

With respect to the Raf target product rights that were originally licensed to Takeda under the Takeda Agreement, we may in the future receive up to \$57.5 million in pre-commercialization, event-based payments related to the development by Takeda of the first two indications for each of the licensed products directed against the Raf target and royalty payments depending on related product sales. The agreement also provides us with future co-development and co-promotion rights. Takeda is currently conducting a Phase 1 clinical study of an oral investigative drug, TAK-580, which is licensed to them under the Amended Takeda Agreement.

#### *Royalty Agreement with RPI*

In March 2012, we entered into a Revenue Participation Agreement (the “Royalty Agreement”), with RPI Finance Trust (“RPI”), an entity related to Royalty Pharma. In September 2012, as a result of the recommendation by the VALOR trial Data and Safety Monitoring Board 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 166,666 shares of our common stock, at exercise prices of \$20.88 and \$27.84 per share, respectively, adjusted for the 2016 reverse split. Of the \$25.0 million, \$21.9 million was recorded 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. Both warrants were exercised in full in 2014.

#### *Revenues*

Over the past three years, we have generated revenue through the Royalty Agreement with RPI and the Biogen 1st ARCA. In 2016, 2015 and 2014, we recognized \$2.4 million, \$2.9 million and \$5.7 million of revenue, respectively, related to the Royalty Agreement with RPI.

#### **Manufacturing**

We do not have internal manufacturing capabilities for the production of clinical or commercial quantities of vosaroxin and SNS-062. 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 and SNS-062 active pharmaceutical ingredients (“API”), and the finished drug products (“FDP”) incorporating the API. We have supply agreements with all 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.

In 2016 we performed process validation studies on API and FDP batches of vosaroxin. The results of these process validation studies met preset criteria. In 2017, we have manufactured one lot of commercial scale vosaroxin finished product. This lot is currently being evaluated for stability. There can be no assurances that this or future lots will meet stability requirements and if it does not, the commercial launch following approval in the EU, if any, of vosaroxin may be delayed.

We currently rely on one contract manufacturer for SNS-062 API and FDP. Third party contract manufacturing organizations are relied on to manufacture key starting materials and intermediates required in the manufacture of SNS-062 API. The manufacturing requires high purity materials to meet the final product specifications. A number of suitable manufacturers are available in North America for the manufacturing of API and FDP. There is limited manufacturing experience. Only two lots of API have been manufactured at a clinical scale. Scale-up to commercial scale has not been done. The cost to manufacture at large scale is unknown.

## **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, MDS and B-cell malignancies. 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, SNS-062 and any future product candidates 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;
- the availability of reimbursement from government agencies and private insurance companies; and
- acceptance of future products by physicians and other healthcare providers.

Vosaroxin is a small molecule therapeutic that, if approved, will compete with other drugs and therapies currently used for AML, such as nucleoside analogs, anthracyclines, hypomethylating agents, 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.

If approved, we expect competition for vosaroxin for the treatment of AML and other potential future indications 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.

## **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.

#### *Vosaroxin Patent Assets*

U.S. Patent No. 5,817,669 B2 covering the vosaroxin composition-of-matter and its counterpart patents in foreign jurisdictions have all expired. However, we are seeking and have been granted numerous patents relating to vosaroxin compositions, and uses and manufacture of vosaroxin, in the U.S and in Europe. In addition to our US and European patents, we have been granted similar and related patents in certain other countries, and patent applications are pending in these and other countries, including major markets, throughout the world. As of December 31, 2016, we own, co-own or have rights to approximately 148 granted U.S. and foreign patents, and approximately 120 pending U.S. and foreign applications, pertaining to vosaroxin and compositions and uses thereof. The expiries of these granted patents and patents that may be granted range from 2025 to 2030.

#### *SNS-062 Patent Assets*

US Patent Nos. 8,785,440 B2 and 9,249,146 B2 covering a genus of compounds including the SNS-062 composition-of-matter and methods of their use have counterpart pending applications or granted patents in the US and Europe (EPO) and other countries, with expiry in 2030. US Patent No. 9,394,277 B2 covering a subgenus of compounds including SNS-062 has counterpart pending applications or granted patents in the US and Europe (EPO) and other countries, with expiry in 2033. As of December 31, 2016, we own, co-own or have rights to approximately 148 granted U.S. and foreign patents, and approximately 120 pending U.S. and foreign applications, pertaining to SNS-062 and compositions and uses thereof. The expiries of these granted patents and patents that may be granted range from 2030 to 2037.

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 or control through licenses, we cannot guarantee that such additional protection will be obtained, and the expiration dates described here do not include such term restoration.

Moreover, when appropriate, we intend to seek 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, which may provide seven years of market exclusivity in the U.S. for the orphan-designated product for the orphan-designated indication.

Our ability to build and maintain our proprietary position for vosaroxin, SNS-062 and any future drug candidates, will depend on our success in obtaining effective claims and enforcing granted claims. 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. 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 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.

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 and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, efficacy, labeling, storage, recordkeeping, approval, advertising and promotion of our product candidates and any future drug candidates we may develop, if any. The application of these regulatory frameworks to the development, approval and commercialization of our drug candidates 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 any of our 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 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 ("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.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that approvals 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.

### ***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 ("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 ("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.
- *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 conditionally approve an NDA for a drug candidate on a sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and/or efficacy after NDA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials.

### ***New Drug Applications***

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee under the Prescription Drug User Fee Act ("PDUFA"), and the sponsor of an approved NDA is also subject to annual product and establishment user fees, which fees are typically increased annually.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the

FDA has committed to review most such applications for non-priority products within 10 months of filing, and most applications for priority review products, that is, drugs that the FDA determines represent a significant improvement over existing therapy, within six months of filing. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA. Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategies, or REMs, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

#### ***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.

In the European Union, orphan status is available for therapies addressing conditions that affect five or fewer out of 10,000 people, and provides for the potential for 10 years of marketing exclusivity in Europe for the orphan-designated product for the orphan-designated indication. 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. In April 2012, the European Commission granted orphan drug designation to vosaroxin for the treatment of AML.

#### ***Fast Track Designation***

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

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, Takeda, or our potential future licensees or collaboration partners, if any, pursuant to FDA approvals are subject to continuing regulation by the FDA, 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. 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. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

#### ***Reimbursement***

Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. These third-party payors have been increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. In particular, government entities have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our ability to achieve significant net sales and results. If these third-party payors do not

consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, implementation of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act (“ACA”), has substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government’s comparative effectiveness research. However, in January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, but it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

### ***Healthcare Law and Regulation***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict our business activities, including certain marketing practices. These laws include, without limitation, anti-kickback laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for either the referral of an individual, or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal healthcare program anti-kickback statute has been violated. Additionally, the intent standard under the federal healthcare program anti-kickback statute was amended by the ACA, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal healthcare program anti-kickback statute, the ACA amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.

Additionally, the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare & Medicaid Services (“CMS”), information related to certain payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. There also are an increasing number of local and state laws that require manufacturers to file reports with states regarding pricing and marketing information, such as tracking and reporting of gifts, compensation, other remuneration and items of value provided to health care professionals and health care entities, or marketing expenditures; require pharmaceutical companies to, among other things, establish and implement commercial compliance programs or codes of conducts; and/or require a pharmaceutical company’s sales representatives to be registered or licensed by the state or local governmental entity. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to a wide range of sanctions and penalties, potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, integrity obligations contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are unable to predict whether we would be subject to actions under these laws or the impact of such actions. However, the cost of defending any such claims, as well as any sanctions imposed, could adversely affect our financial performance and disrupt our business operations.

### ***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 our drug candidates. 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 ("MS"), and the applicable Ethics Committees ("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.

To obtain a marketing authorization of a drug in the European Union, we must submit an MAA under the centralized procedure. The centralized procedure provides for the grant of a single marketing authorization from the European Commission following a favorable opinion by the CHMP of the EMA that is valid in the European Economic Area (the "EEA"), which includes all European Union member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of specified diseases. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP.

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. A European Union orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once a marketing authorization is obtained for a pediatric indication in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years.

In addition to regulations in the United States and the European Union, 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 \$22.9 million, \$23.7 million and \$27.7 million of research and development expenses in 2016, 2015 and 2014, respectively, primarily related to the development of vosaroxin and SNS-062. We expect to continue to incur significant development expenses related to the development of vosaroxin and our other drug candidates.

## 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, 2016, our workforce consisted of 37 full-time equivalent employees, of which 21 are engaged in research and development and 16 are engaged in general and administrative, medical affairs and commercial planning 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. 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](http://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](http://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 (the "SEC"), and any references to our websites are intended to be inactive textual references only. The following filings are available through our website as soon as reasonably practicable 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](http://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 Annual Report on Form 10-K, as each of these risks could adversely affect our business, operating results and financial conditions. 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 pursue our regulatory strategy for the potential commercialization of QINPREZOTM (vosaroxin), and to continue the development of vosaroxin, SNS-062 and our other programs.*

We believe that with \$42.6 million in cash and investments held as of December 31, 2016, we currently have the resources to fund our operations through the first quarter of 2018.

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

- complete the development, regulatory strategy and potential commercialization of vosaroxin for AML in Europe and the United States;
- fund additional clinical trials of vosaroxin and SNS-062 and seek regulatory approvals, including additional clinical evidence the FDA recommended that we provide prior to any regulatory filing for vosaroxin in the United States;
- 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;
- need for additional or expanded clinical trials;
- timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- costs and timing of seeking and obtaining EMA, FDA or other regulatory approvals;
- extent of our other development activities, including our other clinical programs and in-license agreements;
- costs associated with building or accessing commercialization and additional manufacturing capabilities and supplies;
- costs of acquiring or investing in businesses, product candidates and technologies, if any;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- effect of competing technological and market developments; and
- costs of supporting our arrangements with Biogen, Takeda 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, SNS-062 or our other development programs, 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, SNS-062 or other development programs, potentially including any additional clinical trials or subsequent regulatory filings in Europe and the United States 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, 2016, 2015 and 2014 were \$38.0 million, \$36.7 million and \$43.0 million, respectively. As of December 31, 2016, we had an accumulated deficit of \$597.4 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 we seek regulatory approvals for vosaroxin, and as we prepare to 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. We currently have two agreements, the Biogen 2nd ARCA and the Amended Takeda Agreement, which each include certain pre-commercialization event-based and royalty payments. 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 until at least 2017, if at all. 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, SNS-062 or future product candidates 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 and/or SNS-062 could be halted or significantly delayed for various reasons; our clinical trials for vosaroxin and SNS-062 may not lead to regulatory approval.***

Our product candidates are vulnerable to the risks of failure inherent in the drug development process. Our VALOR trial failed to meet its primary endpoint, and we may not be able to obtain regulatory approval for commercialization for vosaroxin in any of the United States, Europe, or other regions. Based upon a meeting with the FDA held in July 2015, the FDA recommended that we provide additional clinical evidence prior to any regulatory filing in the United States. We may also 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 EMA and other regulatory authorities. Failure can occur 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, and the LI-1 trial, conducted by a co-operative group in Europe, was halted at an interim data analysis. 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 our product candidates are 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 any future clinical trials with vosaroxin, SNS-062 or any of our product candidates 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 EMA, 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 or ECs 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 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 and SNS-062 and any drugs to be tested in combination with vosaroxin or SNS-062;
- unforeseen safety issues;
- lack of efficacy during clinical trials;
- 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 and SNS-062 API and FDP to supply us with our vosaroxin and SNS-062 API and FDP. If we fail to obtain sufficient quantities of these materials, the development and potential commercialization of vosaroxin and SNS-062 could be halted or significantly delayed.***

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. The vosaroxin API is classified as a cytotoxic substance, limiting the number of available manufacturers for both API and FDP.

We currently rely on single contract manufacturers for the production of vosaroxin API and 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 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, EMA or other corresponding state agencies 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 and FDP needs for the foreseeable future.

Vosaroxin requires precise, high quality manufacturing. 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, EMA or other 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.

In 2016 we performed process validation studies on API and FDP batches of vosaroxin. The results of these process validation studies met preset criteria. In 2017, we have manufactured one lot of commercial scale vosaroxin finished product. This lot is currently being evaluated for stability. There can be no assurances that this or future lots will meet stability requirements and if it does not, the commercial launch following approval in the EU, if any, of vosaroxin may be delayed.

We currently rely on one contract manufacturer for SNS-062 API and FDP. Third party contract manufacturing organizations are relied on to manufacture key starting materials and intermediates required in the manufacture of SNS-062 API. The manufacturing requires high purity materials to meet the final product specifications. A number of suitable manufacturers are available in North America for the manufacturing of API and FDP. There is limited manufacturing experience. Only two lots of API have been manufactured at a clinical scale. Scale-up to commercial scale has not been done. The cost to manufacture at large scale is unknown.

***The failure to enroll patients for clinical trials may cause delays in developing vosaroxin and SNS-062.***

We may encounter delays if we are unable to enroll enough patients to complete clinical trials of vosaroxin or SNS-062. Based upon a meeting with the FDA held in July 2015 concerning vosaroxin, the FDA recommended that we provide additional clinical evidence prior to any regulatory filing in the United States, therefore we will need to enroll patients in the related clinical trial or trials and may also be required to enroll patients for additional clinical trials required by the EMA or other regulatory authorities. 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 for vosaroxin include nucleoside analogs, anthracyclines and hypomethylating agents. Competing treatments for SNS-062 include other BTK inhibitors, PI3K inhibitors, and several other drug classes. 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.

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

Prior to receiving approval to commercialize vosaroxin, SNS-062 or future product candidates in Europe, the United States or in other territories, we must demonstrate with substantial evidence from well-controlled clinical trials, to the satisfaction of the EMA, 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 based upon a meeting with the FDA held in July 2015, the FDA recommended that we provide additional clinical evidence prior to any regulatory filing for vosaroxin in the United States. Even if we believe preclinical or clinical data from preclinical studies and clinical trials are promising, such data may not be sufficient to support approval by the EMA, FDA and other regulatory authorities.



***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, SNS-062 or other product candidates.***

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 and SNS-062. 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 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 may expand our development capabilities in the future, 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 may expand our research and development capabilities in the future 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, SNS-062 or other product candidates.***

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 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, SNS-062 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, SNS-062 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, SNS-062 or other product candidates, 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, MDS and B-cell malignancies. 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, SNS-062 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;
- the availability of reimbursement from government agencies and private insurance companies; and
- acceptance of future products by physicians and other healthcare providers.

Vosaroxin is a small molecule therapeutic that, if approved, will compete with other drugs and therapies currently used for AML, such as nucleoside analogs, anthracyclines, hypomethylating agents, 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.

If approved, we expect competition for vosaroxin for the treatment of AML and other potential future indications 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, SNS-062 or future product candidates, if any.***

Our commercial success will depend on our ability to obtain patents and maintain adequate protection for vosaroxin, SNS-062 and any future product candidates in Europe, 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 or are subject to marketing exclusivity administered by regulatory authorities.

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, valid, or enforceable 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 complex legal and factual questions for which important legal principles remain unresolved. As a result, the scope, validity and enforceability of patents can vary from country to country, and can change depending on changes in national and international law, and as such, 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, 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;
- because of differences in patent laws of countries, any patent granted in one country or region will be granted in another, or, if so, have the same or a different scope;

- 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
- any patents or other proprietary rights of third parties 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 or collaborators, 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.

***While we have and continue to seek additional patent protection for vosaroxin, SNS-062 and other product candidates, and methods of their manufacture and use, even if one or more of our product candidates are approved by the EMA, FDA or their equivalents in other territories, we may not be able to recover our development costs for these programs prior to the expiration of any patents that are granted.***

The vosaroxin composition-of-matter was covered by U.S. Patent No. 5,817,669 B2 and its counterpart patents in foreign jurisdictions. These patents expired in 2015. We have been granted patents relating to vosaroxin compositions, uses of vosaroxin, and manufacture of vosaroxin, in the United States and other geographies. In addition to the granted US and European patents, we have been granted similar and related patents in certain other countries, and patent applications are pending in these and other countries, including major markets, throughout the world. In addition, other patents have been granted in the United States and other countries claiming certain technology related to vosaroxin and other methods of use of vosaroxin.

We are seeking and have been granted patents relating to the SNS-062 composition of matter, and compositions, and uses and manufacture of vosaroxin, in the U.S., Europe and other geographies, including major markets, throughout the world.

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 or control through licenses, we cannot guarantee that such additional protection will be obtained, and the expiration dates described here do not include such term restoration. However, patent expiration dates described here for U.S. patents may reflect patent term adjustments by the United States patent and Trademark Office or terminal disclaimers over related patents or patent applications.

We do not know when, if ever, vosaroxin, SNS-062 or other product candidates will be approved by the EMA, FDA or other regulatory authorities. Even if one or more of our products are approved for commercial marketing in the future, we may not have sufficient time to commercialize our products to enable us to recover our development costs prior to the expiration of the U.S. and foreign patents covering our products. 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 Sumitomo Dainippon Pharma Co., Ltd., the company from which we licensed vosaroxin, or Biogen, the company from which we licensed SNS-062, may extend beyond the patent expiration, which would further erode the profitability of our products. In addition, our potential obligation to pay RPI royalties on vosaroxin revenues pursuant to the Royalty Agreement would 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, SNS-062 and future product candidates, 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, by contracting with third parties or through collaborations with marketing partners, we will not be successful in commercializing our products.***

We currently have no sales or distribution capabilities and a limited marketing staff. If we receive favorable feedback from our regulatory discussion with the EMA or FDA and are able to pursue and obtain marketing approval for our products in Europe or the U.S., we may establish our own sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our products in these territories, which will be expensive and time consuming. Any failure or delay in the development of our internal or subcontracted 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 in certain territories as part of the commercialization of 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, SNS-062 or our future product candidates, 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, Takeda, 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 (“the Loan Agreement”), with Western Alliance Bank (Western Bank”) and Solar Capital Ltd (“Solar Capital”, and collectively with Western Bank, (“the Lenders”), contains a variety of affirmative covenants, including, without limitation, certain information delivery requirements, obligations to maintain certain insurance and certain notice requirements. Additionally, the Company is bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without the Lenders’ consent, including, without limitation, incurring certain additional indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any non-permitted lien or other encumbrance on the Company’s assets. Upon the occurrence of an event of default under the Loan Agreement (subject to cure periods for certain events of default), all amounts owed by the Company thereunder would begin to bear interest at a rate that is 5.0% higher than the rate that would otherwise be applicable and may be declared immediately due and payable by the Collateral Agent. Events of default under the Loan Agreement include, among other things, the following: the occurrence of certain bankruptcy events; the failure to make payments under the Loan Agreement when due; the occurrence of a material impairment on the Collateral Agent’s security interest over the collateral, a material adverse change in the business, operations or condition (financial or otherwise) of the Company or material impairment of the prospect of repayment of the obligations under the Loan Agreement; the occurrence of a default under certain other agreements entered into by the Company; the rendering of certain types of judgments against the Company; the revocation of certain government approvals of the Company; any breach by the Company of any covenant (subject to cure periods for certain covenants) made in the Loan Agreement; and the failure of any representation or warranty made by the Company in connection with the Loan Agreement to be correct in all material respects when made.

The Collateral Agent, for the benefit of the Lenders, has a perfected security interest in substantially all of the Company’s property, rights and assets, except for intellectual property, to secure the payment of all amounts owed to the Lenders under the Loan Agreement. Upon marketing approval of vosaroxin, the Collateral Agent, for the benefit of the Lenders, will also have a perfected security interest in the Company’s intellectual property rights relating to vosaroxin.

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.

***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 which occurred 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 recent sovereign debt crisis concerning certain European countries and related European financial restructuring efforts has and may continue to cause the value of the Euro to deteriorate. Such deterioration could adversely impact any investments we hold that are denominated in Euros. Rating agency downgrades on European sovereign debt and any potential default of European government issuers further contribute 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, or interruption by man-made problems such as network security breaches, viruses or terrorism, 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. Despite the implementation of network security measures, our networks also may be vulnerable to computer viruses, break-ins and similar disruptions. We rely on information technology systems to operate our business and to communicate among our workforce and with third parties. If any disruption were to occur, whether caused by a natural disaster or by manmade problems, 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 or other product candidates.***

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 Europe or the United States until we receive approval of an MAA or NDA for these respective territories, or in any other country without the equivalent marketing approval from such country. We have not received marketing approval for vosaroxin or SNS-062 in any jurisdiction. In addition, failure to comply with EMA, 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 MAAs, NDAs, supplements to approved MAAs, NDAs or their equivalents in other territories.

Regulatory approval of an MAA or NDA or their equivalent in other territories 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, the VALOR trial failed to meet its primary endpoint, and in July 2015, the FDA recommended that we provide additional clinical evidence before any regulatory filing for vosaroxin for the treatment of AML in the United States.

The EMA, FDA or other 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 EMA, FDA or other foreign regulatory authority might not approve our or our third-party manufacturers' processes or facilities; or
- the EMA, FDA or other 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, SNS-062 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, 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 or other product candidates, the market may not be receptive.***

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, Phase 2 and VALOR 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 or other product candidates fail 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 or any other future product candidate, we will be subject to ongoing EMA, FDA and other regulatory obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize vosaroxin or any other future product candidate.***

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 manufacturing, 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.

The FDA and other agencies, including the Department of Justice (“DOJ”), closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers’ communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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 Europe, the United States or other territories. 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. Other penalties for failing to comply with regulatory requirements include restrictions on such products, manufacturers or manufacturing processes; restrictions on the labeling or marketing of a product; restrictions on distribution or use of a product; requirements to conduct post-marketing studies or clinical trials; warning letters or untitled letters; withdrawal of the products from the market; refusal to approve pending applications or supplements to approved applications that we submit; recall of products; damage to relationships with any potential collaborators; unfavorable press coverage and damage to our reputation; fines, restitution or disgorgement of profits or revenues; suspension or withdrawal of marketing approvals; refusal to permit the import or export of our products; product seizure; injunctions or the imposition of civil or criminal penalties; and litigation involving patients using our products. Additionally, failure to comply with the European Union's requirements regarding the protection of personal information also can lead to significant penalties and sanctions.

***The coverage and reimbursement status of newly approved drugs is uncertain and may be impacted by current and future legislation, and failure to obtain adequate coverage and reimbursement could limit our ability to market our product candidates 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, in the United States and some foreign jurisdictions, there have been a number of legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs that could result in lower prices or rejection of our future products. Changes in coverage and reimbursement policies or healthcare cost containment initiatives that may limit or restrict reimbursement for our future products may reduce any future product revenue.

For example, the ACA, signed into law in 2010, substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research. However, in January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, but it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any future approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.



***Our relationships with healthcare providers, clinical investigators, and third party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, clinical investigators, and third party payors will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current future arrangements with healthcare providers, clinical investigators and third party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable state, federal and foreign healthcare laws and regulations include the following:

- The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for either the referral of an individual, or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs;
- Federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid;
- HIPAA imposes criminal and civil liability prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, among other things, makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity; created four new tiers of civil monetary penalties; amended HIPAA to make civil and criminal penalties directly applicable to business associates; and gave state attorneys general new authority to file civil actions to enforce the federal HIPAA laws;
- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; and
- analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws, transparency statutes, and privacy and security laws. Such laws may be broader than the federal law, including that they may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third party payors, including private insurers. There also are an increasing number of state laws that require manufacturers to file reports with states regarding pricing and marketing information, such as tracking and reporting of gifts, compensation, other remuneration and items of value provided to health care professionals and health care entities, or marketing expenditures; require pharmaceutical companies to, among other things, establish and implement commercial compliance programs or codes of conducts; and/or require a pharmaceutical company's sales representatives to be registered or licensed by the state or local governmental entity. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to a wide range of sanctions and penalties, including potentially significant criminal, and civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, integrity obligations contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are unable to predict whether we would be subject to actions under these laws or the impact of such actions. However, the cost of defending any such claims, as well as any sanctions imposed, could adversely affect our financial performance and disrupt our business operations.

***Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing vosaroxin or other product candidates 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. Except for in the European Union, we have had, and potential future collaboration partners may have, 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 materially from country to country, including in the European Union. Any 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 Europe, the United States and other 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 2016, our common stock traded as low as \$2.63 and as high as \$6.30. 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 and SNS-062, including investigator-sponsored trials;
- announcements of additional FDA requirements for a regulatory path for vosaroxin or non-approval of vosaroxin, such as the July 2015 request that we provide additional clinical evidence prior to any regulatory filing in the United States;
- delays in filing regulatory documents with the EMA, FDA or other regulatory agencies, or delays in the review process by the EMA, FDA or other foreign regulatory agencies;
- announcements relating to restructuring and other operational changes;
- delays in the commercialization of vosaroxin, SNS-062 or our future products, if any;
- our ability to complete a commercialization agreement for vosaroxin in Europe on satisfactory terms;

- 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;
- 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 or SNS-062 drug substance or drug product, or future products, if any;
- market acceptance of vosaroxin, SNS-062 or our future products, if any;
- announcements relating to our arrangements with Biogen, Takeda 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;
- EMA, FDA or other European, 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

***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.

*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**

Our corporate headquarters is currently located at 395 Oyster Point Boulevard in South San Francisco, California. In January 2014, we entered into a lease for 15,378 square feet of office space at this location. We amended the lease in June 2014 to add 6,105 square feet of additional office space within the same building. We last amended the lease in May 2016 to extend the expiration date to June 30, 2018.

**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, effected on September 7, 2016.

<b>Year-Ended December 31, 2015</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 17.64	\$ 11.40
Second Quarter	\$ 18.84	\$ 12.06
Third Quarter	\$ 22.32	\$ 4.44
Fourth Quarter	\$ 6.60	\$ 4.68
<b>Year-Ended December 31, 2016</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 5.73	\$ 2.70
Second Quarter	\$ 3.84	\$ 2.63
Third Quarter	\$ 6.30	\$ 2.99
Fourth Quarter	\$ 5.00	\$ 3.41

As of February 28, 2017, there were approximately 141 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, 2017, the last sale price reported on The NASDAQ Stock Market for our common stock was \$4.21 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 the Lenders, we are precluded from paying cash dividends without the prior written consent of the lenders.

#### ***Recent Sales of Unregistered Securities***

Except as previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the Securities and Exchange Commission during the year ended December 31, 2016, there were no unregistered sales of equity securities by us during the year ended December 31, 2016.

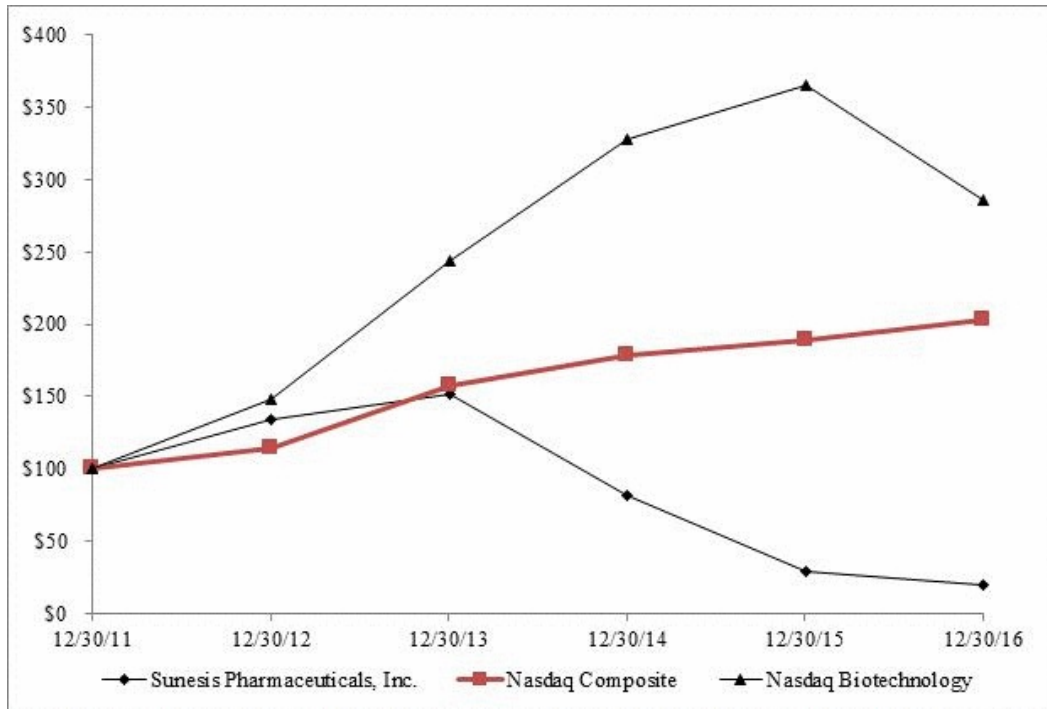
#### ***Stock Performance Graph***

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, 2011 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 (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 December 31, 2011 in stock or index, including reinvestment of any dividends.

**ITEM 6. SELECTED FINANCIAL DATA**

The following selected consolidated financial data should be read together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2016 and 2015 and the selected consolidated statements of operations data for each year ended December 31, 2016, 2015 and 2014 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2014, 2013, and 2012 and the selected consolidated statements of operations data for the years ended December 31, 2013 and 2012 have been derived from our audited consolidated financial statements not included in this report. Historical results are not necessarily indicative of the results to be expected in the future.

Consolidated Statements of Operations:	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands, except per share amounts)				
Revenue:					
License and other revenue	\$ 2,536	\$ 3,061	\$ 5,734	\$ 7,956	\$ 3,754
Total revenues	<u>2,536</u>	<u>3,061</u>	<u>5,734</u>	<u>7,956</u>	<u>3,754</u>
Operating expenses:					
Research and development	22,881	23,701	27,665	28,891	29,185
General and administrative	16,115	18,662	23,112	10,838	9,175
Total operating expenses	<u>38,996</u>	<u>42,363</u>	<u>50,777</u>	<u>39,729</u>	<u>38,360</u>
Loss from operations	(36,460)	(39,302)	(45,043)	(31,773)	(34,606)
Interest expense	(1,721)	(939)	(1,719)	(2,917)	(1,855)
Other income (expense), net(1)	158	3,565	3,760	92	(7,490)
Net loss	<u>\$ (38,023)</u>	<u>\$ (36,676)</u>	<u>\$ (43,002)</u>	<u>\$ (34,598)</u>	<u>\$ (43,951)</u>
Basic and diluted loss per common share:					
Net loss:					
Basic	\$ (38,023)	\$ (36,676)	\$ (43,002)	\$ (34,598)	\$ (43,951)
Diluted	\$ (38,023)	\$ (36,676)	\$ (46,894)	\$ (34,598)	\$ (43,951)
Shares used in computing net loss per common share:					
Basic	15,688	12,156	10,010	8,024	7,735
Diluted	15,688	12,156	10,252	8,024	7,735
Net loss per common share:					
Basic	<u>\$ (2.42)</u>	<u>\$ (3.02)</u>	<u>\$ (4.30)</u>	<u>\$ (4.31)</u>	<u>\$ (5.68)</u>
Diluted	<u>\$ (2.42)</u>	<u>\$ (3.02)</u>	<u>\$ (4.57)</u>	<u>\$ (4.31)</u>	<u>\$ (5.68)</u>

- (1) During 2016, 2015, 2014, 2013 and 2012, we recorded net non-cash credits (charges) of nil, \$3.5 million, \$3.9 million, \$0.1 million and \$(7.5) million, respectively, related to the revaluation of the liability for warrants issued in connection with the underwritten public offering of our common stock in October 2010 (see Note 10 of the accompanying consolidated financial statements).

Consolidated Balance Sheet Data:	As of December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
Cash, cash equivalents and marketable securities	\$ 42,588	\$ 46,430	\$ 42,981	\$ 39,293	\$ 71,227
Working capital	32,292	27,989	16,323	6,520	41,191
Total assets	<u>43,234</u>	<u>47,002</u>	<u>44,246</u>	<u>40,525</u>	<u>73,017</u>
Non-current portion of deferred revenue	—	610	2,563	3,712	11,668
Current portion of notes payable	3,333	7,834	9,257	9,018	6,610
Non-current portion of notes payable	11,102	—	—	9,025	17,651
Convertible preferred stock	18,808	16,459	—	—	—
Common stock and additional paid-in capital	599,634	570,318	536,506	473,514	457,016
Accumulated deficit	(597,396)	(559,373)	(522,697)	(479,695)	(445,097)
Total stockholders' equity (deficit)	<u>21,024</u>	<u>27,393</u>	<u>13,802</u>	<u>(6,184)</u>	<u>11,957</u>

## 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, 2016 and results of operations for the year ended December 31, 2016 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, Section 21E of the Exchange Act, and the Private Securities Litigation Reform Act of 1995, 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 receiving approval of vosaroxin from the European Medicines Agency, our regulatory and clinical strategies for gaining marketing approval in the United States, our marketing plans and commercialization strategies for vosaroxin, if approved, and the commercial potential of vosaroxin in Europe and clinical development of SNS-062, 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

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 January 2014, we announced the expansion of our oncology pipeline through separate global licensing agreements for two preclinical kinase inhibitor programs. The first agreement, with Biogen Idec MA, Inc., "Biogen," is for global commercial rights to SNS-062, a selective non-covalently binding oral inhibitor of BTK. We filed a Clinical Trial Authorization application in the first quarter of 2016 in Belgium and enrolled the first patients in a Phase 1A study of SNS-062 in healthy volunteers. In September and again in December 2016, we announced results from the Company's Phase 1A study in healthy volunteers evaluating oral non-covalent, reversible BTK inhibitor SNS-062. The study demonstrated a favorable safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile for SNS-062 in healthy subjects. In December 2016 we filed an Investigational New Drug ("IND") application with the FDA to conduct a Phase 1B/2 trial in patients with various B-cell malignancies, and in January 2017 the IND was cleared to proceed.

The second agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda, is for global commercial rights to several potential first-in class, pre-clinical inhibitors of the novel target PDK1. In 2014, we selected two PDK1 inhibitors, SNS-229 and SNS-510, which are currently being evaluated in pre-clinical absorption, distribution, metabolism and excretion, and toxicology studies.

Both BTK and PDK1 programs were originally developed under a research collaboration agreement between Biogen and Sunesis. In 2011, Biogen exclusively licensed the PDK1 program to Takeda along with the more advanced program, TAK-580. We currently expect that SNS-062, SNS-510 and SNS-229 will be developed exclusively by Sunesis for the foreseeable future.

In addition, we are in a collaboration with Takeda for the development of TAK-580 (formerly MLN2480), an oral pan-RAF inhibitor, for which Takeda is conducting a multi-arm, open-label Phase 1B study in combination with nivolumab, a PD-1 checkpoint inhibitor; TAK-228, an oral mTORC 1/2 inhibitor; alisertib, an oral aurora A kinase inhibitor; and several chemotherapeutic agents, in adult patients with advanced non-hematologic malignancies.



Our most advanced program is QINPREZO™ (vosaroxin), our product candidate for the potential treatment of acute myeloid leukemia (“AML”). Vosaroxin is an anticancer quinolone derivative (“AQD”)—a class of compounds that has not been used previously for the treatment of cancer.

In October 2014, we announced the results of a Phase 3, multi-national, randomized, double-blind, placebo-controlled trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML, or the VALOR trial. Detailed results of the VALOR trial were presented in the “Late Breaking Abstracts” session of the American Society of Hematology (“ASH”) Annual Meeting in December 2014 and additionally published in the September 2015 issue of *The Lancet Oncology*.

The VALOR trial did not meet its primary endpoint of demonstrating a statistically significant improvement in overall survival, but based upon the favorable results of other predefined analyses of the data, in November 2014, we submitted a letter of intent to the European Medicines Agency (“EMA”), describing our intention to file a marketing authorization application (“MAA”), for marketing authorization of vosaroxin plus cytarabine for the treatment of relapsed or refractory AML in the European Union. In June 2015, we met separately with our Rapporteur and Co-Rapporteur, who are two appointed members of the EMA’s Committee for Medicinal Products for Human Use (“CHMP”). Based upon feedback from these meetings, we filed an MAA with the EMA at the end of 2015. In April 2016 we received a list of questions relating to our MAA filing (the “Day 120 Questions”) We responded to these questions in October 2016 and in December 2016 we received a list of outstanding issues (the “Day 180 LOI”) We are currently in the process of preparing responses to the Day 180 LOI. In July 2015, we met with the U.S. Food and Drug Administration (the “FDA”), to discuss a potential regulatory filing in the U.S. Based upon the meeting, the FDA recommended that we provide additional clinical evidence prior to any regulatory filing in the U.S. As a result, we are evaluating regulatory and clinical strategies with the goal of gaining future marketing approval in the U.S.

## **Recent Financial History**

### ***Equity Financing Agreements***

In October 2016, we completed underwritten offering of (i) 5,675,825 shares of our common stock at a price of \$3.85 per share, and (ii) 1,558 shares of our non-voting Series C Convertible Preferred Stock (“Series C Stock”) at a price of \$3,850.00 per share. Gross proceeds from the sale were \$27.9 million and net proceeds were \$25.9 million. Each share of non-voting Series C Stock is convertible into 1,000 shares of our common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then outstanding.

In December 2015, we completed underwritten offering of (i) 1,832,698 shares of our common stock, that included the exercise of the underwriter’s over-allotment option of 239,047 shares, at a price of \$5.04 per share (as adjusted for the Reverse Split), and (ii) 20,200 shares of our non-voting Series B Convertible Preferred Stock (“Series B Stock”) at a price of \$840.00 per share. Gross proceeds from the sale were \$26.2 million and net proceeds were \$25.2 million. Each share of non-voting Series B Stock is convertible into 166 shares of our common stock (as adjusted for the Reverse Split), provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then outstanding.

In August 2011, we entered into a Controlled Equity Offering<sup>SM</sup> sales agreement (“the Sales Agreement”), with Cantor Fitzgerald & Co. (“Cantor”), as agent and/or principal, pursuant to which we could issue and sell shares of our common stock having an aggregate gross sales price of up to \$20.0 million. In April 2013, the Sales Agreement was amended to provide for an increase of \$30.0 million in the aggregate gross sales price under the Sales Agreement. We will pay Cantor a commission of up to 3.0% of the gross proceeds from any common stock sold through the Sales Agreement, as amended.

During 2016, we sold an aggregate of 57,000 shares of common stock under the Sales Agreement, as amended, at an average price of approximately \$4.73 per share for gross proceeds and net proceeds of \$0.3 million, after deducting Cantor’s commission. As of February 28, 2017, \$17.9 million of common stock remained available to be sold under the Sales Agreement, as amended, subject to certain conditions as specified in the agreement.

### ***Loan Agreement***

On March 31, 2016, we entered into the Loan Agreement with the Lenders and Western Alliance, as Collateral Agent (the “Collateral Agent”). Pursuant to the terms of the Loan Agreement, the Lenders provided us with a loan in the principal amount of \$15,000,000 of which \$12,500,000 was funded on March 31, 2016 and \$2,500,000 was funded on April 1, 2016, for working capital, to fund our general business requirements and to repay our indebtedness to Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation (collectively, the “Existing Lenders”) pursuant to the Loan and Security Agreement, dated as of October 18, 2011, entered into by and among the Existing Lenders and us (the “Oxford Loan Agreement”). On March 31, 2016, we used \$7.2 million of the loan proceeds to repay the outstanding principal of \$6.0 million, a final payment fee of \$1.2 million and accrued interest of \$45,000 under the Oxford Loan Agreement. We paid the Lenders a \$0.1 million facility fee and \$0.1 million in legal fees.

### **Capital Requirements**

We have incurred significant losses in each year since our inception. As of December 31, 2016, we had cash, cash equivalents and marketable securities of \$42.6 million and an accumulated deficit of \$597.4 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 will need to raise substantial additional capital to complete the development and potential commercialization of vosaroxin and future product candidates, 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 or our other development programs, 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 any regulatory filings related to 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.

Our significant accounting policies are more fully described in Note 2 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.

#### ***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* (“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.

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 (“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.

### ***Stock-Based Compensation***

We grant options to purchase common stock to our employees, directors and consultants under our equity incentive plans. Under our employee stock purchase plan, eligible employees can also purchase shares of our common stock at 85% of the lower of the fair market value of our 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.

We value these share-based awards using 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 our stock price as well as assumptions regarding a 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, which require significant analysis and judgment to develop.

### **Overview of Revenues**

We have not generated any revenue from the sale of commercial products, and do not anticipate product sales until at least 2016, if at all. Over the past three years, we have generated revenue primarily through the Royalty Agreement with RPI, and the license and collaboration agreement with Biogen. We cannot predict whether we will receive any additional event-based payments or royalties from these agreements, as amended, 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 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.

The table below sets forth our research and development expense by program for each period presented:

	Year ended December 31,		
	2016	2015	2014
	(in thousands)		
Vosaroxin	\$ 16,220	\$ 20,204	\$ 23,999
SNS-062	4,374	1,211	2,667
SNS-229 & SNS-510	2,287	2,286	999
Total	<u>\$ 22,881</u>	<u>\$ 23,701</u>	<u>\$ 27,665</u>

Vosaroxin development is currently focused on 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. If we proceed to commercialization following the approval of either an MAA filing with the EMA or an NDA filing with the FDA, research and development costs may increase in the future. As of December 31, 2016, we had incurred \$219.1 million of expenses in the development of vosaroxin since it was licensed from Sumitomo in October 2003. We may continue to incur significant expenses related to the development of vosaroxin in 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.

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.

As of December 31, 2016 we incurred a total of \$13.4 million of development expenses associated with advancing the SNS-062 and SNS-229 and SNS-510 programs, and anticipate significantly increased expenditures on these programs in 2017 and beyond. Additionally, under the Takeda Agreement, we have the right to participate in co-development and co-promotion activities for the related product candidates, including TAK-580, a pan-RAF inhibitor currently in the maximum tolerated dose cohort expansion stage of a Takeda Phase 1, multicenter dose escalation study. If we were to exercise our option on this or other product candidates, our research and development expense would increase significantly.

*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. If we proceed to commercialization in either Europe or the United States following our regulatory approval with the EMA and FDA, we anticipate general and administrative expenses to increase in the future, including additional costs related to selling and marketing.

## **Results of Operations**

### *Years Ended December 31, 2016 and 2015*

*Revenue.* Total revenue was \$2.5 million in 2016 as compared to \$3.1 million in 2015, primarily due to deferred revenue recognized related to the Royalty Agreement with RPI in each period. Deferred revenue recognized under the Royalty Agreement was lower in 2016 than in 2015 due to the change in the end date of the estimated performance period through which the balance of deferred revenue will be amortized from June 30, 2015 to March 31, 2017.

*Research and development expense.* Research and development expense was \$22.9 million in 2016 as compared to \$23.7 million in 2015, primarily relating to the vosaroxin development program in each year. The decrease of \$0.8 million in 2016 was primarily due to a decrease of \$2.2 million in personnel costs (including a decrease of \$1.2 million in stock-based compensation expense), \$0.2 million in office and related expenses, partially offset by increases of \$0.6 million in clinical trial expenses, \$0.5 million in professional services and \$0.5 million in medical affairs expenses.

*General and administrative expense.* General and administrative expense was \$16.1 million in 2016 as compared to \$18.7 million in 2015. The decrease of \$2.6 million in 2016 was primarily due to decreases of \$1.8 million in professional services costs, \$1.1 million in personnel costs due to reduction in headcount, partially offset by \$0.3 million in office and related expenses.

*Interest expense.* Interest expense was \$1.7 million in 2016 as compared to \$0.9 million in 2015. The increase in 2016 was due to the interest expense to the Lenders under the Loan Agreement.

*Other income, net.* Net other income was \$0.2 million in 2016 as compared to \$3.6 million in 2015. The 2015 amount was primarily comprised of a net non-cash credit for the revaluation of warrants issued in the 2010 Offering.

### *Years Ended December 31, 2015 and 2014*

*Revenue.* Total revenue was \$3.1 million in 2015 as compared to \$5.7 million in 2014, primarily due to deferred revenue recognized related to the Royalty Agreement with RPI in each period.

*Research and development expense.* Research and development expense was \$23.7 million in 2015 as compared to \$27.7 million in 2014, primarily relating to the vosaroxin development program in each year. The decrease of \$4.0 million in 2015 was primarily due to a decrease of \$5.4 million in clinical trial expenses, partially offset by increases of \$0.9 million in personnel costs (including an increase of \$0.5 million in stock-based compensation expense), and \$0.5 million in other outside services and consulting costs.

*General and administrative expense.* General and administrative expense was \$18.7 million in 2015 as compared to \$23.1 million in 2014. The decrease of \$4.5 million in 2015 was primarily due to decreases of \$2.3 million in professional services costs and \$2.2 million in personnel costs due to reduction in headcount.

*Interest expense.* Interest expense was \$0.9 million in 2015 as compared to \$1.7 million in 2014. The decrease in 2015 was due to the reduced principal balance outstanding on notes payable to the Lenders under the Loan Agreement.

*Other income, net.* Net other income was \$3.6 million in 2015 as compared to \$3.8 million in 2014. The 2014 amount was primarily comprised of a net non-cash credit for the revaluation of warrants issued in the 2010 Offering.

## **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 in other income (expense), net in the statements of operations and comprehensive loss.

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, 2016, we had net operating loss carry-forwards for federal and state income tax purposes of \$413.2 million and \$267.1 million, respectively. We also had federal and state research and development tax credit carry-forwards of \$8.2 million and \$7.2 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 began to expire in 2015. 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 (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 and other equity instruments, debt financings, 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 \$42.6 million as of December 31, 2016, as compared to \$46.4 million as of December 31, 2015. The decrease of \$3.8 million was primarily due to \$37 million of net cash used in operating activities and \$7.2 million of final payments against notes payable and \$0.8 million of principal payments against notes payable, partially offset by net proceeds of \$25.9 million from the underwritten offering and \$14.8 million in net loan proceeds, and \$0.3 million from the sale of our common stock through the Sales Agreement with Cantor and exercise of stock options.

In October 2016, we completed underwritten offering of (i) 5,675,825 shares of our common stock at a price of \$3.85 per share, and (ii) 1,558 shares of our non-voting Series C Stock at a price of \$3,850.00 per share. Gross proceeds from the sale were \$27.9 million and net proceeds were \$25.9 million. Each share of non-voting Series C Stock is convertible into 1,000 shares of our common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then outstanding.

In December 2015, we completed underwritten offering of (i) 1,832,698 shares of our common stock, that included the exercise of the underwriter's over-allotment option of 239,047 shares, at a price of \$5.04 per share (as adjusted for the Reverse Split), and (ii) 20,200 shares of our non-voting Series B Convertible Preferred Stock ("Series B Stock") at a price of \$840.00 per share. Gross proceeds from the sale were \$26.2 million and net proceeds were \$25.2 million. Each share of non-voting Series B Stock is

convertible into 166 shares of our common stock (as adjusted for the Reverse Split), provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then outstanding.

During 2016, we sold an aggregate of 57,000 shares of common stock under the Sales Agreement, as amended, at an average price of approximately \$4.73 per share for gross and net proceeds of \$0.3 million, after deducting Cantor's commission. As of December 31, 2016, \$17.9 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the agreement.

### ***Cash Flows***

Net cash used in operating activities was \$37.0 million in 2016, as compared to \$38.7 million in 2015 and \$43.2 million in 2014. Net cash used in operating activities in 2016 resulted primarily from the net loss of \$38.0 million and net adjustment for the non-cash items of \$5.2 million (including \$4.8 million for stock-based compensation) offset by changes in operating assets and liabilities of \$4.1 million (including \$2.4 million related to recognition of deferred revenue under the Royalty Agreement). Net cash used in operating activities in 2015 resulted primarily from the net loss of \$36.7 million and changes in operating assets and liabilities of \$5.0 million (including \$2.9 million related to recognition of deferred revenue under the Royalty Agreement), partially offset by net adjustments for non-cash items of \$3.0 million (including expenses of \$6.3 million for stock-based compensation and a \$3.5 million credit for the revaluation of warrants issued in the 2010 Offering). Net cash used in operating activities was \$43.2 million in 2014, as compared to \$37.4 million in 2013. Net cash used in 2014 resulted primarily from the net loss of \$43.0 million and changes in operating assets and liabilities of \$2.9 million (including \$5.7 million related to recognition of deferred revenue under the Royalty Agreement), partially offset by net adjustments for non-cash items of \$2.7 million (including expenses of \$6.2 million for stock-based compensation and a \$3.9 million credit for the revaluation of warrants issued in the 2010 Offering).

Net cash used in investing activities was \$15.0 million in 2016 and \$1.3 million in 2015, as compared to \$3.3 million provided by investing activities in 2014. Net cash used in 2016 and 2015 consisted primarily of purchases of marketable securities, partially offset by proceeds from maturities of marketable securities. Net cash provided in 2014 consisted primarily of proceeds from maturities of marketable securities, partially offset by purchases of marketable securities.

Net cash provided by financing activities was \$33.1 million in 2016, as compared to \$42.2 million in 2015 and \$46.9 million in 2014. Net cash provided in 2016 resulted primarily from net proceeds of \$25.9 million from the underwritten offering and \$14.7 million in net loan proceeds, and \$0.4 million from the sale of our common stock through the Sales Agreement with Cantor and exercise of stock options, partially offset by \$7.2 million of final payments against notes payable and \$0.8 million of principal payments against notes payable. Net cash provided in 2015 resulted primarily from net proceeds of \$25.2 million from the underwritten offering, \$18.1 million from sales of our common stock through Cantor and \$0.5 million from the exercise of warrants, stock options and stock purchase rights, partially offset by \$1.6 million of principal payments against notes payable. Net cash provided in 2014 resulted primarily from net proceeds of \$40.0 million from the underwritten offering, \$14.3 million from sales of our common stock through Cantor and \$2.0 million from the exercise of warrants, stock options and stock purchase rights, partially offset by \$9.4 million of principal payments against notes payable.

### ***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, EMA, 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, SNS-062 and future product candidates. 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;
- 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 EMA, FDA, or other regulatory approvals;
- the extent of our other development activities, including our in-license agreements;

- 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 and Takeda.

We believe that we currently have the resources to fund our operations through the first quarter of 2018. We will need to raise substantial additional capital to complete the development and potential commercialization of vosaroxin and SNS-062. Until we can generate a sufficient amount of licensing or collaboration or product revenue to finance our cash 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 and SNS-062, 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 any additional clinical trials or regulatory filings in Europe or United States, 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 contractual obligations as of December 31, 2016 (in thousands):

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	After 5 Years
Debt obligations(1)	\$ 18,180	\$ 4,638	\$ 11,281	\$ 2,261	\$ —
Operating lease obligations(2)	\$ 986	\$ 654	\$ 332	\$ —	\$ —

- (1) Upon the occurrence of an event of default under the Loan Agreement (subject to cure periods for certain events of default), all amounts owed by the Company thereunder would begin to bear interest at a rate that is 5.0% higher than the rate that would otherwise be applicable and may be declared immediately due and payable by the Collateral Agent. A final payment equal to 3.75% of the original principal amount borrowed will be due upon maturity or such earlier date specified in the Loan Agreement. We may elect to prepay all amounts owed under the Loan Agreement prior to the maturity date therefore, subject to a prepayment fee equal to 2.0% of the amount prepaid if the prepayment occurs on or prior to March 31, 2017, 1.0% of the amount prepaid if the prepayment occurs after March 31, 2017 but on or prior to March 31, 2018 and 0.5% of the amount prepaid if the prepayment occurs thereafter.
- (2) Operating lease obligations relate solely to the leasing of office space in a building at 395 Oyster Point Boulevard in South San Francisco, California, which is currently our corporate headquarters. In January 2014, we entered into a lease for 15,378 square feet with an expiration date of April 30, 2015. In June 2014, we amended the lease to add 6,105 square feet of additional office space within the same building. We last amended the lease in May 2016 to extend the expiration date to June 30, 2018.

The above amounts exclude potential payments under:

- our 2003 license agreement with Sumitomo 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, including a payment following the filing of an MAA with the EMA. If vosaroxin is approved for a non-cancer indication, an additional milestone payment becomes payable to Sumitomo. We are also required to make royalty payments to Sumitomo in the event that vosaroxin is commercialized.

- our Royalty Agreement with RPI, pursuant to which we are required to make certain revenue participation payments in the event that vosaroxin is commercialized. Based on the regulatory interactions with the EMA and FDA outlined in Note 1, the Company extended the end date of the estimated performance period through which the balance of deferred revenue will be amortized from September 30, 2016 to March 31, 2017. As a result, the quarterly amortization was adjusted from \$0.9 million per quarter to \$0.6 million per quarter, commencing with the quarter ended September 30, 2015. 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.
- our December 2013 second amended and restated collaboration agreement with Biogen and our January 2014 amended license agreement with Takeda, pursuant to which we are required to make certain milestone and royalty payments.

We also have agreements with contract research organizations 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, 2016 and 2015, we had \$42.6 million and \$46.4 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 (loss) income. 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		Total Fair Value as of December 31, 2016
	0-3 months	Over 3 months	
Available-for-sale securities	\$ 16,074	\$ 22,209	\$ 38,283
Average interest rate	0.5%	0.7%	



	Expected Maturity		Total Fair Value as of December 31, 2015
	0-3 months	Over 3 months	
Available-for-sale securities	\$ 28,264	\$ 11,083	\$ 39,347
Average interest rate	0.2%	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, 2016 and 2015, we held investments denominated in Euros with an aggregate fair value of \$0.7 million. 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), net in the statements of operations and comprehensive loss.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

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## 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, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Redwood City, California  
March 9, 2017

SUNESIS PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS  
(In thousands, except per share amounts)

	December 31,	
	2016	2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,056	\$ 26,886
Marketable securities	34,532	19,544
Prepays and other current assets	643	558
Total current assets	43,231	46,988
Property and equipment, net	3	14
Total assets	<u>\$ 43,234</u>	<u>\$ 47,002</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,871	\$ 2,453
Accrued clinical expense	1,434	1,954
Accrued compensation	2,000	1,606
Other accrued liabilities	1,691	2,711
Current portion of deferred revenue	610	2,441
Current portion of notes payable	3,333	7,834
Total current liabilities	10,939	18,999
Non-current portion of deferred revenue	—	610
Non-current portion of notes payable	11,102	
Other liabilities	169	—
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Convertible preferred stock, \$0.0001 par value; 10,000 shares authorized as of December 31, 2016; 18 and 20 shares issued and outstanding as of December 2016 and 2015, respectively	18,808	16,459
Common stock, \$0.0001 par value; 400,000 shares authorized as of December 31, 2015; 20,925 and 14,420 shares issued and outstanding as of December 31, 2016 and 2015, respectively	2	1
Additional paid-in capital	599,632	570,317
Accumulated other comprehensive loss	(22)	(11)
Accumulated deficit	(597,396)	(559,373)
Total stockholders' equity	21,024	27,393
Total liabilities and stockholders' equity	<u>\$ 43,234</u>	<u>\$ 47,002</u>

See accompanying notes to consolidated financial statements.

SUNESIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(In thousands, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
<b>Revenue:</b>			
License and other revenue	\$ 2,536	\$ 3,061	\$ 5,734
<b>Total revenues</b>	<b>2,536</b>	<b>3,061</b>	<b>5,734</b>
<b>Operating expenses:</b>			
Research and development	22,881	23,701	27,665
General and administrative	16,115	18,662	23,112
<b>Total operating expenses</b>	<b>38,996</b>	<b>42,363</b>	<b>50,777</b>
Loss from operations	(36,460)	(39,302)	(45,043)
Interest expense	(1,721)	(939)	(1,719)
Other income, net	158	3,565	3,760
<b>Net loss</b>	<b>(38,023)</b>	<b>(36,676)</b>	<b>(43,002)</b>
Unrealized loss on available-for-sale securities	(11)	(4)	(4)
<b>Comprehensive loss</b>	<b>(38,034)</b>	<b>(36,680)</b>	<b>(43,006)</b>
<b>Basic and diluted loss per common share:</b>			
<b>Net loss:</b>			
Basic	\$ (38,023)	\$ (36,676)	\$ (43,002)
Diluted	\$ (38,023)	\$ (36,676)	\$ (46,894)
<b>Shares used in computing net loss per common share:</b>			
Basic	15,688	12,156	10,010
Diluted	15,688	12,156	10,252
<b>Net loss per common share:</b>			
Basic	\$ (2.42)	\$ (3.02)	\$ (4.30)
Diluted	\$ (2.42)	\$ (3.02)	\$ (4.57)

See accompanying notes to consolidated financial statements.

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2013</b>			9,057	\$ 1	\$ 473,513	\$ (3)	\$ (479,695)	\$ (6,184)
Issuance of \$43,013 of common stock through controlled equity offering facilities, net of issuance costs of \$2989	—	—	775	—	40,024	—	—	40,024
Issuance of \$14,734 of common stock through controlled equity offering facilities, net of issuance costs of \$442	—	—	852	—	14,292	—	—	14,292
Issuance of common stock pursuant to warrant exercises	—	—	221	—	949	—	—	949
Issuance of common stock pursuant to stock option exercises	—	—	94	—	1,226	—	—	1,226
Issuance of common stock under employee stock purchase plans	—	—	17	—	282	—	—	282
Issuance of common stock to employees	—	—	1	—	—	—	—	—
Stock-based compensation expenses—employees	—	—	—	—	5,882	—	—	5,882
Stock-based compensation expenses—non-employees	—	—	—	—	337	—	—	337
Net loss	—	—	—	—	—	—	(43,002)	(43,002)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(4)	—	(4)
<b>Balance as of December 31, 2014</b>	—	—	11,017	1	536,505	(7)	(522,697)	13,802
Issuance of \$9,236 of common stock in underwritten offering, net of issuance costs of \$527	—	—	1,833	—	8,709	—	—	8,709
Issuance of \$18,564 of common stock through controlled equity offering facilities, net of issuance costs of \$439	—	—	1,160	—	18,125	—	—	18,125
Issuance of common stock pursuant to warrant exercises	—	—	350	—	—	—	—	—
Issuance of common stock pursuant to stock option exercises	—	—	28	—	331	—	—	331
Issuance of common stock under employee stock purchase plans	—	—	22	—	202	—	—	202
Issuance of common stock to employees	—	—	10	—	—	—	—	—
Issuance of preferred stock	20,200	16,459	—	—	—	—	—	16,459
Issuance of warrants to purchase common stock	—	—	—	—	100	—	—	100
Stock-based compensation expenses—employees	—	—	—	—	6,149	—	—	6,149
Stock-based compensation expenses—non-employees	—	—	—	—	196	—	—	196
Net loss	—	—	—	—	—	—	(36,676)	(36,676)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(4)	—	(4)
<b>Balance as of December 31, 2015</b>	20,200	16,459	14,420	1	570,317	(11)	(559,373)	27,393
Issuance of \$21,852 of common stock in underwritten offering, net of issuance costs of \$1,497	—	—	5,676	1	20,324	—	—	20,325
Issuance of \$269 of common stock through controlled equity offering facilities, net of issuance costs of \$5	—	—	57	—	269	—	—	269
Issuance of common stock upon conversion of preferred stock	(3,861)	(3,243)	644	—	3,243	—	—	—
Issuance of common stock under employee stock purchase plans	—	—	129	—	152	—	—	152
Issuance of preferred stock	1,558	5,592	—	—	—	—	—	5,592
Issuance of warrants to purchase common stock	—	—	—	—	536	—	—	536
Stock-based compensation expenses—employees	—	—	—	—	4,600	—	—	4,600
Stock-based compensation expenses—non-employees	—	—	—	—	191	—	—	191
Net loss	—	—	—	—	—	—	(38,023)	(38,023)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(11)	—	(11)
<b>Balance as of December 31, 2016</b>	<u>17,897</u>	<u>18,808</u>	<u>20,925</u>	<u>\$ 2</u>	<u>\$ 599,632</u>	<u>\$ (22)</u>	<u>\$ (597,396)</u>	<u>\$ 21,024</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2016	2015	2014
<b>Cash flows from operating activities</b>			
Net loss	\$ (38,023)	\$ (36,676)	\$ (43,002)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	4,791	6,345	6,219
Depreciation and amortization	11	27	29
Amortization of debt discount and debt issuance costs	359	135	367
Write-off debt discount upon note repayment	27		
Decrease in fair value of warrant liability	—	(3,543)	(3,892)
Changes in operating assets and liabilities:			
Prepays and other assets	(85)	660	(43)
Accounts payable	(582)	(724)	2,224
Accrued clinical expense	(520)	(1,158)	(1,638)
Accrued compensation	394	(681)	568
Other liabilities	169	—	—
Other accrued liabilities	(1,062)	(186)	1,674
Deferred revenue	(2,441)	(2,930)	(5,687)
Net cash used in operating activities	<u>(36,962)</u>	<u>(38,731)</u>	<u>(43,181)</u>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	—	—	(48)
Purchases of marketable securities	(35,530)	(35,683)	(42,463)
Sale and maturities of marketable securities	20,531	36,930	45,836
Net cash (used in) provided by investing activities	<u>(14,999)</u>	<u>1,247</u>	<u>3,325</u>
<b>Cash flows from financing activities</b>			
Proceeds from notes payable	15,000	—	—
Principal payments on notes payable and final payment	(7,983)	(1,642)	(9,356)
Payment of financing fees and debt issuance costs	(266)	—	—
Proceeds from issuance of convertible preferred stock offering, net	5,592	16,459	—
Proceeds from issuance of common stock and warrants	20,367	8,709	40,024
Proceeds from issuance of common stock through controlled equity offering facilities, net	269	18,125	14,292
Proceeds from exercise of warrants, stock options and stock purchase rights	152	533	1,961
Net cash provided by financing activities	<u>33,131</u>	<u>42,184</u>	<u>46,921</u>
Net (decrease) increase in cash and cash equivalents	<u>(18,830)</u>	<u>4,700</u>	<u>7,065</u>
Cash and cash equivalents at beginning of period	26,886	22,186	15,121
Cash and cash equivalents at end of period	<u>\$ 8,056</u>	<u>\$ 26,886</u>	<u>\$ 22,186</u>
<b>Supplemental disclosure of cash flow information</b>			
Interest paid	<u>\$ 1,239</u>	<u>\$ 631</u>	<u>\$ 1,221</u>
<b>Supplemental disclosure of non-cash activities</b>			
Transfer of fair value of exercised warrants to additional paid-in capital	<u>\$ —</u>	<u>\$ 100</u>	<u>\$ 496</u>
Conversion of preferred stock to common stock	<u>\$ (3,243)</u>	<u>\$ —</u>	<u>\$ —</u>
Fair value of warrants issued in connection with notes payable	<u>\$ 536</u>		
Cashless exercise of warrants	<u>\$ —</u>	<u>\$ 4,486</u>	<u>\$ 9,337</u>

See accompanying notes to consolidated financial statements.

**SUNESIS PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Company Overview**

***Description of Business***

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 January 2014, Sunesis announced the expansion of its oncology pipeline through separate global licensing agreements for two preclinical kinase inhibitor programs. The first agreement, with Biogen Idec MA, Inc., "Biogen," is for global commercial rights to SNS-062, a selective non-covalently binding oral inhibitor of BTK. The second agreement, with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda, is for global commercial rights to several potential first-in class, pre-clinical inhibitors of the novel target PDK1.

In addition, the Company is in a collaboration with Takeda for the development of TAK-580 (formerly MLN2480), an oral pan-RAF inhibitor, for which Takeda is conducting a multi-arm, open-label Phase 1B study in combination with nivolumab, a PD-1 checkpoint inhibitor; TAK-228, an oral mTORC 1/2 inhibitor; alisertib, an oral aurora A kinase inhibitor; and several chemotherapeutic agents, in adult patients with advanced non-hematologic malignancies.

Sunesis' most advanced program is QINPREZOTM (vosaroxin), our product candidate for the potential treatment of acute myeloid leukemia ("AML"). Vosaroxin is an anticancer quinolone derivative ("AQD")—a class of compounds that has not been used previously for the treatment of cancer.

In October 2014, the Company announced the results of a Phase 3, multi-national, randomized, double-blind, placebo-controlled trial of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML, or the VALOR trial. The VALOR trial did not meet its primary endpoint of demonstrating a statistically significant improvement in overall survival, but based upon the favorable results of other predefined analyses of the data in November 2014, the Company submitted a letter of intent to the European Medicines Agency ("EMA") describing its intention to file a marketing authorization application ("MAA") for marketing authorization of vosaroxin plus cytarabine for the treatment of relapsed or refractory AML. In June 2015, the Company met separately with its Rapporteur and Co-Rapporteur, who are two appointed members of the EMA's Committee for Medicinal Products for Human Use. Based upon feedback from these meetings, the Company filed an MAA with the EMA at the end of 2015. In July 2015, the Company met with the U.S. Food and Drug Administration ("FDA") to discuss a potential regulatory filing in the U.S. Based upon the meeting, the FDA recommended that the Company provide additional clinical evidence prior to any regulatory filing in the U.S. As a result, the Company is evaluating regulatory and clinical strategies with the goal of gaining future marketing approval in the U.S.

***Significant Risks and Uncertainties***

The Company has incurred significant losses and negative cash flows from operations since its inception, and as of December 31, 2016, had cash, cash equivalents and marketable securities totaling \$42.6 million and an accumulated deficit of \$597.4 million.

The Company will need to raise substantial additional capital to pursue a regulatory strategy for the potential commercialization of QINPREZOTM (vosaroxin), its product candidate for the potential treatment of acute myeloid leukemia, and to continue the development of vosaroxin, SNS-062 and the Company's other programs. The Company 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 and its other development programs, or a combination of the above. However, the Company does not know whether additional funding will be available on acceptable terms, or at all. If the Company is unable to raise required funding on acceptable terms or at all, it 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 or our other development programs, 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 any regulatory filings related to the VALOR trial, and/or limit or cease our operations.



### ***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 24 months and the weighted average maturity of the portfolio to 12 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").

### ***Reverse Stock Split***

On September 7, 2016, the Company effected a one-for-six reverse split of its common stock (the "Reverse Split"), as previously authorized and approved at the annual meeting of stockholders on June 7, 2016. As a result of the Reverse Split, every six shares of common stock were combined into one share of common 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, (c) issuable upon the exercise of outstanding stock options, restricted stock units and warrants and (d) issuable upon conversion of the outstanding Series B Preferred Stock. All share and per-share data in our consolidated financial statements and notes thereto give retroactive effect to the Reverse Split for all periods presented.

### ***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, that will supersede most existing revenue recognition guidance under GAAP. The new revenue standard requires an entity to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received in exchange for those goods or services. Entities can choose either the retrospective or cumulative effect transition method. The new revenue standard as amended by ASU No. 2015-14, is effective for annual and interim periods beginning after December 15, 2017. In March, April and May 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, ASU 2016-10, *Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing*, and ASU 2016-12, *Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients*. These pronouncements have the same effective date as the new revenue standard and provide additional guidance, clarification and practical expedients to reduce the cost and complexity of applying the new standard. The guidance allows for adoption on either a full retrospective or a modified retrospective basis. The Company has identified the contracts that need to be evaluated, but has not yet determined whether it will use the full retrospective or modified retrospective method of adoption. The Company plans to adopt this guidance on January 1, 2018.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which will require a reporting entity to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about the reporting entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. The standard will be effective for annual periods ending after December 15, 2016, with early adoption permitted. The Company adopted ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, for the year ended December 31, 2016. The Company reviewed its available capital, its 2017 operating plans, and its ability to sell up to \$17.9 million of common stock available to be sold under the 2011 Sales Agreement with Cantor and determined that substantial doubt does not exist concerning its ability to meet its obligations. The Company will update and review its analysis for future interim and annual reporting periods.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 made modifications to how certain financial instruments should be measured and disclosed, including using the exit price notion when measuring the fair value, separating the presentation of financial assets and financial liabilities by

measurement category on the balance sheet and eliminating the requirement to disclose the method and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods. The Company will evaluate the guidance and present the required disclosures in its consolidated financial statements at the time of adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-06, *Contingent Put and Call Options in Debt Instruments*. ASU 2016-06 requires a four-step decision sequence to assess whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The economic characteristics and risks of embedded derivatives that are not clearly and closed related to their debt hosts is a criteria pursuant to Topic 815 that requires embedded derivatives be separated from the host contract and accounted for separately as derivatives. ASU 2016-06 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2017 and early adoption is permitted. The Company elected to early adopt the new guidance in the first quarter of fiscal year 2016. There have been no adjustments to existing debt instruments as of the beginning of fiscal 2016 and no significant changes in our reported financial position or results of operations and cash flows as a result of the adoption of ASU 2016-06.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 affects the recognition of excess tax benefits and deficiencies, revises the cash flow classification of share-based compensation related transactions, permits entities to make an accounting policy election to either estimate forfeitures on share-based payment awards, as previously required, or to recognize forfeitures as they occur, and allows more shares to be repurchased for tax withholding purposes without triggering liability accounting. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. The Company elected to early adopt this ASU in the quarter ended September 30, 2016. Effective January 1, 2016, the Company elected to recognize forfeitures as they occur which had no material impact on the Company's unaudited condensed consolidated financial statements or related footnote disclosures. The Company recognized slightly higher share-based payment expense in 2016, relative to prior periods, as the effects of forfeitures are not recognized until they occur, rather than being estimated at the time of grant and subsequently adjusted as and when necessary. The adoption of the remaining provisions in ASU 2016-09 had no effect on the Company's unaudited condensed consolidated financial statements or related footnote disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, which will require a reporting entity to use a new forward-looking impairment model for most financial assets that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, credit losses will be recognized as allowances rather than as reductions in amortized cost. The standard will be effective for annual periods beginning after December 15, 2019, with early adoption permitted beginning in 2019. Entities will apply the guidance as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company will evaluate the guidance and present the impact in its consolidated financial statements at the time of adoption.

In August 2016, The FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, which provides guidance on specific cash flow issues with the objective of reducing diversity in practice in how certain cash receipts and cash payments are presented in the statement of cash flows. ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those fiscal years with early adoption permitted. The Company elected to early adopt this ASU in the quarter ended September 30, 2016. There have been no changes in our reported statements of cash flows as a result of the adoption of ASU 2016-15.

In November 2016, THE FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force)*, which provides guidance on specific classification of Restricted Cash presented in the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. The Company elected to early adopt this ASU in the year ended December 31, 2016. There have been no changes in our reported statements of cash flows as a result of the adoption of ASU 2016-18.

### ***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Sunesis Europe Limited, a United Kingdom corporation, and Sunesis Pharmaceuticals (Bermuda) Ltd., a Bermuda corporation, as well as a Bermuda limited partnership, Sunesis Pharmaceuticals International LP. All intercompany balances and transactions have been eliminated in consolidation.

### ***Segment Reporting***

Management has determined that the Company operates as a single reportable segment.

### ***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 consolidated financial statements and accompanying notes thereto. Actual results could differ materially from these estimates. 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 accounting.

### ***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 (deficit).

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, net in the statements of operations and comprehensive 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, net. 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 defined in 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. As of December 31, 2016 and December 31, 2015, the Company held investments denominated in Euros with an aggregate fair value of \$0.7 million. Any cash, cash equivalent and short-term investment balances denominated in foreign currencies 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 both recorded in other income, net in the statements of operations and comprehensive loss.

### ***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 derived from independent pricing services based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity, or based on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets.

The fair value of the Company's liability for warrants issued in connection with the 2010 Offering (see Note 10) was 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 carrying amounts of the Company's financial instruments, including cash, prepayments, accounts payable, accrued liabilities, deferred revenue and notes payable approximated their fair value as of December 31, 2016 and December 31, 2015.

#### ***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 Royalty Agreement***

The payment of \$25.0 million by RPI under the Royalty Agreement (see Note 6) is non-refundable, and no revenue participation right payments will be made unless vosaroxin is commercialized. Accordingly, the payment received from RPI is being accounted for as a payment for the Company to use commercially reasonable efforts to commercialize vosaroxin. Therefore, the amount is to be deferred and recognized as revenue over the projected performance period under the agreement. The payment, less \$3.1 million representing the fair value of the warrants granted under the arrangement, was initially classified as deferred revenue and is being amortized to revenue over the related performance period. The fair value of the warrants was recorded to additional paid-in capital.

#### ***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, net 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), net in the statements of operations and comprehensive 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 the Company's 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 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, net in the statements of operations and comprehensive 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 in other income, net in the statements of operations and comprehensive loss.

### **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 sets forth the computation of basic and diluted loss per common share for the periods presented (in thousands, except per share amounts):

	Year Ended December 31,		
	2016	2015	2014
<b>Numerator:</b>			
Net loss—basic	\$ (38,023)	\$ (36,676)	\$ (43,002)
Adjustment for change in fair value of warrant liability	—	—	(3,892)
Net loss—diluted	<u>\$ (38,023)</u>	<u>\$ (36,676)</u>	<u>\$ (46,894)</u>
<b>Denominator:</b>			
Weighted-average common shares outstanding—basic	15,688	12,156	10,010
Dilutive effect of warrants	—	—	242
Weighted-average common shares outstanding—diluted	<u>15,688</u>	<u>12,156</u>	<u>10,252</u>
<b>Net loss per common share:</b>			
Basic	<u>\$ (2.42)</u>	<u>\$ (3.02)</u>	<u>\$ (4.30)</u>
Diluted	<u>\$ (2.42)</u>	<u>\$ (3.02)</u>	<u>\$ (4.57)</u>

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,		
	2016	2015	2014
Warrants to purchase shares of common stock	218	938	1,496
Convertible preferred stock	4,270	3,353	—
Options to purchase shares of common stock	2,697	2,153	1,764
Outstanding securities not included in calculations	<u>7,185</u>	<u>6,444</u>	<u>3,260</u>

#### 4. 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):

December 31, 2016	Valuation Input Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	\$ 3,270	\$ —	\$ —	\$ 3,270
U.S. Treasury securities	Level 1	16,029	—	(9)	16,020
U.S. certificates of deposit	Level 1	4,868	—	—	4,868
U.S. corporate debt obligations	Level 2	11,617	—	(11)	11,606
U.S. commercial paper	Level 2	2,521	—	(2)	2,519
Total available-for-sale securities		38,305	—	(22)	38,283
Less amounts classified as cash equivalents		(3,751)	—	—	(3,751)
Amounts classified as marketable securities		<u>\$ 34,554</u>	<u>\$ —</u>	<u>\$ (22)</u>	<u>\$ 34,532</u>

<b>December 31, 2015</b>	<b>Valuation Input Level</b>	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Money market funds	Level 1	\$ 17,200	\$ —	\$ —	\$ 17,200
U.S. Treasury securities	Level 1	1,003			1,003
U.S. certificates of deposit	Level 1	5,001	—	—	5,001
Debt securities of U.S. government agencies	Level 2	4,494			4,494
U.S. corporate debt obligations	Level 2	11,660	—	(11)	11,649
Total available-for-sale securities		39,358	—	(11)	39,347
Less amounts classified as cash equivalents		(19,803)	—	—	(19,803)
Amounts classified as marketable securities		<u>\$ 19,555</u>	<u>\$ —</u>	<u>\$ (11)</u>	<u>\$ 19,544</u>

The following table summarizes the available-for-sale securities that were in an unrealized loss position as of December 31, 2016, each having been in such a position for less than 12 months, and none deemed to be other-than-temporarily impaired (in thousands):

<b>December 31, 2016</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
U.S. Treasury securities	\$ (9)	\$ 16,020
U.S. corporate debt obligations	(11)	11,606
U.S. commercial paper	(2)	2,519
Total available-for-sale securities in an unrealized loss position	<u>\$ (22)</u>	<u>\$ 30,145</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 generally been for relatively short durations. 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, 2016, 2015 and 2014.

#### ***Financial Liabilities***

The warrants issued in connection with the 2010 Offering were classified as a liability on the Company's consolidated balance sheet as of December 31, 2014 due to the potential for the warrants to be settled in cash upon the occurrence of certain transactions 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, net in the statements of operations and comprehensive loss, and the fair value of warrant exercises transferred to additional paid-in capital. In October 2015 all outstanding warrants related to the 2010 Offering expired unexercised.

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):

	<b>Warrant Liability</b>
Balance as of December 31, 2014	\$ 3,543
Change in fair value of warrant liability	(3,543)
Exercise of warrants	—
Balance as of December 31, 2015 and 2016	\$ —

## 5. Other Accrued Liabilities

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

	2016	2015
Accrued outside services	\$ 1,192	\$ 2,011
Accrued professional services	381	644
Other accruals	118	56
Total other accrued liabilities	<u>\$ 1,691</u>	<u>\$ 2,711</u>

## 6. Royalty Agreement

In March 2012, the Company entered into a Revenue Participation Agreement (the “Royalty Agreement”), with RPI Finance Trust (“RPI”), an entity related to Royalty Pharma. In September 2012, pursuant to the provisions of the Royalty Agreement, RPI made a \$25.0 million cash payment to the Company. The payment, less \$3.1 million representing the fair value of the warrants granted under the arrangement, was initially classified as deferred revenue and is being amortized to revenue over the related performance period.

Based on the regulatory interactions with the EMA and FDA outlined in Note 1, the Company extended the end date of the estimated performance period through which the balance of deferred revenue will be amortized from September 30, 2016 to March 31, 2017. As a result, the quarterly amortization was adjusted from \$0.9 million per quarter to \$0.6 million per quarter, commencing with the quarter ended September 30, 2015.

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.

## 7. License Agreements

### Overview

In August 2004, the Company entered into a collaboration agreement with Biogen MA, Inc. (“Biogen”) to discover, develop and commercialize small molecule inhibitors of the human protein Raf kinase, including family members Raf-1, A-Raf, B-Raf and C-Raf (collectively “Raf”) and up to five additional targets that play a role in oncology and immunology indications (the “Biogen OCA”). In connection with the Company’s June 2008 restructuring, the parties agreed to terminate the research obligations and related funding as of June 30, 2008.

In March 2011, as part of a series of agreements among the Company, Biogen and Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, (“Takeda”), the Company entered into: (a) an amended and restated collaboration agreement with Biogen (the “Biogen 1st ARCA”); (b) a license agreement with Takeda (the “Takeda Agreement”); and (c) a termination and transition agreement among the Company, Biogen and Takeda (the “Termination and Transition Agreement”).

The Termination and Transition Agreement provided for (a) the termination of Biogen’s exclusive rights under the Biogen OCA to all discovery programs under such agreement other than for small molecule inhibitors of the human protein Bruton’s tyrosine kinase (“BTK”); (b) the permitted assignment to Takeda of all related Company collaboration assets and rights to Raf kinase and the human protein phosphoinositide-dependent kinase-1 (“PDK1”); and (c) the payment of \$4.0 million upfront from Takeda to the Company, which was recorded as revenue in March 2011.

### Biogen Idec

The Biogen 1st ARCA amended and restated the Biogen OCA, to provide for the discovery, development and commercialization of small molecule BTK inhibitors. Under this agreement, the Company no longer has research obligations, but licenses granted to Biogen with respect to the research collaboration under the Biogen OCA (other than the licenses transferred to Takeda under the Takeda Agreement) remain in effect.



In June 2012, the Company received an event-based payment and recognized as revenue of \$1.5 million from Biogen for the advancement of pre-clinical work in connection with the Biogen 1st ARCA. 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 by Biogen of the first two indications for licensed products against the BTK target. The Company is also eligible to receive royalty payments depending on related product sales, if any.

In December 2013, the Company entered into a second amended and restated collaboration agreement with Biogen (the "Biogen 2nd ARCA"), to provide the Company with an exclusive worldwide license to develop, manufacture and commercialize SNS-062, a BTK inhibitor synthesized under the Biogen 1st ARCA, solely for oncology indications. The Company may be required to make a \$2.5 million milestone payment depending on its development of SNS-062 and royalty payments depending on related product sales of SNS-062. All other of Sunesis' rights and obligations contained in the Biogen 1st ARCA remain unchanged, except that potential future royalty payments to Sunesis were reduced to equal those amounts due to Biogen for potential future sales of SNS-062.

### ***Takeda***

Under the Takeda Agreement, the Company granted exclusive licenses to products against two oncology targets originally developed under the Biogen OCA, Raf and PDK1, under substantially the same terms as under the Biogen OCA.

In January 2014, the Company entered into an amended and restated license agreement with Takeda (the "Amended Takeda Agreement"), to provide the Company with an exclusive worldwide license to develop and commercialize preclinical inhibitors of PDK1. In connection with the execution of the Amended Takeda Agreement, the Company paid an upfront fee of \$0.4 million and may be required to make up to \$9.2 million in pre-commercialization milestone payments depending on its development of PDK1 inhibitors and royalty payments depending on related product sales, if any.

With respect to the Raf target product rights that were originally licensed to Takeda under the Takeda Agreement, the Company may in the future receive up to \$57.5 million in pre-commercialization event-based payments related to the development by Takeda of the first two indications for each of the licensed products directed against the Raf target and royalty payments depending on related product sales. Takeda is currently conducting a Phase 1 clinical study of an oral investigative drug, TAK-580, which is licensed to them under the Amended Takeda Agreement.

## **8. Notes Payable**

On March 31, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Western Alliance Bank ("Western Bank") and Solar Capital Ltd. ("Solar Capital," and collectively with Western Bank, the "Lenders") and Western Alliance, as Collateral Agent (the "Collateral Agent"). Pursuant to the terms of the Loan Agreement, the Lenders provided the Company with a loan in the principal amount of \$15,000,000 of which \$12,500,000 was funded on March 31, 2016 and \$2,500,000 was funded on April 1, 2016, for working capital, to fund its general business requirements and to repay indebtedness of the Company to Oxford Finance LLC, Silicon Valley Bank and Horizon Technology Finance Corporation (collectively, the "Existing Lenders") pursuant to the Loan and Security Agreement, dated as of October 18, 2011, entered into by and among the Existing Lenders and the Company (the "Oxford Loan Agreement"). On March 31, 2016, the Company used \$7.2 million of the loan proceeds to repay the outstanding principal of \$6.0 million, a final payment fee of \$1.2 million and accrued interest of \$45,000 under the Oxford Loan Agreement. The Company paid the Lenders a \$0.1 million facility fee and \$0.1 million in legal fees.

The Company will be required to pay interest on the borrowings under the Loan Agreement at a per annum rate equal to 8.54% plus the then effective one-month U.S. LIBOR rate. Payments under the Loan Agreement are monthly in arrears and interest-only for the first 12-months. Thereafter and until the scheduled maturity date of April 1, 2020, in addition to interest accrued during such period, the monthly payments will include an amount equal to the outstanding principal divided by 36 months, unless the interest only period is extended by a further six months, in which case the amortization period will be 30 months. A final payment equal to 3.75% of the original principal amount borrowed will be due upon maturity or such earlier date specified in the Loan Agreement. If the Company repays all amounts owed under the Loan Agreement prior to the maturity date, the Company will pay a prepayment fee equal to 2.0% of the amount prepaid if the prepayment occurs on or prior to March 31, 2017, 1.0% of the amount prepaid if the prepayment occurs after March 31, 2017 but on or prior to March 31, 2018 and 0.5% of the amount prepaid if the prepayment occurs thereafter.

The facility fee and legal fees related to the debt are being accounted for as a debt discount and classified within notes payable on the Company's balance sheet and 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 loan using the effective interest method and is included as a component of non-current portion of notes payable on the Company's consolidated balance sheet.

In conjunction with the Loan Agreement, the Lenders were issued five-year warrants to purchase an aggregate of up to 208,002 shares of the Company's common stock at a per share exercise price of \$3.2454. The fair value of the warrants issued was estimated to be \$0.5 million using a Black-Scholes valuation model with the following assumptions: common stock price at issuance of \$3.24; exercise price of \$3.2454; risk-free interest rate of 1.21% based upon observed risk-free interest rates; expected volatility of 111.96% based on the Company's average historical volatility; expected term of five years, which is the contractual life of the warrants; and a dividend yield of 0%. The fair value was 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 Agreement, using the effective interest method.

Pursuant to the Loan Agreement, the Company is bound by a variety of affirmative covenants during the term of the Loan Agreement, including, without limitation, certain information delivery requirements, notice requirements and obligations to maintain certain insurance. Additionally, the Company is bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without the Lenders' consent, including, without limitation, incurring certain additional indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any non-permitted lien or other encumbrance on the Company's assets. Upon the occurrence of an event of default under the Loan Agreement (subject to cure periods for certain events of default), all amounts owed by the Company thereunder would begin to bear interest at a rate that is 5.0% higher than the rate that would otherwise be applicable and may be declared immediately due and payable by the Collateral Agent. Events of default under the Loan Agreement include, among other things, the following: the occurrence of certain bankruptcy events; the failure to make payments under the Loan Agreement when due; the occurrence of a material impairment on the Collateral Agent's security interest over the collateral, a material adverse change in the business, operations or condition (financial or otherwise) of the Company or material impairment of the prospect of repayment of the obligations under the Loan Agreement; the occurrence of a default under certain other agreements entered into by the Company; the rendering of certain types of judgments against the Company; the revocation of certain government approvals of the Company; any breach by the Company of any covenant (subject to cure periods for certain covenants) made in the Loan Agreement; and the failure of any representation or warranty made by the Company in connection with the Loan Agreement to be correct in all material respects when made.

The Collateral Agent, for the benefit of the Lenders, has a perfected security interest in substantially all of the Company's property, rights and assets, except for intellectual property, to secure the payment of all amounts owed to the Lenders under the Loan Agreement. Upon marketing approval of vosaroxin, the Collateral Agent, for the benefit of the Lenders, will also have a perfected security interest in the Company's intellectual property rights relating to vosaroxin.

Aggregate future minimum payments due under the Loan Facility as of December 31, 2016 were as follows (in thousands):

Year ending December 31,	Total
2017	\$ 4,638
2018	5,874
2019	5,407
2020	2,261
Total minimum payments	18,180
Less amount representing interest	(3,180)
Total notes payable as of December 31, 2016	15,000
Less unamortized debt discount and issuance costs	(565)
Less current portion of notes payable	(3,333)
Non-current portion of notes payable	<u>\$ 11,102</u>

## 9. Commitments and Contingencies

### *Commitments*

The Company's operating lease obligations as of December 31, 2016 relate solely to the leasing of office space in a building at 395 Oyster Point Boulevard in South San Francisco, California, which is currently the Company's headquarters. In January 2014, a lease for 15,378 square feet was entered into with an expiry date of April 30, 2015. In June 2014, the lease was amended to extend the expiration date to June 30, 2015, and to add 6,105 square feet of additional office space within the same building. The lease has been amended in January 2015 and September 2015 to extend the expiration date to December 31, 2016 and in September 2016, respectively and in May 2016, the lease was again amended to extend the expiration date to June 30, 2018.

Aggregate non-cancelable future minimum rental payments under operating leases as of December 31, 2016, were as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Payments</u>
2017	\$ 654
2018	\$ 332
Total rental payments	\$ 986

The Company recognizes rent expense on a straight-line basis. The Company recorded rent expense of \$0.6 million, \$0.5 million and \$0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

### ***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 17,897 shares and 20,200 shares of preferred stock outstanding as of December 31, 2016 and 2015, respectively. These shares are non-voting Series B and Series C Convertible Preferred Stock at a price of \$840 and \$3,850 per share, respectively. Each share of non-voting Series B is convertible into 166 shares of our common stock (as adjusted for the Reverse Split) and each share of non-voting Series C Stock is convertible into 1000 shares of our common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of Series B and Series C Stock will receive a payment equal to \$0.0001 per share of Series B and Series C Stock before any proceeds are distributed to the holders of Common Stock. Shares of Series B and Series C Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B and Series C Stock will be required to amend the terms of the Series B and Series C Stock. Shares of the Series B and Series C Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all of the Company's Common Stock;
- senior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms junior to the Series B and Series C Stock;
- on parity with any class or series of the Company's capital stock hereafter created specifically ranking by its terms on parity with the Series B and Series C Stock;
- junior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms senior to the Series B and Series C Stock; in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

### ***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. Under the terms of the Loan Agreement with the Lenders, the Company is precluded from paying cash dividends without the prior written consent of the Lenders.

### ***Underwritten Offering***

In December 2015, the Company completed underwritten offering of (i) 1,832,698 shares of its common stock, that included the exercise of the underwriter's over-allotment option of 239,047 shares, at a price of \$5.04 per share (as adjusted for the Reverse Split), and (ii) 20,200 shares of its non-voting Series B Convertible Preferred Stock ("Series B Stock") at a price of \$840.00 per share. Gross proceeds from the sale were \$26.2 million and net proceeds were \$25.2 million. Each share of non-voting Series B Stock is convertible into 166 shares of Sunesis common stock (as adjusted for the Reverse Split), provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of Sunesis common stock then outstanding.

In October 2016, the Company completed underwritten offering of (i) 5,675,825 shares of its common stock at a price of \$3.85 per share, and (ii) 1,558 shares of its non-voting Series C Convertible Preferred Stock ("Series C Stock") at a price of \$3,850.00 per share. Gross proceeds from the sale were \$27.9 million and net proceeds were \$25.9 million. Each share of non-voting Series C Stock is convertible into 1,000 shares of Sunesis common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.98% of the total number of shares of Sunesis common stock then outstanding.

### ***Controlled Equity Offerings***

In August 2011, the Company entered into a Controlled Equity Offering<sup>SM</sup> sales agreement (the "Sales Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), as agent and/or principal, pursuant to which the Company could issue and sell shares of its common stock having an aggregate gross sales price of up to \$20.0 million. In April 2013, the Sales Agreement was amended to provide for an increase of \$30.0 million in the aggregate gross sales price under the Sales Agreement. The Company will pay Cantor a commission of 3.0% of the gross proceeds from any common stock sold through the Sales Agreement, as amended.

During the year ended December 31, 2016, the Company sold an aggregate of 57,000 shares of common stock under the Sales Agreement, as amended, at an average price of approximately \$4.73 per share for gross and net proceeds of \$0.3 million, after deducting Cantor's commission. As of December 31, 2016, \$17.9 million of common stock remained available to be sold under this facility.

### ***2010 Offering***

In October 2010, the Company completed an underwritten offering, pursuant to which the Company issued an aggregate of 1,226,268 shares of common stock and warrants to purchase 613,133 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 had an exercise price of \$15.12 per share. In October 2015, all outstanding warrants related to the 2010 Offering expired unexercised.

### ***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 with various vesting schedules over three to four years, (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 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"). No additional stock awards will be granted under the Prior Plans.

The Company initially reserved a total of 1,006,976 shares of common stock for issuance under the 2011 Plan, which is the sum of (i) the 89,967 shares remaining available as of the Effective Date under the Prior Plans, (ii) an additional 733,333 new shares, and (iii) that portion of the 183,676 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, 2016 and 2015, in accordance with the above, the number of shares of common stock available for issuance under the 2011 Plan was increased by 576,785 and 440,679 shares, respectively.

During the year ended December 31, 2016, options to purchase 777,049 shares of the Company's common stock were granted under the 2011 Plan. As of December 31, 2016, there were 88,411 shares available for future grants under the 2011 Plan.

#### ***Employee Stock Purchase Plans***

On March 5, 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. Subsequent 12-month offerings commenced or will commence on or around June 1st of each year.

The Company initially reserved a total of 83,333 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.

A total of 59,086 shares were issued under the 2011 ESPP during the year ended December 31, 2016. As of December 31, 2016, there were 46,179 shares available for future issuance under the ESPP.

#### ***Warrants***

Warrants to purchase shares of the Company's common stock outstanding as of December 31, 2016 were as follows (in thousands, except per share amounts):

<b>Date Issued</b>	<b>Shares</b>	<b>Exercise Price Per Share</b>	<b>Expiration</b>
February 2015	10	\$ 13.32	February 2020
March 2016	208	\$ 3.25	March 2021
<b>Total warrants outstanding and exercisable</b>	<b>218</b>		

#### ***Reserved Shares***

Shares of the Company's common stock reserved for future issuance as of December 31, 2016 were as follows (in thousands):

	<b>Shares Available for Future Grant</b>	<b>Outstanding Securities</b>	<b>Total Shares Reserved</b>
Warrants	—	218	218
Convertible preferred stock	—	4,270	4,270
Stock option plans	89	2,698	2,787
Employee stock purchase plan	46	—	46
<b>Total reserved shares of common stock</b>	<b>135</b>	<b>7,186</b>	<b>7,321</b>

## 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, and recognized under the straight-line attribution method, assuming that all stock-based awards will vest. Effective January 1, 2016, the Company has elected to recognize forfeitures as they occur, as permitted by ASU 2016-09, Compensation – Stock Compensation (Topic 718), Improvement to Employee Share-Based Payment Accounting. Refer to Note 2 for further details. In prior periods, the Company estimated forfeitures at time of grant and revised the estimates in subsequent periods if actual forfeitures differed 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,		
	2016	2015	2014
Research and development	\$ 1,630	\$ 2,856	\$ 2,201
General and administrative	2,970	3,292	3,681
Employee stock-based compensation expense	4,600	6,148	5,882
Non-employee stock-based compensation expense	191	196	337
Total stock-based compensation expense	<u>\$ 4,791</u>	<u>\$ 6,344</u>	<u>\$ 6,219</u>

### 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,		
	2016	2015	2014
<b>Assumptions:</b>			
Expected term (years)	5.3	5.2	5.2
Expected volatility	110.0%	99.9%	88.1%
Risk-free interest rate	1.9%	1.7%	1.7%
Expected dividend yield	0.0%	0.0%	0.0%
<b>Fair value:</b>			
Weighted-average estimated grant date fair value per share	\$ 3.12	\$ 6.20	\$ 19.10
Options granted to employees (in thousands)	750	531	613
Total estimated grant date fair value (in thousands)	<u>\$ 2,344</u>	<u>\$ 3,294</u>	<u>\$ 11,704</u>

The estimated fair value of stock options that vested in the years ended December 31, 2016, 2015 and 2014, was \$4.6 million, \$5.8 million and \$2.6 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
<b>Outstanding as of December 31, 2015</b>	2,083	\$ 18.32		
Options granted	777	\$ 3.89		
Options exercised	—	—		
Options forfeited or expired	(219)	\$ 25.77		
<b>Outstanding as of December 31, 2016</b>	<u>2,641</u>	<u>\$ 13.50</u>	<u>6.90</u>	<u>\$ 48</u>
Vested and expected to vest as of December 31, 2016	2,641	\$ 13.50	6.90	\$ 48
Exercisable as of December 31, 2016	1,524	\$ 18.23	5.28	\$ 12

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, 2016.

The intrinsic value of options exercised during the years ended December 31, 2016, 2015 and 2014 was nil, \$0.2 million and \$2.7 million, 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 \$5.3 million as of December 31, 2016, 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 2.7 years.

### Bonus Awards

On February 11, 2016, the Compensation Committee of the Company's Board of Directors approved cash bonuses to certain of the Company's employees, including its named executive officers, pursuant to the Company's 2015 Bonus Program. Under the 2015 Bonus Program, each participant was eligible to receive a cash bonus in an amount up to a specified target percentage of such participant's annual base salary for 2015 based on the level of achievement of certain corporate and individual objectives. The bonus payment amounts approved by the Compensation Committee were based on its determination of the degree to which such corporate and individual objectives were achieved. A portion of the bonuses awarded consisted of 122,000 fully vested shares of the Company's common stock granted under the 2011 Plan. The stock portion of the bonus awards were granted effective as of February 29, 2016 and the cash portion of the bonus awards were paid on February 29, 2016. The number of shares of the Company's common stock awarded to Mr. Daniel N. Swisher, Jr., the Company's CEO and President, and Mr. Eric H. Bjerkholt, the Company's Executive Vice President, Corporate Development and Finance, Chief Financial Officer and Corporate Secretary, under the 2011 Plan were determined based on the closing price of the Company's common stock as quoted on the NASDAQ Capital Market on February 29, 2016, rounded down to the nearest whole share.

### Performance Awards

On February 25, 2015, the Compensation Committee of the Board approved equity awards in the form of restricted stock units ("RSUs") for certain of the Company's employees ("participant") under 2011 Stock Incentive Plan. The RSUs have an exercise price of \$0 and vesting is subject to the achievement of the earlier of one of two milestones: acceptance of NDA (U.S.) or approval of MAA (EU) and the participant being an employee at time of milestone achievement. As of December 31, 2016, none of the RSUs were vested.

The following table summarizes the Company's RSU activity for the year ended December 31, 2016 (in thousands, except per share amounts):

	Number of Shares
<b>Performance based restricted stock units</b>	
<b>Outstanding as of December 31, 2015</b>	71
Stocks granted	—
Stocks exercised	—
Stocks forfeited or expired	(15)
<b>Outstanding as of December 31, 2016</b>	<u>56</u>

## 12. Income Taxes

Loss before the provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
U.S. operations	\$ (26,942)	\$ (23,705)	\$ (32,696)
Foreign operations	(11,081)	(12,971)	(10,306)
Loss before provision for income taxes	<u>\$ (38,023)</u>	<u>\$ (36,676)</u>	<u>\$ (43,002)</u>

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,		
	2016	2015	2014
Tax at statutory rate	\$ (12,928)	\$ (12,470)	\$ (14,620)
Current year net operating losses and temporary differences for which no tax benefit is recognized	9,500	9,596	14,104
Foreign tax rate differential	3,768	4,410	3,504
Deferred revenue	(830)	(996)	(1,934)
Change in fair value of warrant liability	0	(1,204)	(1,313)
Other permanent differences	490	664	259
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,	
	2016	2015
Deferred tax assets:		
Federal and state net operating loss carry-forwards	\$ 156,066	\$ 147,408
Federal and state research credit carry-forwards	13,177	12,557
Capitalized research costs	4,824	5,119
Deferred revenue	244	1,221
Stock-based compensation	5,739	5,275
Property and equipment	120	127
Accrued liabilities	207	133
Gross deferred tax assets	<u>180,377</u>	<u>171,840</u>
Valuation allowance	(180,377)	(171,840)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>



The Company's unrecognized tax benefits relate to research and development tax credits claimed on the Company's tax returns. The research and development tax credits have not been utilized, are fully offset by a valuation allowance, and currently have no tax expense impact.

A reconciliation of the Company's beginning and ending amount of unrecognized tax benefits is follows (in thousands):

	December 31,	
	2016	2015
Unrecognized tax benefits at beginning of period	\$ 1,381	\$ —
Increases related to prior year tax positions	—	1,285
Increases related to current year tax positions	60	96
Unrecognized tax benefits at the end of period	<u>\$ 1,441</u>	<u>\$ 1,381</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 \$8.5 million, \$8.4 million and \$14.6 million during the years ended December 31, 2016, 2015 and 2014, respectively.

As of December 31, 2016, the Company had federal net operating loss carry-forwards of \$413.2 million and federal research and development tax credit carry-forwards of \$9.1 million. If not utilized, the federal net operating loss and tax credit carry-forwards will expire at various dates beginning in 2018. As of December 31, 2016, the Company had state net operating loss carry-forwards of \$267.1 million, net of \$38.2 million of state net operating losses that had expired as of December 31, 2016, and state research and development tax credit carry-forwards of \$8.0 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, 2016 and 2015, the Company had unrecognized tax benefits of \$1.4 million. The Company did not have any unrecognized tax positions as of December 31, 2014.

The Company files U.S. federal and California tax returns. The Company's wholly owned subsidiaries, Sunesis Europe Limited and Sunesis Pharmaceuticals (Bermuda) Ltd., are currently not required to file tax returns. To date, neither the Company nor any of its subsidiaries have been audited by the Internal Revenue Service, any state income tax authority or tax authority in the related jurisdictions. 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, 2016.

### 14. Subsequent Events

None.

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

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

	Three Months Ended							
	Mar. 31, 2016	June 30, 2016	Sep. 30, 2016	Dec. 31, 2016	Mar. 31, 2015	June 30, 2015	Sep. 30, 2015	Dec. 31, 2015
Revenue	\$ 640	\$ 610	\$ 610	\$ 676	\$ 854	\$ 854	\$ 683	\$ 670
Net loss:								
Basic	\$ (10,086)	\$ (10,446)	\$ (8,954)	\$ (8,537)	\$ (9,128)	\$ (8,949)	\$ (7,021)	\$ (11,578)
Diluted	\$ (10,086)	\$ (10,446)	\$ (8,954)	\$ (8,537)	\$ (9,128)	\$ (10,816)	\$ (7,021)	\$ (11,578)
Shares used in computing net loss per common share:								
Basic	14,443	14,493	14,503	19,285	11,274	12,086	12,463	12,781
Diluted	14,443	14,493	14,503	19,285	11,274	12,088	12,463	12,781
Net loss per common share(1):								
Basic	\$ (0.70)	\$ (0.72)	\$ (0.62)	\$ (0.44)	\$ (0.81)	\$ (0.12)	\$ (0.56)	\$ (0.91)
Diluted	\$ (0.70)	\$ (0.72)	\$ (0.62)	\$ (0.44)	\$ (0.81)	\$ (0.15)	\$ (0.56)	\$ (0.91)

- (1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarter per-share calculations will not necessarily equal the annual per share calculation.

**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, 2016, 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 Securities Exchange Act 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, 2016. Management based its assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) in *Internal Control—Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2016, our internal control over financial reporting was effective at the reasonable assurance level.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2016 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 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.

**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, 2016, 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](http://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.

## Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2016:

Plan Category	(A) Number of Securities to be Issued upon Exercise of Outstanding Options	(B) Weighted Average Exercise Price of Outstanding Options	(C) 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)	2,641,058 (2)	\$ 13.50	134,590 (3)
Equity Compensation Plans Not Approved by Stockholders	—	\$ —	—
<b>Total</b>	<b>2,641,058</b>	<b>\$ 13.50</b>	<b>134,590</b>

- (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) 88,411 shares of common stock available for issuance under our 2011 Plan and (ii) 46,179 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>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	51
<a href="#">Consolidated Balance Sheets</a>	52
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	53
<a href="#">Consolidated Statements of Stockholders' Equity (Deficit)</a>	54
<a href="#">Consolidated Statements of Cash Flows</a>	55
<a href="#">Notes to Consolidated Financial Statements</a>	56

(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.

**ITEM 16. FORM 10-K SUMMARY**

None.



**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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	
3.8	Certificate of Designation of Series B Convertible Preferred Stock	8-K	000-51531	3.1	12/16/2015	
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	000-51531	3.1	9/7/2016	
3.10	Certificate of Designation of Series C Convertible Preferred Stock	8-K	000-51531	3.1	10/19/2016	
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10 above.					
4.2	Specimen Common Stock certificate of the Registrant	10-K	000-51531	4.2	3/29/2011	
4.3	Specimen Preferred Stock Certificate	8-K	000-51531	4.1	12/16/2015	
4.4	Specimen Preferred Stock Certificate	8-K	000-51531	4.1	10/19/2016	
10.1*	2005 Equity Incentive Award Plan, as amended, and Form of Stock Option Agreement	10-K/A	000-51531	10.3	4/30/2009	
10.2*	Form of Indemnification Agreement for directors and executive officers	S-1	333-121646	10.5	12/23/2004	
10.3†	License Agreement, dated October 14, 2003, by and between the Registrant and Sumitomo Dainippon Pharma Co., Ltd. (formerly known as Dainippon Pharmaceutical Co., Ltd.)	S-1/A	333-121646	10.36	4/29/2005	
10.4*	Amended and Restated 2006 Employment Commencement Incentive Plan	10-K/A	000-51531	10.32	4/30/2009	



Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.5*	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	
10.6*	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	
10.7*	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	
10.8	Form of Warrant to purchase shares of Common Stock	8-K	000-51531	10.2	4/3/2009	
10.9	Form of Warrant to Purchase Common Stock of the Registrant	8-K	000-51531	4.1	10/1/2010	
10.10	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	
10.11	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	
10.12	Amended and Restated Collaboration Agreement, dated March 31, 2011, by and between the Registrant and Biogen MA Inc.	10-Q/A	000-51531	10.4	6/30/2011	
10.13	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	
10.14	Termination and Transition Agreement, dated March 31, 2011, by and between the Registrant, Biogen MA Inc. and Millennium Pharmaceuticals, Inc.	10-Q	000-51531	10.6	5/12/2011	
10.15*	Sunesis Pharmaceuticals, Inc. 2011 Equity Incentive Plan	S-8	333-174732	99.1	6/6/2011	
10.16*	Sunesis Pharmaceuticals, Inc. 2011 Employee Stock Purchase Plan	S-8	333-174732	99.2	6/6/2011	
10.17	Sales Agreement, dated August 11, 2011, between Sunesis Pharmaceuticals, Inc. and Cantor Fitzgerald & Co.	8-K	000-51531	10.1	8/11/2011	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.18*	Forms of Stock Option Grant Notice and Option Agreement under the 2011 Equity Incentive Plan	10-K	000-51531	10.57	3/14/2012	
10.19*	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	
10.20†	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	
10.21	Amendment No. 1 to Sales Agreement, dated August 11, 2011, between the Registrant and Cantor Fitzgerald & Co., dated April 10, 2013	8-K	000-51531	10.1	4/10/2013	
10.22	Termination and Registration Rights Agreement, dated June 7, 2013, by and among the Registrant and the investors identified on the signature pages thereto	8-K	000-51531	10.1	6/11/2013	
10.23†	Second Amended and Restated Collaboration Agreement, dated December 16, 2013, by and between the Registrant and Biogen MA Inc.	10-K	000-51531	10.46	3/6/2014	
10.24†	Amended and Restated License Agreement, dated January 8, 2014, by and between the Registrant and Millennium Pharmaceuticals, Inc.	10-K	000-51531	10.47	3/6/2014	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.25	Lease Agreement, dated January 14, 2014, by and between the Registrant and Kashiwa Fudosan America, Inc., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-K	000-51531	10.45	3/6/2014	
10.26	First Amendment to Office Lease, dated June 3, 2014, by and between the Registrant and Kashiwa Fudosan America, Inc., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-Q	000-51531	10.1	8/05/2014	
10.27	Second Amendment to Office Lease, dated January 28, 2015, by and between the Registrant and Kashiwa Fudosan America, Inc., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-K	000-51531	10.44	3/12/2015	
10.28	Third Amendment to Office Lease, dated September 1, 2015, by and between the Registrant and Kashiwa Fudosan America, Inc., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-Q	000-51531	10.5	11/5/2015	
10.29	Amendment No. 2 to Sales Agreement, dated August 11, 2011, between the Registrant and Cantor Fitzgerald & Co., dated March 12, 2015	8-K	000-51531	10.1	3/12/2015	
10.30	Sunesis Pharmaceuticals, Inc. 2016 Bonus Program	8-K	000-51531	10.1	3/28/2016	
10.31	Loan and Security Agreement, dated March 31, 2016, by and among the Registrant, Western Alliance Bank, Solar Capital Ltd. And Western Alliance, as Collateral Agent	10-Q	000-51531	10.3	5/9/2016	
10.32	Warrant, dated March 31, 2016, issued to Solar Capital Ltd.	10-Q	000-51531	10.4	5/9/2016	
10.33	Warrant, dated March 31, 2016, issued to Western Alliance Bank	10-Q	000-51531	10.5	5/9/2016	
10.34*	Third Amended and Restated Executive Severance Benefits Agreement, dated April 13, 2016, by and between the Registrant and Daniel N. Swisher, Jr.	10-Q	000-51531	10.6	5/9/2016	
10.35*	Third Amended and Restated Executive Severance Benefits Agreement, dated April 13, 2016, by and between the Registrant and Eric H. Bjerkholt	10-Q	000-51531	10.7	5/9/2016	
10.36*	Amended and Restated Non-Employee Director Compensation Policy	10-Q	000-51531	10.3	7/29/2016	
10.37	Fourth Amendment to Office Lease, dated May 11, 2016, by and between the Registrant and Kashiwa Fudosan America, Inc., for office space located at 395 Oyster Point Boulevard, South San Francisco, California	10-Q	000-51531	10.4	7/29/2016	
21.1	Subsidiaries of the Registrant	10-Q	000-51531	21.1	8/02/2013	
23.1	Consent of Independent Registered Public Accounting Firm					X

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

\* 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.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-168191) of Sunesis Pharmaceuticals, Inc.,
- (2) Registration Statement (Form S-3 No. 333-187854) of Sunesis Pharmaceuticals, Inc.,
- (3) Registration Statement (Form S-3 No. 333-194166) of Sunesis Pharmaceuticals, Inc.,
- (4) Registration Statement (Form S-3 No. 333-195779) of Sunesis Pharmaceuticals, Inc.,
- (5) Registration Statement (Form S-8 No. 333-128647) pertaining to the 1998 Stock Plan, the 2001 Stock Plan, the 2005 Equity Incentive Award Plan and the Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (6) Registration Statement (Form S-8 No. 333-132679) pertaining to the 2006 Employment Commencement Incentive Plan of Sunesis Pharmaceuticals, Inc.,
- (7) Registration Statement (Form S-8 No. 333-138758) pertaining to the 2001 Stock Plan, the 2005 Equity Incentive Award Plan and the Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (8) Registration Statement (Form S-8 No. 333-145404) pertaining to the 2005 Equity Incentive Award Plan, the Amended and Restated 2006 Employment Commencement Incentive Plan and the Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (9) Registration Statement (Form S-8 No. 333-150834) pertaining to the 2005 Equity Incentive Award Plan, the Amended and Restated 2006 Employment Commencement Incentive Plan and the Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (10) Registration Statement (Form S-8 No. 333-160528) pertaining to the 2005 Equity Incentive Award Plan and the Amended and Restated 2006 Employment Commencement Incentive Plan of Sunesis Pharmaceuticals, Inc.,
- (11) Registration Statement (Form S-8 No. 333-174732) pertaining to the 2011 Equity Incentive Plan and the 2011 Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (12) Registration Statement (Form S-8 No. 333-180101) pertaining to the 2011 Equity Incentive Plan of Sunesis Pharmaceuticals, Inc.,
- (13) Registration Statement (Form S-8 No. 333-187234) pertaining to the 2011 Equity Incentive Plan of Sunesis Pharmaceuticals, Inc.,
- (14) Registration Statement (Form S-8 No. 333-195781) pertaining to the 2011 Equity Incentive Plan and the 2011 Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc.,
- (15) Registration Statement (Form S-8 No. 333-202696) pertaining to the 2011 Equity Incentive Plan and the 2011 Employee Stock Purchase Plan of Sunesis Pharmaceuticals, Inc., and
- (16) Registration Statement (Form S-8 No. 333-210183) pertaining to the 2011 Equity Incentive Plan of Sunesis Pharmaceuticals, Inc.

of our report dated March 9, 2017, with respect to the consolidated financial statements of Sunesis Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ ERNST & YOUNG LLP

Redwood City, California  
March 9, 2017

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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 9, 2017

/s/ DANIEL N. SWISHER, JR.

Daniel N. Swisher, Jr.  
President and Chief Executive Officer

## CERTIFICATION OF CHIEF FINANCIAL OFFICER

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 9, 2017

/s/ ERIC H. BJERKHOLT

Eric H. Bjerkholt  
Executive Vice President, Corporate  
Development and Finance,  
Chief Financial Officer and Corporate Secretary

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER**

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., President and Chief Executive Officer and Eric H. Bjerkholt, Executive Vice President, Corporate Development and Finance and Chief Financial Officer, of Sunesis Pharmaceuticals, Inc. (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, 2016 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, 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.

Date: March 9, 2017

/s/ DANIEL N. SWISHER, JR.

Daniel N. Swisher, Jr.  
President and Chief Executive Officer

Date: March 9, 2017

/s/ ERIC H. BJERKHOLT

Eric H. Bjerkholt  
Executive Vice President, Corporate  
Development and Finance,  
Chief Financial Officer and Corporate Secretary

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.



