

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0001 par value	SNSS	The Nasdaq Stock Market LLC

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 shorter period that the registrant was required to file reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The registrant had approximately 111,320,000 shares of common stock, \$0.0001 par value per share, outstanding as of November 5, 2019.

**SUNESIS PHARMACEUTICALS, INC.**  
**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <a href="#"><u>Financial Statements:</u></a>	3
<a href="#"><u>Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018</u></a>	3
<a href="#"><u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2019 and 2018</u></a>	4
<a href="#"><u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2019 and 2018</u></a>	5
<a href="#"><u>Condensed Consolidated Statement of Stockholders' Equity for the Three and Nine Months Ended September 30, 2019 and 2018</u></a>	6
<a href="#"><u>Notes to Condensed Consolidated Financial Statements</u></a>	7
Item 2. <a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	15
Item 3. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	22
Item 4. <a href="#"><u>Controls and Procedures</u></a>	22
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <a href="#"><u>Legal Proceedings</u></a>	23
Item 1A. <a href="#"><u>Risk Factors</u></a>	23
Item 2. <a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	39
Item 3. <a href="#"><u>Defaults Upon Senior Securities</u></a>	39
Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>	39
Item 5. <a href="#"><u>Other Information</u></a>	39
Item 6. <a href="#"><u>Exhibits</u></a>	39
<a href="#"><u>Signatures</u></a>	41

---

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

SUNESIS PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(In thousands)

	September 30, 2019 (Unaudited)	December 31, 2018 (1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,733	\$ 13,696
Restricted cash	5,500	—
Marketable securities	13,080	—
Prepays and other current assets	2,236	1,504
Total current assets	<u>40,549</u>	<u>15,200</u>
Property and equipment, net	5	11
Operating lease right-of-use asset	954	—
Other assets	102	113
Total assets	<u>\$ 41,610</u>	<u>\$ 15,324</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 770	\$ 1,393
Accrued clinical expense	544	500
Accrued compensation	1,177	943
Other accrued liabilities	398	1,091
Notes payable	5,460	7,396
Operating lease liability - current	545	—
Total current liabilities	<u>8,894</u>	<u>11,323</u>
Other liabilities	13	8
Operating lease liability - long term	409	—
Total liabilities	<u>9,316</u>	<u>11,331</u>
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock	11,763	20,998
Common stock	11	4
Additional paid-in capital	698,032	642,460
Accumulated deficit	(677,512)	(659,469)
Total stockholders' equity	<u>32,294</u>	<u>3,993</u>
Total liabilities and stockholders' equity	<u>\$ 41,610</u>	<u>\$ 15,324</u>

(1) The condensed consolidated balance sheet as of December 31, 2018, has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

See accompanying notes to condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
<b>Revenue:</b>				
License and other revenue	\$ —	\$ —	\$ —	\$ 237
<b>Total revenues</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>237</b>
<b>Operating expenses:</b>				
Research and development	3,534	3,587	10,465	11,314
General and administrative	2,507	2,690	7,469	8,873
<b>Total operating expenses</b>	<b>6,041</b>	<b>6,277</b>	<b>17,934</b>	<b>20,187</b>
Loss from operations	(6,041)	(6,277)	(17,934)	(19,950)
Interest expense	(71)	(291)	(443)	(859)
Other income, net	170	63	334	191
<b>Net loss</b>	<b>(5,942)</b>	<b>(6,505)</b>	<b>(18,043)</b>	<b>(20,618)</b>
Unrealized gain on available-for-sale securities	—	1	—	7
<b>Comprehensive loss</b>	<b>\$ (5,942)</b>	<b>\$ (6,504)</b>	<b>\$ (18,043)</b>	<b>\$ (20,611)</b>
<b>Basic and diluted loss per common share:</b>				
<b>Net loss</b>	<b>\$ (5,942)</b>	<b>\$ (6,505)</b>	<b>\$ (18,043)</b>	<b>\$ (20,618)</b>
Shares used in computing net loss per common share	105,070	36,095	78,969	34,956
<b>Net loss per common share</b>	<b>\$ (0.06)</b>	<b>\$ (0.18)</b>	<b>\$ (0.23)</b>	<b>\$ (0.59)</b>

See accompanying notes to condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2019	2018
	(Unaudited)	
<b>Cash flows from operating activities</b>		
Net loss	\$ (18,043)	\$ (20,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,276	2,185
Depreciation and amortization	6	6
Amortization of debt discount and debt issuance costs	112	144
Changes in operating assets and liabilities:		
Prepays and other assets	(721)	1,154
Accounts payable	(623)	(420)
Accrued clinical expense	44	(123)
Accrued compensation	234	(254)
Other accrued liabilities	(722)	28
Net cash used in operating activities	<u>(18,437)</u>	<u>(17,898)</u>
<b>Cash flows from investing activities</b>		
Purchases of marketable securities	(13,080)	—
Proceeds from maturities of marketable securities	—	4,780
Net cash (used in) provided by investing activities	<u>(13,080)</u>	<u>4,780</u>
<b>Cash flows from financing activities</b>		
Proceeds from notes payable, net of issuance cost	5,453	—
Principal payments on notes payable	(7,500)	—
Proceeds from issuance of convertible preferred stock offering, net	12,533	—
Proceeds from issuance of common stock, net	32,068	—
Proceeds from issuance of common stock through controlled equity offering facilities, net	464	6,040
Proceeds from exercise of stock options and stock purchase rights	36	263
Net cash provided by financing activities	<u>43,054</u>	<u>6,303</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	11,537	(6,815)
Cash, cash equivalents and restricted cash at beginning of period	13,696	26,977
Cash, cash equivalents and restricted cash at end of period	<u>\$ 25,233</u>	<u>\$ 20,162</u>
<b>Supplemental disclosure of non-cash activities</b>		
Commitment shares issued as cost of equity financing	\$ —	\$ 448
Conversion of preferred stock to common stock	\$ 21,762	\$ —
Legal expenses accrued as cost of equity financing	\$ 33	\$ 125

See accompanying notes to condensed consolidated financial statements.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
<b>Total stockholders' equity, beginning balances</b>	<b>\$ 11,739</b>	<b>\$ 9,975</b>	<b>\$ 3,993</b>	<b>\$ 21,544</b>
Convertible preferred stock:				
Beginning balances	7,113	20,966	20,998	20,966
Issuance of preferred stock in underwritten offering, net of issuance costs	4,650	—	12,527	—
Conversion of preferred stock to common stock	—	—	(21,762)	—
Ending balances	<u>11,763</u>	<u>20,966</u>	<u>11,763</u>	<u>20,966</u>
Common stock:				
Beginning balances	7	4	4	3
Issuance of common stock in underwritten offering, net of issuance costs	4	—	6	—
Conversion of preferred stock to common stock	—	—	1	—
Issuance of common stock through controlled equity offering facilities, net of issuance cost	—	—	—	1
Ending balances	<u>11</u>	<u>4</u>	<u>11</u>	<u>4</u>
Additional paid-in capital				
Beginning balances	676,189	635,973	642,460	633,436
Issuance of common stock in underwritten offering, net of issuance costs	21,378	—	32,035	—
Conversion of preferred stock to common stock	—	—	21,761	—
Issuance of common stock through controlled equity offering facilities, net of issuance cost	—	5,188	464	5,914
Issuance of common stock pursuant to stock option exercises	—	—	—	164
Issuance of common stock from vesting of restricted stock awards, net of shares withheld for taxes	—	—	54	83
Issuance of common stock pursuant to employee stock purchase plan	—	—	36	99
Stock-based compensation expenses	465	637	1,222	2,102
Ending balances	<u>698,032</u>	<u>641,798</u>	<u>698,032</u>	<u>641,798</u>
Accumulated other comprehensive loss				
Beginning balances	—	(1)	—	(7)
Unrealized gain on available-for-sale securities	—	1	—	7
Ending balances	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Accumulated deficit				
Beginning balances	(671,570)	(646,967)	(659,469)	(632,854)
Net loss	(5,942)	(6,505)	(18,043)	(20,618)
Ending balances	<u>(677,512)</u>	<u>(653,472)</u>	<u>(677,512)</u>	<u>(653,472)</u>
<b>Total stockholders' equity, ending balances</b>	<b><u>\$ 32,294</u></b>	<b><u>\$ 9,296</u></b>	<b><u>\$ 32,294</u></b>	<b><u>\$ 9,296</u></b>

See accompanying notes to condensed consolidated financial statements.

**SUNESIS PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2019**  
**(Unaudited)**

**1. Company Overview**

***Description of Business***

Sunesis Pharmaceuticals, Inc. (“Sunesis” or the “Company”) is a biopharmaceutical company focused on the development of novel targeted inhibitors for the treatment of hematologic and solid 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.

The Company’s lead program is vecabrutinib, a selective non-covalent inhibitor of Bruton’s Tyrosine Kinase (“BTK”) with activity against both wild-type and C481-mutated BTK, the most common mutation associated with resistance to the covalent BTK inhibitor ibrutinib. This C481 mutation has also been seen in patients who developed resistance to acalabrutinib, another covalent BTK inhibitor that is completing Phase 3 clinical trials in chronic lymphocytic leukemia (“CLL”) and was recently approved for treatment of mantle cell lymphoma (“MCL”). Ibrutinib was the first BTK inhibitor approved for the treatment of CLL, MCL and other B-cell malignancies.

Vecabrutinib is being studied in a Phase 1b/2 clinical trial to assess safety and activity in patients with CLL and other advanced B-cell malignancies after two or more prior therapies, including ibrutinib or another covalent BTK inhibitor where approved for the disease. The Phase 1b portion of the study will define a recommended Phase 2 dose and/or a maximum tolerated dose. The Company has completed the safety evaluation period for the 300 mg cohort and the sixth cohort, testing 400 mg twice daily, is now open.

The Company is developing SNS-510, a PDK1 inhibitor that it in-licensed from Takeda Oncology, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda. In October 2019 the Company presented positive results assessing SNS-510 in multiple preclinical pharmacology studies.

Takeda is the Company’s licensee for TAK-580, an oral pan-RAF inhibitor, which is under investigation for pediatric low-grade glioma.

***Liquidity and Going Concern***

The Company has incurred significant losses and negative cash flows from operations since its inception, and as of September 30, 2019, the Company had cash and cash equivalents, restricted cash, and marketable securities totaling \$38.3 million and an accumulated deficit of \$677.5 million.

The Company expects to continue to incur significant losses for the foreseeable future as it continues development of its kinase inhibitor pipeline, including its BTK inhibitor, vecabrutinib. The Company has prioritized development funding on its kinase inhibitor portfolio with a focus on vecabrutinib. The Company has two product candidates that are in the early stages of development and will require significant additional future investment.

The Company’s cash and cash equivalents, restricted cash, and marketable securities are not sufficient to support its operations for a period of twelve months from the date these condensed consolidated financial statements are available to be issued. These factors raise substantial doubt about its ability to continue as a going concern. The Company will require additional financing to fund working capital, repay debt and pay its obligations as they come due. Additional financing might include one or more offerings and one or more of a combination of equity securities, debt arrangements or partnership or licensing collaborations. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms favorable to the Company. If the Company is unsuccessful in its efforts to raise additional financing in the near term, the Company will be required to significantly reduce or cease operations. The principal payments due under the SVB Loan Agreement (as defined in Note 6) have been classified as a current liability as of September 30, 2019 due to the considerations discussed above and the assessment that the material adverse change clause under the SVB Loan Agreement is not within the Company’s control. The SVB Loan Agreement also contains customary events of default, including among other things, the Company’s failure to make principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or its breach of the covenants under the SVB Loan Agreement. Upon the occurrence of an event of default (as defined in Note 6), SVB may, among other things, accelerate the Company’s obligations under the SVB Loan Agreement. The Company has not been notified of an event of default by SVB as of the date of the filing of this Form 10-Q. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern.

### **Concentrations of Credit Risk**

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

## **2. Summary of Significant Accounting Policies**

### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for a fair presentation of the periods presented. The balance sheet as of December 31, 2018 was derived from the audited consolidated financial statements as of that date. These interim financial results are not necessarily indicative of results to be expected for the full year or any other period. These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2018.

### **Adopted Accounting Pronouncements**

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments)*. This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. The guidance will generally be applied retrospectively and is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted this ASU during the quarter ended March 31, 2019. The adoption of this ASU did not have a significant impact on its condensed financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (“ASC 842”). ASC 842 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. ASC 842 is effective for Sunesis’ interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, ASU 2018-11, *Leases (Topic 842): Targeted Improvements* and issued ASU 2019-01, *Leases (Topic 842): Codification Improvements* in March 2019. These pronouncements have the same effective date as the new leases standard and provide additional guidance, clarification and practical expedients to reduce the cost and complexity of applying the new standard. The Company adopted the new guidance on January 1, 2019 using the modified retrospective method at the effective date.

The Company has elected the package of practical expedients permitted under ASC 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs before transition adjustments would have met the definition of initial direct costs in ASC Topic 842 at lease commencement. In addition, the Company made an accounting policy election to combine the lease and non-lease components and the short-term lease practical expedients allowed under ASC 842. As a result of the adoption of ASC 842, the Company recognized on January 1, 2019 (a) a lease liability of approximately \$1,362,000, which represents the present value of the remaining lease payments of approximately \$1,434,000, discounted using the Company’s incremental borrowing rate of 4.0%, and (b) a right-of-use (“ROU”) asset equal to the lease liability of approximately \$1,362,000. Once recorded, the Company also evaluates the right-of-use asset for impairment as part of an asset group, following the principles of ASC 360, *Property, Plant, and Equipment*. The adoption of the new standard resulted in changes to the Company’s accounting policies for leases as detailed below.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. This new guidance is effective for the Company in fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. On January 1, 2019, the Company adopted this new guidance and the measurement of equity-classified nonemployee awards will be fixed at the grant date. Upon adoption, the Company applied the new guidance to equity-classified nonemployee awards for which a measurement date has not been established and compared the cumulative amounts that were recorded for its nonemployee share-based payments through the end of December 31, 2018 to the cumulative amounts that should be recognized at the adoption date to calculate the transition adjustment. On January 1, 2019, the Company recognized the transition adjustment as an adjustment to retained earnings, which had no material impact on the Company's unaudited condensed consolidated financial statements or related footnote disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. The Company adopted the amendments during the quarter ended March 31, 2019, and as a result, disclosed in its condensed consolidated statements of stockholders' equity the quarterly activity of each caption of stockholders' equity for the three and nine months ended September 30, 2019 and 2018.

#### **Recent Accounting Pronouncements**

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. In April 2019, the FASB issued ASU 2019-04, "Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments," to increase stakeholders' awareness of the amendments and to expedite improvements to the Codification. In May 2019, the FASB issued ASU 2019-05, "Financial Instruments—Credit Losses, Topic 326," providing an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. These ASUs do not change the core principle of the guidance in ASU 2016-13. Instead these amendments are intended to clarify and improve operability of certain topics. The Company does not expect the adoption of this standard will have a material impact on its financial statements and accompanying footnotes.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. The amendments in this ASU modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. Various disclosure requirements have been removed, including the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, the valuation processes for Level 3 fair value measurements held at the end of the reporting period. The ASU also modified various disclosure requirements and added some disclosure requirements for Level 3 fair value measurements. The amendments in this ASU are effective for the Company on January 1, 2020. The additional disclosures on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this ASU and delay adoption of the additional disclosures until their effective date. The Company does not expect the adoption of this ASU will have a material impact on its financial statements.

#### **Leases**

The Company determines if an arrangement is or contains a lease at inception. In determining whether an arrangement is a lease, the Company considers whether (1) explicitly or implicitly identified assets have been deployed in the arrangement and (2) the Company obtains substantially all of the economic benefits from the use of that underlying asset and directs how and for what purpose the asset is used during the term of the contract.

ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized based on the present value of lease payments over the lease term. When an implicit rate is not readily determinable, the Company uses its incremental borrowing rate based on the information available at commencement date for new leases or effective date for existing leases, in determining the present value of lease payments.

Leases may contain initial periods of free rent and/or periodic escalations. When such items are included in a lease agreement, the Company records rent expense on a straight-line basis over the initial term of a lease. The difference between the rent payment and the straight-line rent expense is recorded as a deferred rent liability. The Company expenses any additional payments under its operating leases for taxes, insurance or other operating expenses as incurred.

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

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

### ***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 condensed 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 debt instruments, stock-based compensation, ROU assets, lease liabilities, and clinical trial accounting.

### ***Cash Equivalents, Restricted Cash, 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, repurchase agreements, and corporate debt securities. Restricted cash consists of amounts pledged as collateral for term loan agreement as contractually required by the lender. 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.

### ***Fair Value Measurements***

The Company measures cash equivalents 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 carrying amounts of the Company's financial instruments, including cash, prepayments, accounts payable, accrued liabilities, and notes payable approximated their fair value as of September 30, 2019 and December 31, 2018.

### **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 loss per common share is computed by dividing (a) net loss, by (b) the weighted-average number of common shares outstanding for the period plus dilutive potential common shares as determined using the treasury stock method for options and warrants to purchase common stock.

The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted loss per common share because their inclusion would have had an anti-dilutive effect (in thousands):

	<b>Three and nine months ended</b>	
	<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>
Warrants to purchase shares of common stock	218	5,218
Convertible preferred stock	19,714	6,331
Options to purchase shares of common stock	5,002	3,474
Outstanding securities not included in calculations	<u>24,934</u>	<u>15,023</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 are comprised solely of available-for-sale marketable securities with remaining contractual maturities of one year or less (in thousands):

September 30, 2019	Input Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	\$ 7,953	\$ —	\$ —	\$ 7,953
U.S. Treasury securities	Level 1	1,587	—	—	1,587
Repurchase agreements	Level 2	5,000	—	—	5,000
U.S. corporate debt obligations	Level 2	5,338	—	—	5,338
U.S. commercial paper	Level 2	11,648	—	—	11,648
Total available-for-sale securities		31,526	—	—	31,526
Less amounts classified as cash equivalents		(18,446)	—	—	(18,446)
Amounts classified as marketable securities		\$ 13,080	\$ —	\$ —	\$ 13,080

December 31, 2018	Input Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	Level 1	\$ 10,845	\$ —	\$ —	\$ 10,845
Total available-for-sale securities		10,845	—	—	10,845
Less amounts classified as cash equivalents		(10,845)	—	—	(10,845)
Amounts classified as marketable securities		\$ —	\$ —	\$ —	\$ —

There were no available-for-sale securities in an unrealized gain or loss position as of September 30, 2019 and December 31, 2018. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of these securities. As of September 30, 2019, we did not hold any investments with a maturity exceeding 12 months or that have been in a continuous loss position for 12 months or more. There were no realized gains or losses on the available-for-sale securities during three and nine months ended September 30, 2019 and 2018.

#### 5. License Agreements

##### Biogen

In December 2013, the Company entered into a second amended and restated collaboration agreement with Biogen Inc. (the "Biogen 2nd ARCA"), to provide the Company with an exclusive worldwide license to develop, manufacture and commercialize vecabrutinib, a BTK inhibitor synthesized under an earlier collaboration with Biogen, solely for oncology indications. During the third quarter of 2017, the Company made the final milestone payment of \$2.5 million to Biogen upon the dosing of the first patient in the Phase 1b/2 study to assess the safety and activity of vecabrutinib in patients with advanced B-cell malignancies. The payment was recorded in the research and development expenses line item in the consolidated statement of operations. The Company may also be required to make tiered royalty payments based on percentages of net sales of vecabrutinib, if any, in the mid-single-digits.

##### Takeda

In March 2011, Takeda Oncology, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") purchased exclusive rights to the PDK1 inhibitor and pan-Raf inhibitor programs which were both originally developed through the Company's collaboration with Biogen. 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 and may be required to make up to \$9.2 million in pre-commercialization milestone payments depending on its development of PDK1 inhibitors and tiered royalty payments based on percentages of net sales, if any, beginning in the mid-single-digits and not to exceed the low-teens.

With respect to the pan-Raf inhibitor program, TAK-580 (formerly MLN2480), 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. TAK-580 is currently being studied in a Phase 1b/2 clinical study for children with low-grade gliomas. As of September 30, 2019, all future event-based payments and royalty payments are considered fully constrained variable considerations and therefore, no contract assets have been recorded and no revenue have been recognized.

## 6. Notes Payable

In April 2019, the Company entered into a term loan agreement with Silicon Valley Bank (“SVB Loan Agreement”), pursuant to which the Company borrowed \$5.5 million. The Company used the proceeds of the SVB Loan Agreement plus cash on hand to repay its remaining obligations in the amount of \$5.9 million under its existing loan agreement with Western Alliance Bank and Solar Capital Ltd. The maturity date of the SVB Loan Agreement is December 1, 2022. Under the terms of the SVB Loan Agreement, the Company is required to make interest-only payments through December 31, 2020 on the borrowings at a floating rate equal to the greater of the Prime Rate as defined in the SVB Loan Agreement minus 2.25%, or 3.25%, followed by an amortization period of 24 months of equal monthly payments of principal plus interest amounts until paid in full. In addition to and not in substitution for the regular monthly payments of principal plus accrued interest, the Company is required to make a final payment equal to 4% of the original principal amount of the borrowings (“Final Payment Fee”). Additionally, the Company may prepay all, but not less than all, of the borrowings at any time upon 30 days’ prior notice to Silicon Valley Bank (“SVB”). Any such prepayment would require, in addition to payment of principal and accrued interest as well as the Final Payment Fee, a prepayment fee, in the amount of (a) \$165,000 if the prepayment occurs prior to the 1st anniversary of April 26, 2019, or the Effective Date; (b) \$110,000 if the prepayment occurs on or after the 1st anniversary of the Effective Date but prior to the 2nd anniversary of the Effective Date; or (c) \$55,000 if the prepayment occurs on or after the 2nd anniversary of the Effective Date.

The Company’s obligations under the SVB Loan Agreement are secured by a first priority security interest in cash held at an account with SVB (the “Collateral Account”). The Company is obligated to maintain sufficient cash in the Collateral Account at all times in an amount equal to or greater than the outstanding balance of the borrowings. The Company has classified the Collateral Account as restricted cash on its condensed consolidated balance sheets as of September 30, 2019.

The SVB Loan Agreement contains customary affirmative and negative covenants which, among other things, limit the Company’s ability to (i) incur additional indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of its assets, grant liens or encumber its assets or (iv) fundamentally alter the nature of its business. These covenants are subject to a number of exceptions and qualifications. The SVB Loan Agreement also contains customary events of default, including among other things, the Company’s failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or its breach of the covenants under the SVB Loan Agreement. Upon the occurrence of an event of default, SVB may, among other things, accelerate the Company’s obligations under the SVB Loan Agreement. The Company was in compliance with all applicable covenants set forth in the SVB Loan Agreement as of September 30, 2019. The principal payments due under the SVB Loan Agreement have been classified as a current liability at September 30, 2019 due to the considerations discussed in Note 1 and the assessment that the material adverse change clause under the SVB Loan Agreement is not within the Company’s control. The Company has not been notified of an event of default by the Lenders as of the date of the filing of this Form 10-Q.

Aggregate future minimum payments due under the SVB Loan Agreement as of September 30, 2019 were as follows (in thousands):

<u>Through December 31,</u>	<u>Total</u>
2019	\$ 45
2020	179
2021	2,888
2022	3,018
Total minimum payments	6,130
Less amount representing interest	(630)
Total notes payable as of September 30, 2019	5,500
Less unamortized debt discount and issuance costs	(40)
Less carrying amount of notes payable	(5,460)
Non-current portion of notes payable	<u>\$ —</u>

## **7. Stockholders' Equity**

### ***Underwritten Offerings***

In July 2019, the Company completed underwritten public offerings of (i) 38,333,717 shares of its common stock at a price to the public of \$0.60 for each share of common stock, including the full exercise of the underwriters' option to purchase 5,000,050 additional shares of common stock to cover over-allotments, and (ii) 8,333 shares of its non-voting Series F Convertible Preferred Stock ("Series F Stock") at a price to the public of \$600.00 for each share of Series F Stock. Gross proceeds from the sale were approximately \$28.0 million and net proceeds were approximately \$26.1 million. Each share of non-voting Series F Stock is convertible into 1,000 shares of the Company's 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 the Company's common stock then outstanding; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable).

In January 2019, the Company completed underwritten public offerings of (i) 23,000,000 shares of its common stock at a price to the public of \$0.50 for each share of common stock, and (ii) 17,000 shares of its non-voting Series E Convertible Preferred Stock ("Series E Stock") at a price to the public of \$500.00 for each share of Series E Stock. Gross proceeds from the sale were \$20.0 million and net proceeds were approximately \$18.6 million. Each share of non-voting Series E Stock is convertible into 1,000 shares of the Company's 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 the Company's common stock then outstanding; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable).

### ***Preferred Stock Conversion***

During the nine months ended September 30, 2019, the Company issued a total of 11,950,165 shares of its common stock upon conversion of 13,639 shares of its non-voting Series B Convertible Preferred Stock, 1,558 shares of its non-voting Series C Convertible Preferred Stock, 1,119 shares of its non-voting Series D Convertible Preferred Stock, and 7,000 shares of Series E Stock. No shares of non-voting Series B or Series C Convertible Preferred Stock remain outstanding after the conversion. 1,381 shares of non-voting Series D Convertible Preferred Stock, 10,000 shares of Series E Stock, and 8,333 shares of Series F Stock remain outstanding after the conversion.

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

#### ***Cantor Controlled Equity Offering***

During the three and nine months ended September 30, 2019, no shares and 0.4 million shares of common stock, respectively, were sold under the Controlled Equity Offering<sup>SM</sup> sales agreement, as amended (the "Sales Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), as agent and/or principal. The shares were sold at an average price of approximately \$1.19 per share for gross and net proceeds of \$0.5 million, after deducting Cantor's commission. As of September 30, 2019, \$43.1 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the Sales Agreement.

#### ***Aspire Common Stock Purchase Agreement***

During the three and nine months ended September 30, 2019, no shares were issued under the Common Stock Purchase Agreement (the "CSPA") with Aspire Capital Fund, LLC ("Aspire"). Aspire's remaining purchase commitment was \$10.9 million as of September 30, 2019.

## **8. Stock-Based Compensation**

Employee and non-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. Forfeitures are recognized as they occur.

The following table summarizes stock-based compensation expense related to the Company's stock-based awards for the periods indicated (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 104	\$ 152	\$ 400	\$ 446
General and administrative	200	203	614	644
Employee stock-based compensation expense	304	355	1,014	1,090
Non-employee stock-based compensation expense	161	282	262	1,095
Total stock-based compensation expense	<u>\$ 465</u>	<u>\$ 637</u>	<u>\$ 1,276</u>	<u>\$ 2,185</u>

## 9. Leases

The Company's operating lease obligations as of September 30, 2019 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. The lease was entered into in January 2014 and was amended several times since 2014. The lease was last amended in December 2017 to extend the expiration date to June 30, 2021, with an option to extend the lease for two additional years. The Company did not assume the option to extend the lease term for two additional years in its determination of the lease term as the exercise of the option was not reasonably certain when the lease was last amended in December 2017. The remaining lease term as of September 30, 2019 was 1.75 years.

The cash paid for operating lease liability was \$0.4 million and the ROU asset obtained in exchange for new operating lease liability was \$1.4 million, for the nine months ended September 30, 2019.

Maturity of lease liability is as follows (in thousands):

<u>Through December 31,</u>	
2019	\$ 143
2020	579
2021	294
Total rental payments	1,016
Less imputed interest	(62)
Present value of lease liability	<u>\$ 954</u>

The Company recognizes rent expense on a straight-line basis. The Company recorded rent expense of \$0.1 million for each of the three months ended September 30, 2019 and 2018. The Company recorded rent expense of \$0.4 million for each of the nine months ended September 30, 2019 and 2018.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis of our financial condition as of September 30, 2019 and results of operations for the three and nine months ended September 30, 2019 and 2018 should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings, including our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 7, 2019.*

*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 expectations for gaining marketing approval in the United States, including the continued development and commercialization of vecabrutinib (formerly SNS-062), SNS-510, TAK-580, vosaroxin, and other product candidates, the timing of our Phase 1b/2 trial of vecabrutinib, 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, including any partnering arrangements related to further vosaroxin development, 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. 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 except as required by law.*

*"Sunesis," "we," "us," and "our" refer to Sunesis Pharmaceuticals, Inc. and its wholly-owned subsidiaries, except where it is made clear that the term means only the parent company.*

### Overview

Sunesis is a biopharmaceutical company focused on the development of novel targeted inhibitors for the treatment of hematologic and solid cancers. Our primary activities since incorporation have been conducting research and development internally and through collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, conducting clinical trials, and raising capital.

Our lead program is vecabrutinib, a selective non-covalent inhibitor of Bruton's Tyrosine Kinase ("BTK") with activity against both wild-type and C481-mutated BTK, the most common mutation associated with resistance to the covalent BTK inhibitor ibrutinib. This C481 mutation has also been seen in patients who developed resistance to acalabrutinib, another covalent BTK inhibitor that is completing Phase 3 clinical trials in chronic lymphocytic leukemia ("CLL") and was recently approved for treatment of mantle cell lymphoma ("MCL"). Ibrutinib was the first BTK inhibitor approved for the treatment of CLL, MCL and other B-cell malignancies. Ibrutinib is the market leader in CLL, marketed by Johnson & Johnson and AbbVie, with approximately \$5 billion in net revenues in 2018.

Vecabrutinib is being studied in a Phase 1b/2 clinical trial to assess safety and activity in patients with CLL and other advanced B-cell malignancies after two or more prior therapies, including ibrutinib or another covalent BTK inhibitor where approved for the disease. The Phase 1b portion of the study will define a recommended Phase 2 dose and/or a maximum tolerated dose. We completed the safety evaluation period for the 300 mg cohort and thus far vecabrutinib has a favorable safety profile. We have not seen any Grade 3 or higher drug-related adverse events in cohorts above 50mg. The sixth cohort, testing 400 mg twice daily, is now open. Upon identifying the Phase 2 dose, the Phase 2 portion will further explore clinical activity and safety in CLL patients, including those with and without BTK C481 mutations. We plan to open additional sites, including sites in Europe, when this study advances to Phase 2. Preparation for the Phase 2 is advanced, and we have secured FDA agreement on the protocol.

We are developing SNS-510, a PDK1 inhibitor that we licensed from Takeda Oncology, a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda. In October 2019 we presented positive results assessing SNS-510 in multiple preclinical pharmacology studies, including evaluation in the Eurofins Oncopanel™, a panel of 320 genomically profiled cancer cell lines from diverse tissue origins, and in vivo studies in FLT3-mutated and wild-type AML xenograft models. These studies indicated that *CDKN2A*-mutated tumors are particularly sensitive to SNS-510, supporting a potential role in combination with CDK4/6 inhibitors to address resistance and improve activity. SNS-510 also demonstrated potent, pathway-mediated antitumor activity in the AML models. These results were presented at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. We are currently manufacturing doing pharmacology work and preparing for Good Laboratory Practice (“GLP”) toxicology studies for SNS-510.

Takeda is our licensee for TAK-580, an oral pan-RAF inhibitor which is under investigation for pediatric low-grade glioma.

We are evaluating strategic alternatives for vosaroxin, a topoisomerase 2 inhibitor for which we conducted a Phase 3 trial in patients with relapsed or refractory acute myeloid leukemia that did not meet our primary endpoint of demonstrating a statistically significant improvement in overall survival.

## **Recent Financial History**

### ***Underwritten Offerings***

In July 2019, we completed underwritten public offerings of (i) 38,333,717 shares of our common stock at a price to the public of \$0.60 for each share of common stock, including the full exercise of the underwriters’ option to purchase 5,000,050 additional shares of common stock to cover over-allotments, and (ii) 8,333 shares of our non-voting Series F Convertible Preferred Stock (“Series F Stock”) at a price to the public of \$600.00 for each share of Series F Stock. Gross proceeds from the sale were approximately \$28.0 million and net proceeds were approximately \$26.1 million. Each share of non-voting Series F 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; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable).

In January 2019, we completed underwritten public offerings of (i) 23,000,000 shares of our common stock at a price to the public of \$0.50 for each share of common stock, and (ii) 17,000 shares of our non-voting Series E Convertible Preferred Stock, or Series E Stock, at a price to the public of \$500 for each share of Series E Stock. Gross proceeds from the sale were \$20.0 million and net proceeds were approximately \$18.6 million. Each share of non-voting Series E 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; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable). During the nine months ended September 30, 2019, 7,000 shares of Series E Stock were converted into 7,000,000 shares of common stock with the remaining 10,000 shares of Series E Stock outstanding as of September 30, 2019.

### ***Debt Refinancing***

In April 2019, we entered into a term loan agreement with Silicon Valley Bank, the SVB Loan Agreement, pursuant to which we borrowed \$5.5 million and used the proceeds of the SVB Loan Agreement plus cash on hand to repay our remaining obligations in the amount of \$5.9 million under our existing loan agreement, or the Loan Agreement and Amendments, with Western Alliance Bank and Solar Capital Ltd and Western Alliance, as Collateral Agent.

The maturity date of the SVB Loan Agreement is December 1, 2022. Under the terms of the SVB Loan Agreement, we are required to make interest-only payments through December 31, 2020 on the borrowings at a floating rate equal to the greater of the Prime Rate as defined in the SVB Loan Agreement minus 2.25%, or 3.25%, followed by an amortization period of 24 months of equal monthly payments of principal plus interest amounts until paid in full. In addition to and not in substitution for the regular monthly payments of principal plus accrued interest, we are required to make a final payment equal to 4% of the original principal amount of the borrowings, or Final Payment Fee. Additionally, we may prepay all, but not less than all of the borrowings at any time upon 30 days’ prior notice to Silicon Valley Bank, or SVB. Any such prepayment would require, in addition to payment of principal and accrued interest as well as the Final Payment Fee, a prepayment fee, in the amount of (a) \$165,000 if the prepayment occurs prior to the 1st anniversary of April 26, 2019, or the Effective Date; (b) \$110,000 if the prepayment occurs on or after the 1st anniversary of the Effective Date but prior to the 2nd anniversary of the Effective Date; or (c) \$55,000 if the prepayment occurs on or after the 2nd anniversary of the Effective Date.

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

#### ***Cantor Controlled Equity Offering***

During the three and nine months ended September 30, 2019, no shares and 0.4 million shares of common stock, respectively, were sold under the Controlled Equity Offering<sup>SM</sup> sales agreement, as amended, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent and/or principal. The shares were sold at an average price of approximately \$1.19 per share for gross and net proceeds of \$0.5 million, after deducting Cantor's commission. As of September 30, 2019, \$43.1 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the Sales Agreement.

#### ***Aspire Common Stock Purchase Agreement***

During the nine months ended September 30, 2019, no shares were issued under the Common Stock Purchase Agreement, or CSPA, with Aspire Capital Fund, LLC, or Aspire. Aspire's remaining purchase commitment was \$10.9 million as of September 30, 2019.

### **Capital Requirements**

We have incurred significant losses in each year since our inception. As of September 30, 2019, we had cash and cash equivalents, restricted cash, and marketable securities of \$38.3 million and an accumulated deficit of \$677.5 million. We expect to continue to incur significant losses for the foreseeable future as we continue the development of our kinase inhibitor pipeline, including our BTK inhibitor vecabrutinib. We have a limited number of products that are still in the early stages of development and will require significant additional future investment.

We expect our cash and cash equivalents and marketable securities of \$32.8 million, which excludes restricted cash of \$5.5 million, as of September 30, 2019 are not sufficient to support our operations for a period of twelve months from the date the condensed consolidated financial statements for the quarter ended September 30, 2019, are available to be issued. We will require additional financing to fund working capital, repay debt and pay our obligations as they come due. Additional financing might include one or more offerings and one or more of a combination of equity securities, debt arrangements or partnership or licensing collaborations. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date our condensed consolidated financial statements for the quarter ended September 30, 2019, are available to be issued. If we are unsuccessful in our efforts to raise additional financing in the near term, we will be required to significantly reduce or cease operations. Our accompanying condensed consolidated financial statements for the quarter ended September 30, 2019, have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Except for the change in accounting policy noted below, there have been no significant changes during the three and nine months ended September 30, 2019 to our critical accounting policies and significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2018.

### ***Leases***

We determine if an arrangement is or contains a lease at inception. In determining whether an arrangement is a lease, we consider whether (1) explicitly or implicitly identified assets have been deployed in the arrangement and (2) we obtain substantially all of the economic benefits from the use of that underlying asset and direct how and for what purpose the asset is used during the term of the contract.

Right-of-Use, or ROU, assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized based on the present value of lease payments over the lease term. When an implicit rate is not readily determinable, we use our incremental borrowing rate based on the information available at commencement date for new leases or effective date for existing leases, in determining the present value of lease payments.

Leases may contain initial periods of free rent and/or periodic escalations. When such items are included in a lease agreement, we record rent expense on a straight-line basis over the initial term of a lease. The difference between the rent payment and the straight-line rent expense is recorded as a deferred rent liability. We expense any additional payments under its operating leases for taxes, insurance, or other operating expenses as incurred.

## **Revenues**

We have not generated any revenue from the sale of commercial products. Over the past several years, we have generated revenue primarily through the Royalty Agreement with RPI (each as defined below), and the Biogen 2<sup>nd</sup> ARCA with Biogen, which was fully amortized to revenue over the related performance period. We cannot predict if our collaboration will continue development or whether we will receive any additional event-based payments or royalties from these agreements, as amended, in the foreseeable future, or at all.

## **Operating Expenses**

*Research and Development expense.* Research and development expense consists primarily of clinical trial costs, which include payments for: work performed by our contract research organizations, clinical trial sites, and labs and other clinical service providers; drug packaging, storage, and distribution; drug manufacturing, which includes producing drug substance and drug product and stability and other testing; personnel, including non-cash stock-based compensation; other outside services and consulting; and license agreements. We expense all research and development costs as they are incurred.

We are currently focused on the development of vecabrutinib for the treatment of B-cell malignancies. We are also developing our other product candidate, SNS-510, for the treatment of solid tumor and hematologic malignancies. Research and development costs typically increase as product development candidates move from early stage to later stage, larger clinical trials. As a result, our research and development costs may increase in the future. 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 development of our product candidates in the future.

If we engage a development or commercialization partner for our development programs, 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.

We anticipate continuing expenditures associated with advancing the vecabrutinib and SNS-510 programs in 2019 and beyond. Additionally, under the Amended Takeda Agreement, we have the right to participate in co-development and co-promotion activities for TAK-580. 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; outside service costs, including fees paid to external legal advisors, marketing consultants and our independent registered public accounting firm; facilities expenses; and other administrative costs.

## **Results of Operations**

### ***Revenue***

Total revenue was nil for the three and nine months ended September 30, 2019, and nil and \$0.2 million for the same periods in 2018. The decrease in revenue for the comparable nine months periods was primarily due to an event-based payment received in 2018 related to a license agreement for certain of our proprietary technology.

### ***Research and Development Expense***

Research and development expense was \$3.5 million and \$10.5 million for the three and nine months ended September 30, 2019, respectively, compared to \$3.6 million and \$11.3 million for the same periods in 2018. The decrease of \$0.1 million between the comparable three months periods was primarily due to a \$0.4 million decrease in salary and personnel expenses due to lower headcount and a \$0.2 million decrease in clinical expense due to timing, partially offset by a \$0.6 million increase in professional services related to the preparation for the Phase 2 portion of our ongoing clinical trial for vecabrutinib. The decrease of \$0.8 million in the comparable nine months period was primarily due to a \$0.9 million decrease in salary and personnel expenses due to lower headcount and a \$0.1 million decrease in clinical expense due to timing, partially offset by \$0.3 million increase in professional services related to the preparation for the Phase 2 portion of our ongoing clinical trial for vecabrutinib.

### **General and Administrative Expense**

General and administrative expense was \$2.5 million and \$7.5 million for the three and nine months ended September 30, 2019, respectively, compared to \$2.7 million and \$8.9 million for the same periods in 2018. The decrease of \$0.2 million between the comparable three months periods was primarily due to a \$0.3 million decrease in professional services expenses due to lower legal and vosaroxin patent expenses, offset by a \$0.1 increase in director and officer insurance premiums. The decrease of \$1.4 million between the comparable nine months periods was primarily due to a \$1.0 million decrease in salary and personnel expenses due to lower headcount and stock-based compensation and a \$0.8 million decrease in professional services expenses due to lower legal and vosaroxin patent expenses. The decreases in the comparable nine months periods were partially offset by a \$0.3 increase in director and officer insurance premiums.

### **Interest Expense**

Interest expense was \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2019, respectively, compared to \$0.3 million and \$0.9 million for the same periods in 2018. The decreases in interest expenses from both periods resulted from the lower interest rate paid on the lower principal amount under the SVB Loan Agreement.

### **Other Income, Net**

Other income, net, was \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2019, respectively, compared to \$0.1 million and \$0.2 million for the same periods in 2018. The other income, net, was primarily comprised of interest income from our money market funds, and the increase of \$0.1 million between the comparable nine months periods was primarily due to increase in marketable securities investments.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

We have incurred significant losses in each year since our inception. As of September 30, 2019, we had cash and cash equivalents, restricted cash, and marketable securities of \$38.3 million and an accumulated deficit of \$677.5 million, compared to cash and cash equivalents of \$13.7 million and an accumulated deficit of \$659.5 million as of December 31, 2018. We expect to continue to incur significant losses for the foreseeable future. Our products are still in the early stages of development and will require significant additional investment.

We expect our cash and cash equivalents and marketable securities of \$32.8 million, which excludes restricted cash of \$5.5 million, as of September 30, 2019 are not sufficient to support our operations for a period of twelve months beyond the date the condensed consolidated financial statements for the quarter ended September 30, 2019, are available to be issued. We will require additional financing to fund working capital, repay debt and pay our obligations as they come due, so substantial doubt exists about our ability to continue as a going concern. Additional financing might include one or more of a combination of offerings of equity securities or debt arrangements or partnerships or licensing collaborations. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us.

During the three and nine months ended September 30, 2019, no shares and 0.4 million shares of common stock, respectively, were sold under the Sales Agreement with Cantor, for net proceeds of nil and \$0.5 million, respectively, after deducting Cantor's commission. As of September 30, 2019, \$43.1 million of common stock remains available to be sold under the Sales Agreement with Cantor, subject to certain conditions as specified in the Sales Agreement. As of September 30, 2019, the remaining purchase commitment for Aspire under the CSPA was \$10.9 million.

In July 2019, we completed underwritten public offerings of (i) 38,333,717 shares of our common stock at a price to the public of \$0.60 for each share of common stock, and (ii) 8,333 shares of our non-voting Series F Convertible Preferred Stock ("Series F Stock") at a price to the public of \$600.00 for each share of Series F Stock. Gross proceeds from the sale were approximately \$28.0 million and net proceeds were approximately \$26.1 million. Each share of non-voting Series F 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; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable).

In January 2019, we completed underwritten public offerings of (i) 23,000,000 shares of our common stock at a price to the public of \$0.50 for each share of common stock, and (ii) 17,000 shares of our non-voting Series E Convertible Preferred Stock, or Series E Stock, at a price to the public of \$500 for each share of Series E Stock. Gross proceeds from the sale were \$20.0 million and net proceeds were approximately \$18.6 million. Each share of non-voting Series E 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; provided, however, that a holder may, upon written notice, elect to increase or decrease this percentage (not to exceed the limits under Nasdaq Marketplace Rule 5635(b), to the extent applicable). During the nine months ended September 30, 2019, 7,000 shares of Series E Stock were converted into 7,000,000 shares of common stock with the remaining 10,000 shares of Series E Stock outstanding as of September 30, 2019.

Our cash and cash equivalents, restricted cash, and marketable securities totaled \$38.3 million as of September 30, 2019, as compared to \$13.7 million as of December 31, 2018. The increase of \$24.6 million was primarily due to \$45.1 million net proceeds from issuance common and preferred stock and \$5.5 million proceeds from SVB Loan Agreement, partially offset by \$18.4 million net cash used in operating activities and \$7.5 million principal payment on the Loan Agreement and Amendments.

In April 2019, we entered into a term loan agreement with Silicon Valley Bank, or SVB Loan Agreement, pursuant to which we borrowed \$5.5 million and used the proceeds of the SVB Loan Agreement plus cash on hand to repay our remaining obligations in the amount of \$5.9 million under our Loan Agreement and Amendments.

The maturity date of the SVB Loan Agreement is December 1, 2022. Under the terms of the SVB Loan Agreement, we are required to make interest-only payments through December 31, 2020 on the borrowings at a floating rate equal to the greater of the Prime Rate as defined in the SVB Loan Agreement minus 2.25%, or 3.25%, followed by an amortization period of 24 months of equal monthly payments of principal plus interest amounts until paid in full. In addition to and not in substitution for the regular monthly payments of principal plus accrued interest, we are required to make a final payment equal to 4% of the original principal amount of the borrowings, or Final Payment Fee. Additionally, we may prepay all, but not less than all of the borrowings at any time upon 30 days' prior notice to Silicon Valley Bank, or SVB. Any such prepayment would require, in addition to payment of principal and accrued interest as well as the Final Payment Fee, a prepayment fee, in the amount of (a) \$165,000 if the prepayment occurs prior to the 1st anniversary of April 26, 2019, or the Effective Date; (b) \$110,000 if the prepayment occurs on or after the 1st anniversary of the Effective Date but prior to the 2nd anniversary of the Effective Date; or (c) \$55,000 if the prepayment occurs on or after the 2nd anniversary of the Effective Date.

If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our consolidated financial statements, and stockholders may lose all or part of their investment in our common stock. Other than raising additional funds from investors or business partners, management cannot identify conditions or events to mitigate the substantial doubt that exists about our ability to continue as a going concern.

### ***Cash Flows***

Net cash used in operating activities was \$18.4 million for the nine months ended September 30, 2019, as compared to \$17.9 million for the same period in 2018. Net cash used in the nine months ended September 30, 2019, resulted primarily from the net loss of \$18.0 million and changes in operating assets and liabilities of \$1.8 million, offset by adjustments for non-cash items of \$1.4 million. Net cash used in the nine months ended September 30, 2018, resulted primarily from the net loss of \$20.6 million, partially offset by adjustments for non-cash items of \$2.3 million and changes in operating assets and liabilities of \$0.4 million.

Net cash used in investing activities was \$13.1 million for the nine months ended September 30, 2019, as compared to net cash provided by investing activities of \$4.8 million for the same period in 2018. Net cash used in investing activities in 2019 consists of purchase of marketable securities and net cash provided in 2018 consisted of proceeds from maturities of marketable securities.

Net cash provided by financing activities was \$43.1 million for the nine months ended September 30, 2019, as compared to \$6.3 million for the same period in 2018. Net cash provided in 2019 resulted primarily from \$45.1 million net proceeds from issuance of common and preferred stock, and \$5.5 million proceeds from the SVB Loan Agreement, offset by \$7.5 million principal payment on the Loan Agreement and Amendments. Net cash provided in the 2018 period resulted primarily from issuances of common stock of \$6.0 million and net proceeds of \$0.3 million from the exercise of stock options and ESPP purchases.

### ***Operating Capital Requirements***

We have incurred significant operating losses and negative cash flows from operations since our inception. As of September 30, 2019, we had cash and cash equivalents, restricted cash, and marketable securities of \$38.3 million and cash used in operating activities of \$18.4 million for the nine months ended September 30, 2019.

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 U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, or similar regulatory agencies in other countries, and has been successfully commercialized, if ever. We will need to raise substantial additional funding to complete the development and potential commercialization of any of our development programs. 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 timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA, EMA, or other regulatory approvals;
- 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.

Our failure to raise significant additional capital in the future would force us to delay or reduce the scope of our vecabrutinib and other development programs, potentially including any additional clinical trials or subsequent regulatory filings in the United States or Europe, 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.

### **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 3. Quantitative and Qualitative Disclosures About Market Risk**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures, as such term is defined in SEC Exchange Act Rule 13a-15(e) and 15d-15(e), that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Exchange Act Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our interim Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting, as defined in Rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended, that occurred during the quarter ended September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. 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 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 Quarterly Report on Form 10-Q, 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 the language regarding forward-looking statements in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

We have marked with an asterisk (\*) those risks described below that reflect material changes from, or additions to, the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2018 that was filed with the SEC on March 7, 2019.

### Risks Related to Our Business

#### *We need to raise substantial additional funding to continue the development of vecabrutinib, SNS-510, and our other programs.*

We will need to raise substantial additional capital to:

- fund additional nonclinical and clinical trials of vecabrutinib prior to any regulatory filing for approval;
- fund preclinical and clinical development of SNS-510;
- 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;
- 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 vecabrutinib, SNS-510, 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 vecabrutinib, SNS-510, or other development programs.

***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 nine months ended September 30, 2019 and the years ended December 31, 2018 and 2017 were \$18.0 million, \$26.6 million and \$35.5 million, respectively. As of September 30, 2019, we had an accumulated deficit of \$677.5 million. We do not currently have any products that have been approved for marketing, and we expect to incur significant losses for the foreseeable future as we continue to incur substantial development and general and administrative expenses related to our operations. We have prioritized development funding on kinase inhibitors with a focus on vecabrutinib. We have a limited number of products that are still in the early stages of development and will require significant additional investment. 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 one agreement, the Amended Takeda Agreement, which includes certain pre-commercialization event-based and royalty payments. We cannot predict if our collaborator will continue development or whether we will receive any such payments under these agreements in the foreseeable future, or at all.

We are unable to predict when we will generate revenue from the sale of products, if at all. In the absence of additional sources of capital or partnering opportunity, which may not be available to us on acceptable terms, or at all, the development of vecabrutinib 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.

***There is substantial doubt about our ability to continue as a going concern.***

We adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) effective December 31, 2016, which requires us to make certain disclosures if we conclude that there is substantial doubt about our ability to continue as a going concern within one year from the date our financial statements contained in this Quarterly Report on Form 10-Q are available to be issued.

We have incurred significant losses and negative cash flows from operations since our inception, and as of September 30, 2019, had cash and cash equivalents, restricted cash, and marketable securities totaling \$38.3 million and an accumulated deficit of \$677.5 million. We expect our cash equivalents and marketable securities of \$32.8 million, which excludes restricted cash of \$5.5 million, as of September 30, 2019 are not sufficient to support our operations for a period of twelve months from the date our financial statements contained in this Quarterly Report on Form 10-Q are available to be issued. We will require additional financing to fund working capital, repay debt and pay our obligations as they come due. Additional financing might include one or more offerings and one or more of a combination of equity securities, debt arrangements or partnership or licensing collaborations. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date our financial statements contained in this Quarterly Report on Form 10-Q are available to be issued. If we are unsuccessful in our efforts to raise additional financing in the near term, we will be required to significantly reduce or cease operations. The accompanying financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

***The development of vecabrutinib, SNS-510, or other product candidates could be halted or significantly delayed for various reasons; our clinical trials for vecabrutinib, SNS-510, or other product candidates may not lead to regulatory approval.***

Our product candidates are vulnerable to the risks of failure inherent in the drug development process. 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.

Our product candidates may experience toxicities that lead to a maximum tolerated dose that is not effective, or they may fail to demonstrate efficacy at the doses tested. If this were the case for vecabrutinib, for example, such a result would delay or prevent further development, which would severely and adversely affect our financial results, business and business prospects.

We do not know whether our current or any future clinical trials with vecabrutinib, SNS-510, 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 and completion of future clinical trials could be substantially delayed or prevented by several factors, including:

- delays or failures to raise additional funding;
- delays or failures in obtaining regulatory approval to commence a clinical trial;
- delays or failures in obtaining approval from independent IRBs 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.
- delays or failures in obtaining sufficient clinical materials, including any of our product and any drugs to be tested in combination with our products;
- failure of third parties such as Contract Research Organizations and medical institutions to perform their contractual duties and obligations;
- 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;
- 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 for reasons such as change in protocol. 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 parties to supply us with our Active Pharmaceutical Ingredient (“API”) and Finished Drug Product (“FDP”). If we fail to obtain sufficient quantities of these materials, the development and potential commercialization of vecabrutinib, SNS-510 and future products, if any, could be halted or significantly delayed.***

We currently rely on contract manufacturers for all API and FDP. Additional third-party contract manufacturing organizations are relied on to manufacture key starting materials and intermediates required in the manufacture of API. We have limited manufacturing experience, and we have not yet scaled-up to commercial scale. The cost to manufacture at commercial scale may materially exceed the cost of clinical-stage manufacturing.

If our third-party API or FDP manufacturers are unable or unwilling to produce the 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 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 API and FDP needs for the foreseeable future.

Our products require 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 our products, cost overruns or other problems that could seriously harm our business. This would deprive us of potential product revenue and result in additional losses.

The stability of API and FDP is also a key risk, as we must demonstrate that products continue to meet product specifications over time. There can be no assurances that future lots will meet stability requirements and if they do not, development and commercialization of our products may be delayed.

***The failure to enroll patients for clinical trials may cause delays in developing vecabrutinib or other product candidates.***

We may encounter delays if we are unable to enroll enough patients to complete clinical trials of vecabrutinib or other product candidates. 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. In a Phase 1 dose escalation, slots are assigned to sites to avoid over-enrolling. After allocating a slot to a patient, patients may be unable to commence the study if eligibility criteria are not met or they withdraw consent. Patients participating in our trials may come off study due to progressive disease, adverse events, or they or their physician may choose to discontinue study participation.

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

Prior to receiving approval to commercialize vecabrutinib, SNS-510, 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 FDA, EMA 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. 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 FDA, EMA and other regulatory authorities. Results in preclinical studies may not be predictive of results in human clinical trials and early stage human clinical trials may not be predictive of results in later, larger trials.

***Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.***

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of that product;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

***We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Both the FDA and the EMA have granted us orphan designation for vosaroxin.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not be maintained or effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a new drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***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, vecabrutinib 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 vecabrutinib and other product candidates. 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 retain, attract 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 vecabrutinib, SNS-510, 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, our licensors, collaboration partners, or any employees thereof have misappropriated their intellectual property, or otherwise claim that we, our licensors, or collaboration partners are using technology claimed in issued and unexpired patents, or other proprietary rights, owned or controlled by the third party, even if the technology is regarded as our own intellectual property, we may need to obtain a license, enter into litigation to challenge the validity or enforceability of the patents or other rights or incur the risk of litigation in the event that a third party asserts that we infringe its patents or have misappropriated other rights.

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 vecabrutinib, SNS-510, or any future product candidates infringe a third party's patent or other proprietary rights;
- a court order prohibiting us from selling or licensing vecabrutinib, SNS-510, 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 more popular than vecabrutinib, SNS-510, 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 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 expect competition during the development and commercialization of all of our products in all of their potential future indications. Competition is likely to increase as additional products are developed and approved in various patient populations. If our competitors market products that are more effective, safer, and/or less expensive than our 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 any of our future product candidates obsolete.

***Our proprietary rights may not adequately protect vecabrutinib, SNS-510, or future product candidates, if any.***

We use patents, trade secrets, trademarks, service marks, and marketing exclusivity administered by regulatory authorities to protect our products from generic copies of our products. Our ability to build and maintain our proprietary position for any future drug candidates will depend on our success in obtaining effective patent 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 vecabrutinib, SNS-510, or other product 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.

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, throughout the world, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad, valid, enforceable, or extend globally in order to prevent others from practicing our technologies or from developing competing products and technologies. Further, obtaining and maintaining patent protection relies on compliance with various procedural requirements imposed by governmental patent agencies, including, for example, mandatory document submissions and fee payments. Failure to comply with these requirements may reduce or eliminate opportunities for, or rights to, patent protection. 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. Similarly, we do not exclusively control patent prosecution in jurisdictions outside of the United States. 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 in addition to the related cost, 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;
- we, our licensors, or our collaboration partners will be subject to claims challenging the inventorship, ownership, or rights to claim priority with regard to our patents and other intellectual property; or
- any patents or other proprietary rights of third parties will have an adverse effect on our business.

We may need to commence or defend administrative proceedings or 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 a proceeding or litigation affecting proprietary rights we own or have licensed could present significant risk of competition for drug candidates that we market or seek to develop. Any adverse outcome in a proceeding or 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.

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.

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 and enforce. 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.

There can be no assurance that the confidentiality and other agreements we put in place with employees, consultants, and partners 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 do not know whether the patent term for any drug candidate or product will offer protection for an adequate or profitable amount of time. We do not know whether patent term extensions and data exclusivity periods will be available in the future for any or all of the patent rights we own or have licensed. While it is possible that patent term restoration and/or supplemental patent certificates would be available for some of the 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. Our obligation to pay royalties to licensors may extend beyond the patent expiration, which would further erode the profitability of our products.

Intellectual property rights may not address all potential threats to our competitive position for at least the reasons described above and below.

***We may not succeed in finding a third party to license and complete development of vosaroxin, which may result in completely discontinuing development and returning rights to our licensor, Sumitomo Dainippon.***

We are evaluating strategic alternatives, including seeking a partner to license vosaroxin for the purpose of completing development and commercializing the product. There is no certainty that we will find a commercial or financial partner to fund and undertake development, and failure to find such a partner will result in the complete discontinuation of vosaroxin development. In this case, the core IP will revert to Sumitomo Dainippon Pharma Co., Ltd. and there will be no possibility of any future upside from the product. We may also incur costs to wind down all of our activities related to this product.

Even if we do secure a partner for vosaroxin, there is no guarantee the transaction will result in significant revenue or other upside for Sunesis. Following the purchase of the revenue participation right by RPI Finance Trust ("RPI"), an entity related to Royalty Pharma, 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. We will not realize any gain from a vosaroxin licensing agreement until all of our obligations are met.

***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 previously implemented 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 confidentiality of certain proprietary information and knowledge 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 vecabrutinib, SNS-510, and other 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 may lose key employees or have difficulty hiring employees to fill key roles.***

A loss of key personnel or difficulty in hiring employees to fill key roles could slow or prevent our ability to develop and commercialize our products. For example, we are currently operating with an interim Chief Executive Officer. If we have difficulty hiring a Chief Executive Officer it may adversely impact our future prospects.

***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, clinical and nonclinical pharmacology, 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, or a failure or dispute of reporting or diligence efforts 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.

We and our current collaboration partners have certain reporting and diligence obligations to each other, and failure to report, or disagreement over the impact of information reported, or a lack of diligent efforts, or dispute of the impact of the efforts, may be adverse to our interests, the development of the product candidates and could lead to an ultimate withdrawal or dispute of the rights to a product candidate covered by the license or collaboration agreement.

***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. Our Directors and Officers insurance provides certain coverage to our board members and executive officers, but the cost of coverage may be prohibitively expensive or not provide enough coverage.

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

In April 2019, we used the proceeds of the SVB Loan Agreement plus cash on hand to repay our remaining obligations in the amount of \$5.9 million under our existing Loan Agreement and Amendments. Our obligations under the SVB Loan Agreement are secured by a first priority security interest in cash held at an account with SVB, the Collateral Account. We are obligated to maintain sufficient cash in the Collateral Account at all times in an amount greater than the outstanding balance of the borrowings.

The SVB Loan Agreement contains customary affirmative and negative covenants which, among other things, limit the Company's ability to (i) incur additional indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of its assets, grant liens or encumber its assets or (iv) fundamentally alter the nature of its business. These covenants are subject to a number of exceptions and qualifications. The SVB Loan Agreement also contains customary events of default, including among other things, our failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or its breach of the covenants under the SVB Loan Agreement. Upon the occurrence of an event of default, SVB may, among other things, accelerate our obligations under the SVB Loan Agreement.

***We are exposed to risks related to foreign currency exchange rates.***

Some of our costs and expenses are denominated in foreign currencies. 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.

***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.

Our systems are potentially vulnerable to data security breaches, whether by employees or others, that may expose sensitive data to unauthorized persons. If we are unable to prevent such data security breaches or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

## 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 our 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, and regulations differ from country to country. Neither we nor our present or potential future collaboration or licensing partners, if any, are permitted to market our product candidates in the United States or Europe 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 vecabrutinib in any jurisdiction. In addition, failure to comply with FDA, EMA, 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.

The FDA, EMA 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 FDA, EMA or other foreign regulatory authority might not approve our or our third-party manufacturers' processes or facilities; or
- the FDA, EMA 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 vecabrutinib, SNS-510, or other 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 vecabrutinib, SNS-510, or other product candidates, the market may not be receptive.***

Even if one of our product candidates 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:

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

If vecabrutinib, SNS-510, 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 vecabrutinib, SNS-510, or any other future product candidate, we will be subject to ongoing FDA, EMA and other regulatory obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize vecabrutinib, SNS-510, or any other future product candidate.***

Any regulatory approvals that we or our potential future collaboration partners receive for vecabrutinib, SNS-510, 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 the United States, Europe or other territories. If we are not able to maintain regulatory compliance, we might not be permitted to market 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 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. Such efforts have resulted in several recent United States congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government reimbursement methodologies for products.

For example, at the federal level, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Additionally, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. In the years since its enactment, there have been, and continue to be, significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the TCJA. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business and operations.

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 and 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 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 HITECH and its implementing regulations, among other things, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. HITECH, 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 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 drug pricing and marketing information, 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, 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 governments often impose strict price controls, which may adversely affect our future profitability.***

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. 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 our products to other available therapies. If reimbursement 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.

***Our ability to use net operating loss carryforwards to offset future taxable income, and our ability to use tax credit carryforwards, may be subject to certain limitations.***

Our ability to use our federal and state net operating losses, or NOLs, to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

As of December 31, 2018, we reported U.S. federal and state NOLs of approximately \$448.2 million and \$288.3 million, respectively. Our federal NOLs generated prior to 2018 will continue to be governed by the NOL tax rules as they existed prior to the adoption of the Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws, and our state NOLs will begin to expire in 2028. Accordingly, these federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOL's is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations.

## 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 the nine months ended September 30, 2019, our common stock traded as low as \$0.37 and as high as \$1.77. Factors that could cause continued volatility in the market price of our common stock include, but are not limited to:

- all the other risks mentioned herein, including but not limited to our ability to raise additional capital to fund our operations and complete our clinical development plans, compliance with government regulations, the safety and efficacy of our products, and our ability to protect our intellectual property;
- announcements relating to restructuring and other operational changes;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- issuance of new or changed securities analysts' reports or recommendations;
- 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;
- litigation or public concern about the safety of future products, if any;
- failure to develop or sustain an active and liquid trading market for our common stock;
- short-selling or manipulation of our common stock by investors;
- sales of our common stock by our officers, directors or significant stockholders; and
- additions or departures of key personnel.

*Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.\**

Our common stock is listed on The Nasdaq Capital Market, which imposes, among other requirements a minimum bid requirement. Our common stock traded for less than \$1.00 for 30 consecutive trading days, and we received notice of this from the Listing Qualifications Staff of The Nasdaq Stock Market LLC on July 9, 2019. Under Nasdaq Listing Rule 5810(c)(3)(A), we were granted a 180 calendar day grace period, or until January 6, 2020, to regain compliance with the minimum bid price requirement. The minimum bid price requirement will be met if our common stock has a minimum closing bid price of at least \$1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. There can be no assurance that we will be able to regain compliance or that Nasdaq will grant us a further extension of time to regain compliance, if necessary.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future, or at all. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if our common stock were to be delisted from The Nasdaq Capital Market, our common stock would cease to be recognized as a covered security and we would be subject to additional regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Nasdaq minimum bid requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the Nasdaq minimum bid price required for continued listing again, or prevent future non-compliance with Nasdaq's listing requirements.

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, or other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

***Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called “penny stock” rules that impose restrictive sales practice requirements.\****

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called “penny stock” rules if the shares have a market value of less than \$5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than \$5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded \$200,000, or whose joint annual income with a spouse exceeded \$300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of \$1.0 million, not including the value of the investor’s principal residence and excluding mortgage debt secured by the investor’s principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor’s net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser’s written consent to the transaction prior to sale. This means that if we are unable to maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC’s rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer’s presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer’s account and information on the limited market in penny stocks.

***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 the SVB Loan Agreement, we are precluded from paying cash dividends without the prior written consent of SVB. 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.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more transactions at prices and in a manner we determine from time to time, including pursuant to our Controlled Equity Offering<sup>SM</sup> sales agreement (the “Sales Agreement”), with Cantor Fitzgerald & Co. (“Cantor”), Common Stock Purchase Agreement (the “CSPA”) with Aspire Capital Fund, LLC (“Aspire”), or any similar arrangements into which we may enter. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions or in-licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. In the event securities or industry analysts who cover us downgrade our stock or publish unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

A list of exhibits filed with this report or incorporated herein by reference is found in the Exhibit Index below:

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Here with
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant</a>	10-K/A	000-51531	3.1	5/23/2007	
3.2	<a href="#">Amended and Restated Bylaws of the Registrant</a>	8-K	000-51531	3.2	12/11/2007	
3.3	<a href="#">Certificate of Designation of the Series A Preferred Stock of the Registrant</a>	8-K	000-51531	3.3	4/3/2009	
3.4	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant</a>	S-8	333-160528	3.4	7/10/2009	
3.5	<a href="#">Certificate of Amendment of the Certificate of Designation of the Series A Preferred Stock of the Registrant</a>	8-K	000-51531	3.4	11/2/2009	
3.6	<a href="#">Certificate of Amendment of the Certificate of Designation of the Series A Preferred Stock of the Registrant</a>	8-K	000-51531	3.5	1/21/2010	
3.7	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant</a>	8-K	000-51531	3.1	2/14/2011	
3.8	<a href="#">Certificate of Designation of Series B Convertible Preferred Stock of the Registrant</a>	8-K	000-51531	3.1	12/16/2015	
3.9	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant</a>	8-K	000-51531	3.1	9/7/2016	
3.10	<a href="#">Certificate of Designation of the Series C Convertible Preferred Stock of the Registrant</a>	8-K	000-51531	3.1	10/19/2016	
3.11	<a href="#">Certificate of Designation of the Series D Convertible Preferred Stock of the Registrant</a>	8-K	000-51531	3.1	10/26/2017	
3.12	<a href="#">Certificate of Designation of the Series E Convertible Preferred Stock of the Registrant</a>	8-K	000-51531	3.1	1/22/2019	
3.13	<a href="#">Certificate of Validation of Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant</a>	10-Q	000-51531	3.11	8/8/2018	
3.14	<a href="#">Certificate of Designation of the Series F Convertible Preferred Stock of the Registrant</a>	8-K	000-51531	3.1	7/12/2019	
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act</a>					X
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act</a>					X
32.1	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 13a-14(b) or 15d-14(b) of the Exchange Act</a>					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					

# 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-Q 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.



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, Dayton Misfeldt, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 12, 2019

/s/ DAYTON MISFELDT  
Dayton Misfeldt  
Interim Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, William P. Quinn, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 12, 2019

/s/ WILLIAM P. QUINN

William P. Quinn  
Senior Vice President, Finance and Corporate Development,  
Chief Financial Officer

**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), Dayton Misfeldt, Interim Chief Executive Officer and William P. Quinn, Senior Vice President, Finance and Corporate Development and Chief Financial Officer, of Sunesis Pharmaceuticals, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019 (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

/s/ DAYTON MISFELDT  
Dayton Misfeldt  
Interim Chief Executive Officer

Date: November 12, 2019

//s/ WILLIAM P. QUINN  
William P. Quinn  
Senior Vice President, Finance and Corporate Development, Chief Financial Officer

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.