UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2016

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: 001-37718

Spring Bank Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**52-2386345**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
86 South Street Hopkinton, MA	**01748**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (508) 473-5993

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 such 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a small reporting company)	Small reporting company	☐

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

As of October 27, 2016, the registrant had 7,767,981 shares of common stock, $0.0001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions.

These forward-looking statements include, among other things, statements about:

- the anticipated timing, cost and conduct of our ongoing Phase 2a clinical trial of SB 9200 in chronic hepatitis B virus;
- the anticipated timing, cost and conduct of additional clinical trials of SB 9200 in chronic hepatitis B virus and in other indications and of other product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our plans to seek and enter into clinical trial collaborations and other broader collaborations;
- our intellectual property position and strategy;
- the rate and degree of market acceptance and clinical utility of our products
- our commercialization, marketing and manufacturing capabilities and strategy; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

SPRING BANK PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(In Thousands, Except Share and Per Share Data)

	September 30, 2016	December 31, 2015
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,332	$ 4,347
Marketable securities	10,313	5,335
Prepaid expenses and other current assets	1,059	313
Total current assets	16,704	9,995
Marketable securities	—	3,189
Property and equipment, net	496	427
Other assets	35	966
Total	$ 17,235	$ 14,577
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,340	$ 2,183
Accrued expenses and other current liabilities	1,360	1,369
Total liabilities	3,700	3,552
Commitments (Note 7)		
Stockholders' equity:		
Convertible preferred stock, $0.0001 par value—authorized, no shares and 5,000,000 shares at September 30, 2016 and December 31, 2015, respectively; no shares and 1,000,000 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Preferred stock, $0.0001 par value—authorized, 10,000,000 and no shares at September 30, 2016 and December 31, 2015, respectively; no shares issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value—authorized, 200,000,000 and 50,000,000 shares at September 30, 2016 and December 31, 2015, respectively; 7,767,981 and 5,796,091 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	1	1
Additional paid-in capital	62,669	45,211
Accumulated deficit	(49,135)	(34,169)
Other comprehensive income (loss)	—	(18)
Total stockholders' equity	13,535	11,025
Total	$ 17,235	$ 14,577

See notes to consolidated financial statements.

SPRING BANK PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In Thousands, Except Share and Per Share Data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Grant revenue	$ -	$ 260	$ 352	$ 841
Operating expenses:				
Research and development	2,723	2,101	11,247	4,779
General and administrative	1,452	1,566	4,136	3,695
Total operating expenses	4,175	3,667	15,383	8,474
Loss from operations	(4,175)	(3,407)	(15,031)	(7,633)
Other income (expense):				
Interest income (expense), net	27	10	65	15
Net loss	(4,148)	(3,397)	(14,966)	(7,618)
Unrealized gain (loss) on marketable securities	(3)	2	18	(3)
Comprehensive loss	$ (4,151)	$ (3,395)	$ (14,948)	$ (7,621)
Net loss per common share – basic and diluted	$ (0.53)	$ (0.59)	$ (2.18)	$ (1.35)
Weighted-average number of shares outstanding – basic and diluted	7,759,630	5,796,091	6,856,876	5,644,587

See notes to consolidated financial statements.

SPRING BANK PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In Thousands)

	For the Nine Months Ended September 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (14,966)	$ (7,618)
Adjustments for:		
Depreciation and amortization	87	61
Non-cash stock-based compensation	1,015	693
Non-cash issuance of common stock and warrants connected to license agreement	2,780	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(781)	(39)
Accounts payable	148	169
Accrued expenses and other	(19)	392
Net cash used in operating activities	(11,736)	(6,342)
Cash flows from investing activities:		
Purchases of marketable securities	(6,693)	(7,704)
Proceeds from sale of marketable securities	4,922	—
Purchases of property and equipment	(156)	(324)
Net cash used in investing activities	(1,927)	(8,028)
Cash flows from financing activities:		
Proceeds from issuance of common stock	11,339	21,648
Payment of financing costs related to issuance of common stock	(2,128)	(1,754)
Proceeds from exercise of stock options	95	—
Proceeds from exercise of warrants	5,342	25
Cash provided by financing activities	14,648	19,919
Net increase in cash and cash equivalents	985	5,549
Cash and cash equivalents, beginning of period	4,347	1,570
Cash and cash equivalents, end of period	$ 5,332	$ 7,119
Supplemental disclosures of noncash financing activities:		
Issuance of common stock warrants in connection with initial public offering	$ 218	$ —
Financing costs related to the issuance of common stock included in accounts payable and accrued expenses	$ 19	$ —
Issuance of common stock warrants to brokers in connection with sale of common stock	$ —	$ 334

See notes to consolidated financial statements.

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Business

Spring Bank Pharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company engaged in the discovery and development of a novel class of therapeutics using a proprietary small molecule nucleic acid hybrid, or SMNH, chemistry platform. Since inception in 2002 and prior to its initial public offering in May 2016, the Company built its technology platform and product candidate pipeline using a semi-virtual business model, supported by grants and direct funding from the United States National Institutes of Health ("NIH") as well as through private financings. In September 2015, the Company formed a wholly owned subsidiary, Sperovie Biosciences, Inc.

On May 11, 2016 the Company completed its initial public offering of 920,000 shares of common stock at a price to the public of $12.00 per share, resulting in net proceeds of approximately $10.2 million, after underwriting discounts and commissions, but before deducting offering-related expenses. In addition, on June 3, 2016, the Company issued and sold an additional 24,900 shares of common stock at the initial public offering price of $12.00 per share pursuant to the underwriter's partial exercise of their option to purchase additional shares of common stock, resulting in net proceeds of approximately $275,000, after underwriting discounts and commissions, but before deducting offering-related expenses. In connection with the initial closing of the initial public offering, the Company received approximately $5.3 million in proceeds upon the exercise of previously issued warrants to purchase 641,743 shares of common stock of the Company.

The Company's success is dependent upon its ability to successfully complete clinical development and obtain regulatory approval of its product candidates, successfully commercialize approved products, generate revenue, and, ultimately, attain profitable operations.

Basis of Presentation and Liquidity

The accompanying consolidated financial statements have been prepared in accordance with United States ("U.S.") generally accepted accounting principles ("U.S. GAAP").

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses from operations and negative operating cash flows since inception, and expects to incur additional operating losses. The Company's current resources include cash resources of approximately $5,332,000 and marketable securities of $10,313,000 at September 30, 2016. The Company believes that its cash, cash equivalents and marketable securities will be sufficient to allow the Company to fund its current operating plan and continue as a going concern.

The accompanying interim financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015, and related interim information contained within the notes to the financial statements are unaudited. In management's opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's financial position as of September 30, 2016, results of operations for the three and nine months ended September 30, 2016 and 2015, and its cash flows for the nine months ended September 30, 2016 and 2015. These interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2015 filed with the Securities and Exchange Commission on May 6, 2016. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Sperovie Biosciences, Inc. Sperovie did not have any assets, liabilities or operations for any period presented.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities (including clinical trial accruals), the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it

believes to be reasonable under the circumstances. Significant estimates relied upon in preparing the accompanying financial statements related to the fair value of common stock and other equity instruments, accounting for stock-based compensation, income taxes, useful lives of long-lived assets, and accounting for certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates.

Cash and Cash Equivalents

Cash equivalents are stated at fair value and include short-term, highly liquid investments with remaining maturities of 90 days or less at the date of purchase.

Included in cash and cash equivalents as of September 30, 2016 and December 31, 2015 are money market fund investments of $3,993,000 and $2,422,000 as of September 30, 2016 and December 31, 2015, respectively, and commercial paper of $450,000 as of December 31, 2015, which are reported at fair value (Note 4).

Concentration of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. Substantially all of the Company's cash is held at financial institutions that management believes to be of high-credit quality. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits; however, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

The Company had one source of revenue, grants from the NIH, during all periods presented, representing 100% of total revenue for each period.

Investments in Marketable Securities

The Company invests excess cash balances in short-term and long-term marketable securities. The Company classifies investments in marketable securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time of purchase. At each balance sheet date presented, all investments in securities are classified as available-for-sale. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the intention to sell and, if so, marks the investment to market through a charge to the Company's consolidated statements of operations and comprehensive loss.

Property and Equipment, Net

Property and equipment are recorded at cost. Costs associated with maintenance and repairs are expensed as incurred. Depreciation and amortization are provided using the straight-line method over the estimated useful lives:

Asset Category	Useful Life
Equipment	5-7 years
Furniture and fixtures	5 years
Leasehold improvements	10 years or the remaining term of respective lease, if shorter

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, an impairment loss is recorded for the difference between the carrying value and fair value of the asset. Through September 30, 2016, no such impairment has occurred.

Deferred Public Offering Costs

Deferred public offering costs, which primarily consist of direct and incremental legal and accounting fees relating to the Company's initial public offering, are capitalized. As of December 31, 2015, deferred public offering costs were $966,000, and recorded in other assets in the accompanying consolidated balance sheet. In May 2016, in connection with the consummation of the Company's initial public offering, total deferred public offering costs of $2.1 million were fully offset against proceeds received by the Company in the initial public offering. There were no deferred public offering costs as of September 30, 2016.

Deferred Rent

The Company's operating leases include rent escalation payment terms and other incentives received from landlords. Deferred rent represents the difference between actual operating lease payments due and straight-line rent expense over the term of the lease, which is recorded in accrued expenses and other current liabilities. The Company had deferred aggregate rent for its research and development facility in Milford, Massachusetts and its headquarters in Hopkinton, Massachusetts of $33,000 and $6,000 as of September 30, 2016 and December 31, 2015, respectively.

Revenue Recognition

The Company recognizes revenue when all of the following criteria are met: there is persuasive evidence of an arrangement, the fee is fixed or determinable, delivery has occurred or services we recognized have been rendered and collection of the related receivable is reasonably assured. Generally, these criteria were met and revenue from grants from the NIH, which subsidized certain of our research projects, as efforts were expended and as eligible project costs were incurred.

Research and Development Costs

Research and development expenses consist primarily of costs incurred for the Company's research activities, including discovery efforts, and the development of product candidates, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on the Company's behalf as well as contract manufacturing organizations, or CMOs, that manufacture drug products for use in the Company's preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in the Company's research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

The Company expenses research and development costs as incurred. The Company recognizes external development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors and its clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in the Company's consolidated financial statements as prepaid or accrued research and development expenses.

Warrants

The Company reviews the terms of all warrants issued and classifies the warrants as a component of permanent equity if they are freestanding financial instruments that are legally detachable and separately exercisable, contingently exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the warrants must require physical settlement and may not provide any guarantee of value or return. Warrants that meet these criteria are initially recorded at their grant date fair value and are not subsequently remeasured.

Stock-Based Compensation

The Company accounts for all stock-based payment awards granted to employees and nonemployees using a fair value method. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The

measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. The measurement date for nonemployee awards is the date the services are completed, resulting in periodic adjustments to stock-based compensation during the vesting period for changes in the fair value of the awards. Stock-based compensation costs for nonemployees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the department to which the related services are provided.

Financial Instruments

The Company's financial instruments consist of cash equivalents, marketable securities, and accounts payable. The carrying amounts of cash and cash equivalents and accounts payable approximate their fair value due to the short-term nature of those financial instruments. The fair value of the marketable securities are remeasured each reporting period as described in Note 4.

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The Company's assets and liabilities measured at fair value on a recurring basis include cash equivalents and marketable securities.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as if-converted method, for convertible securities, if inclusion of these instruments is dilutive.

In May and June 2016, the Company issued 944,900 shares of common stock in connection with its initial public offering and 641,743 shares of common stock upon the exercise of outstanding warrants to purchase common stock of the Company. Additionally, upon the closing of the initial public offering, all outstanding shares of the Company's preferred stock automatically converted into 250,000 shares of the Company's common stock. The issuance of these shares resulted in a significant increase in the Company's shares outstanding, to 7,767,981 shares as of September 30, 2016, and weighted average shares outstanding for the three and nine months ended September 30, 2016, when compared to the comparable prior year period, is expected to continue to impact the year-over-year comparability of the Company's loss per share calculations through 2017.

Income Taxes

Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax basis of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the

years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company assesses its income tax positions and records tax benefits based upon management's evaluation of the facts, circumstances and information available at the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the consolidated financial statements. The Company classifies interest and penalties associated with such uncertain tax positions as a component of interest expense. As of September 30, 2016 and December 31, 2015, the Company has not identified any material uncertain tax positions.

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity.

The Company leases office and laboratory space in Hopkinton, Massachusetts and Milford, Massachusetts, under non-cancelable operating leases. The Company has standard indemnification arrangements under these leases that require it to indemnify the landlords against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or nonperformance under the Company's lease.

Through September 30, 2016, the Company had not experienced any losses related to these indemnification obligations and no material claims were outstanding. The Company does not expect significant claims related to these indemnification obligations, and consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment and does not track expenses on a program-by-program basis.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09-*Revenue from Contracts with Customers (Topic 606)*, which will supersede nearly all existing revenue recognition guidance under US GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In July 2015, the FASB delayed the effective date of the new standard by one year to December 15, 2017, for annual and interim reporting periods beginning after that date. In accordance with the delay, the new standard will be effective for the Company beginning January 1, 2018. Early adoption is permitted, but not before the original effective date of December 15, 2016. The new standard allows for the amendment to be applied either retrospectively to each prior reporting period presented or retrospectively as a cumulative-effect adjustment as of the date of adoption. In April 2016, the FASB issued ASU 2016-10—*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the implementation guidance on identifying performance obligations. The Company is currently evaluating the impact that the adoption of the standards may have on its consolidated financial statements and additional changes may be identified. The Company has not elected a transition method.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern and to provide related disclosures in certain circumstances. The requirements of ASU 2014-15 will be effective for the annual financial statement period beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact that the adoption of the standards may have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the current leasing guidance and upon adoption, will require lessees to recognize right-of-use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for the Company for the annual period beginning after December 15, 2018, and can be early adopted by applying a modified retrospective approach for leases existing at, and entered into after, the beginning of the earliest comparable period presented in the financial statements. The Company is currently evaluating the impact that the adoption of the standards may have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, *Compensation – Stock Compensation*, and includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The new standard is effective for the Company for the annual period ending after December 15, 2016, and for annual and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact that the adoption of the standards may have on its consolidated financial statements.

2. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share data):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (4,148)	$ (3,397)	$ (14,966)	$ (7,618)
Weighted-average number of common shares-basic and diluted	7,759,630	5,796,091	6,856,876	5,644,587
Net loss per common share-basic and diluted	$ (0.53)	$ (0.59)	$ (2.18)	$ (1.35)

Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact due to the losses reported:

	For the Three and Nine Months Ended September 30,	
	2016	2015
Preferred stock	—	1,000,000
Common stock warrants	153,347	1,181,776
Stock options	718,065	485,481

Upon the closing of the initial public offering, all outstanding shares of the Company's 1,000,000 shares of preferred stock automatically converted into 250,000 shares of the Company's common stock.

3. PROPERTY AND EQUIPMENT, NET

Property and equipment as of September 30, 2016 and December 31, 2015, consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Equipment	$ 515	$ 448
Furniture and fixtures	144	55
Leasehold improvements	133	133
Total property and equipment	792	636
Less: accumulated depreciation and amortization	(296)	(209)
Property and equipment, net	$ 496	$ 427

Depreciation and amortization expense for the three and nine months ended September 30, 2016 was $30,000 and $87,000, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2015 was $27,000 and $61,000, respectively.

4. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the

measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company classified its money market funds within Level 1 because their fair values are based on their quoted market prices. The Company classified its commercial paper and fixed income securities within Level 2 because their fair values are determined using alternative pricing sources or models that utilized market observable inputs.

A summary of the assets and liabilities that are measured at fair value as of September 30, 2016 and December 31, 2015 is as follows (in thousands):

		Fair Value Measurement Using		
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2016				
Money market funds (1)	$ 3,993	$ 3,993	$ —	$ —
Fixed income securities	10,313	—	10,313	—
Total September 30, 2016	$ 14,306	$ 3,993	$ 10,313	$ —
December 31, 2015				
Money market funds (1)	$ 2,422	$ 2,422	$ —	$ —
Commercial paper (1)	450	—	450	—
Fixed income securities	8,524	—	8,524	—
Total December 31, 2015	$ 11,396	$ 2,422	$ 8,974	$ —

(1) Money market funds and commercial paper are included within cash and cash equivalents in the accompanying consolidated balance sheets recognized at fair value.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses as of September 30, 2016 and December 31, 2015, consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Clinical	$ 521	$ 259
Compensation and benefits	635	684
Accounting and legal	169	416
Other	35	10
Total accrued expenses	$ 1,360	$ 1,369

6. STOCKHOLDERS' EQUITY

Common and Preferred Stock

Effective February 1, 2016, the Company amended and restated its license agreement with BioHEP Technologies Ltd. ("BioHEP") (Note 7). In connection with the amendment and restatement, the Company issued 125,000 shares of its common stock to BioHEP and granted to BioHEP a warrant to purchase an additional 125,000 shares of its common stock at a purchase price of $16.00 per share, which warrant will expire on August 1, 2018. The fair value of the common stock as of the date of issuance, $2.0 million, was expensed as research and development costs.

The Company effected a 1-for-4 reverse stock split of its common stock on March 8, 2016. All share and per share amounts, and the number of shares of common stock into which each share of preferred stock converted in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

On May 11, 2016, the Company completed its initial public offering of 920,000 shares of common stock at a price to the public of $12.00 per share, resulting in gross proceeds of approximately $11.0 million, before deducting underwriting discounts and

commissions and offering-related expenses. Upon the closing of its initial public offering, the Company filed an amended and restated certificate of incorporation, which authorizes the Company to issue 200,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share.

Upon the closing of the initial public offering, all outstanding shares of the Company's preferred stock automatically converted into 250,000 shares of the Company's common stock.

On June 3, 2016, the Company issued and sold an additional 24,900 shares of common stock at the initial public offering price of $12.00 per share, pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in gross proceeds of approximately $0.3 million, before deducting underwriting discounts and commissions and offering-related expenses.

Warrants

In connection with the amendment and restatement of a license agreement, the Company issued a warrant to purchase 125,000 shares of the Company's common stock to BioHEP, effective February 1, 2016 (Note 7). The Company evaluated the terms of the warrant and concluded that it should be equity-classified. The fair value of the warrant, $0.8 million, was estimated on the issuance date using a Black Scholes pricing model based on the following assumptions: an expected term of two and a half years, expected stock price volatility of 71%, a risk free rate of 1.01%, and a dividend yield of 0%. The fair value was expenses as research and development costs.

The Company issued to Dawson James Securities, Inc., the sole book-running manager for the initial public offering, a warrant to purchase 27,600 share of common stock in May 2016, and a warrant to purchase 747 shares of common stock in June 2016 (the "Dawson James Warrants"). The Dawson James Warrants are exercisable for cash at an exercise price of $15.00 per share commencing on November 5, 2016. The Dawson James Warrants expire on May 5, 2021. The Company evaluated the terms of the Dawson James Warrants and concluded that they should be equity-classified. The fair value of the May 2016 Dawson James Warrants were estimated on the applicable issuance dates using a Black Scholes pricing model based on the following assumptions: an expected term of 4.99 years; expected stock price volatility of 87%; a risk free rate of 1.20%; and a dividend yield of 0%. The fair value of the June 2016 Dawson James Warrants were estimated on the applicable issuance dates using a Black Scholes pricing model based on the following assumptions: an expected term of 4.92 years; expected stock price volatility of 87%; a risk free rate of 1.23%; and a dividend yield of 0%.

The Company received approximately $5.3 million in proceeds upon the exercise of warrants to purchase 641,743 shares of common stock of the Company, which were exercised in connection with the closing of the initial public offering. Upon the closing of the initial public offering, all of the outstanding warrants that were not exercised, except the warrant issued to BioHEP on February 1, 2016 and the Dawson James Warrants, terminated in accordance with their original terms.

A summary of warrant activities during the nine months ended September 30, 2016 follows:

	Warrants
Outstanding at December 31, 2015	1,181,776
Grants	153,347
Exercises	(641,743)
Expirations/cancellations	(540,033)
Outstanding at September 30, 2016	153,347

2014 Stock Incentive Plan

In April 2014, the Company's board of directors (the "Board") approved the 2014 Stock Incentive Plan (the "2014 Plan"). The Company's 2014 Plan provides for the issuance of common stock, stock options and other stock-based awards to employees, officers, directors, consultants, and advisors. As of September 30, 2016, the Board had authorized 750,000 shares of common stock to be issued under the 2014 Plan. Awards under the 2014 Plan may include options (incentive and non-statutory), stock appreciation rights, restricted stock, restricted stock units or dividend equivalent right, or a combination of them. Under the 2014 Plan, the Board, or a committee authorized by the Board, determines the number of shares of common stock to be granted pursuant to the awards, as well as the exercise price and terms of such awards.

The Company's 2015 Stock Incentive Plan (the "2015 Plan") became effective immediately prior to the closing of the Company's initial public offering on May 11, 2016. Upon the effectiveness of the 2015 Plan, the 116,863 shares of common stock that remained

available for grant under the 2014 Plan became available for grant under the 2015 Plan, and no further awards were available to be issued under the 2014 Plan.

2015 Stock Incentive Plan

In December 2015, the Company's Board approved the 2015 Plan, which became effective immediately prior to the closing of the Company's initial public offering on May 11, 2016. The 2015 Plan provides for the issuance of common stock, stock options and other stock-based awards to employees, officers, directors, consultants, and advisors. The number of shares reserved for issuance under the 2015 Plan is the sum of 750,000 shares of common stock, plus the number of shares equal to the sum of (i) 116,863 shares of common stock, which was the number of shares reserved for issuance under the 2014 Plan that remained available for grant under the 2014 Plan immediately prior to the closing of the Company's initial public offering, and (ii) the number of shares of common stock subject to outstanding awards under the 2014 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right. The exercise price of stock options cannot be less than the fair value of the common stock on the date of grant. Stock options awarded under the 2015 Plan expire 10 years after the grant date, unless the Board sets a shorter term.

The following table summarizes the option activity for the nine months ended September 30, 2016, under the 2014 Plan and the 2015 Plan (the "Plans"):

	Options	Weighted-Average Exercise Price Per Share
Outstanding at December 31, 2015	610,481	$ 11.99
Granted	123,334	10.42
Exercised	(10,247)	9.28
Cancelled	(5,503)	11.96
Outstanding at September 30, 2016	718,065	$ 11.76
Exercisable at September 30, 2016	205,059	$ 11.01

All stock options granted have a ten-year term. As of September 30, 2016, all options granted are expected to vest and the weighted-average remaining contractual life of all options is 8.8 years.

Prior to the initial public offering on May 11, 2016, the Board determined the estimated fair value of the Company's common stock on the date of grant based on a number of objective and subjective factors, including third party valuations. Since the initial public offering, the fair value of the Company's common stock on the date of the grant is based on the closing price per share of the Common Stock on the NASDAQ Capital Market on the date of grant. The computation of expected volatility is based on the historical volatilities of peer companies. The peer companies include organizations that are in the same industry, with similar size and stage of growth. The Company estimates that the expected life of the options granted using the simplified method allowable under Staff Accounting Bulletin No. 107, *Share Based Payments*. The interest rate is based on the U.S. Treasury bill rates for U.S. treasury bills with terms commensurate with the expected term of the option grants on the grant date of the option.

The following table summarizes the stock-based compensation expense for the three and nine months ended September 30, 2016, under the Plans:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
(in thousands)				
Stock-based compensation:				
Research and development	$ 104	$ 97	$ 286	$ 187
General and administrative	274	336	729	506
Total Stock-based compensation	$ 378	$ 433	$ 1,015	$ 693

The fair value of stock options vested during the nine months ended September 30, 2016 was $1,088,000. At September 30, 2016, there was $4,051,000 of unrecognized stock-based compensation expense relating to stock options granted pursuant to the Plans, which will be recognized over the weighted-average remaining vesting period of 2.9 years. Total unrecognized stock-based compensation expense may be adjusted for future changes in the estimated forfeiture rate.

Reserved Shares

As of September 30, 2016 and 2015, the Company has reserved the following shares of common stock for potential conversion of the Preferred Stock, exercise of warrants and outstanding options and issuance of shares available for grant under the 2015 Plan:

	September 30,	
	2016	2015
Preferred Stock	—	250,000
2012 Convertible financing warrants	—	798,653
2013 Convertible financing warrants	—	238,804
2014 Financing warrants	—	144,319
2015 BioHEP warrants	125,000	—
2015 Dawson James warrants	28,347	—
2014 and 2015 Stock incentive plans	1,475,000	725,000
Total	1,628,347	2,156,776

7. COMMITMENTS

Leases

In April 2015, the Company entered into an amendment to the lease for its research and development facility in Milford, Massachusetts to extend the term of the lease through March 31, 2018 and expand the leased laboratory space.

On March 24, 2016, the Company entered into a new operating lease for its headquarters in Hopkinton, Massachusetts with a lease term through May 31, 2021. The total payments due during the term of the lease are approximately $771,000.

Rent paid for the three and nine months ended September 30, 2016 was $56,000 and $110,000, respectively. Rent paid for the three and nine months ended September 30, 2015 was $20,000 and $34,000, respectively.

Future minimum commitments due under all leases at September 30, 2016 are as follows (in thousands):

Year	
2016 (three months from October 2016 through December 2016)	$ 56
2017	232
2018	174
2019	158
2020	164
Thereafter	70
Total minimum lease payments	$ 854

BioHEP Technologies Ltd. License Agreement

In January 2016, the Company entered into an amended and restated license agreement with BioHEP, which amended and restated the prior license agreement with BioHEP which the Company had entered into in December 2003. The amendment and restatement of the license agreement became effective on February 1, 2016.

Under the amended and restated license agreement, the Company agreed to pay BioHEP up to $3.5 million in development and regulatory milestone payments for disease(s) caused by each distinct virus for which the Company develops licensed product(s). BioHEP is also eligible to receive tiered royalties in the low-to-mid single-digits on net product sales of licensed products by the Company and its affiliates and sub licensees, and a specified share of non-royalty sublicensing revenues the Company and its affiliates receive from sub licensees, which share of sublicensing revenues is capped at a maximum aggregate of $2.0 million under all such sublicenses.

Contingencies

The Company is subject to claims in the ordinary course of business, however, the Company is not currently a party to any pending or threatened litigation, the outcome of which would be expected to have a material adverse effect on its financial condition or the results

of its operations. The Company accrues for contingent liabilities to the extent that the liability is probable and estimable, but there are no accruals for contingent liabilities in these consolidated financial statements.

8. RELATED PARTY TRANSACTIONS

The Company incurred no advisory fees during the three and nine months ended September 30, 2016 and incurred $19,000 and $56,000 in advisory fees to one of its directors during the three and nine months ended September 30, 2015, respectively.

9. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date on which the consolidated financial statements were issued, to ensure that this submission includes appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred subsequently but were not recognized in the consolidated financial statements.

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

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and in our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or SEC, on May 6, 2016. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Quarterly Report.

Overview

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of a novel class of therapeutics using our proprietary small molecule nucleic acid hybrid, or SMNH, chemistry platform. We are developing our most advanced SMNH product, SB 9200, for the treatment of viral diseases. We have designed SB 9200 to selectively activate within infected cells the cellular proteins retinoic acid-inducible gene 1, or RIG-I, and nucleotide-binding oligomerization domain-containing protein 2, or NOD2, to inhibit viral replication and to cause the induction of intracellular interferon signaling pathways for antiviral defense. We believe that SB 9200 can play an important role in antiviral therapy by modulating the body's immune response to fight viral infections. In 2014, we completed a Phase 1 clinical trial of SB 9200 in 38 non-cirrhotic patients infected with the hepatitis C virus, or HCV, who had not received any prior antiviral treatment. In June 2016, we dosed the first patient in our ongoing Phase 2a clinical trial of SB 9200 for the treatment of chronic hepatitis B virus, or HBV. We expect to report top line monotherapy data from the first cohort (25 mg) of the Phase 2a clinical trial of SB 9200 in the first half of 2017. Subject to obtaining additional financing, we also plan to explore the potential use of SB 9200 in other viral diseases, including respiratory syncytial virus, or RSV, human immunodeficiency virus, or HIV, and latency and hepatitis delta virus, or HDV, conduct preclinical research of additional SMNH product candidates or compounds as antiviral therapies and conduct early-stage research programs exploring the use of SMNH compounds against targets implicated in certain inflammatory diseases and cancers.

We have not generated any revenue to date other than from grants from the National Institutes of Health, or NIH. We have incurred significant annual net operating losses in every year since our inception and expect to continue to incur net operating losses for the foreseeable future. Our net losses were $11.6 million for the year ended December 31, 2015 and $14.9 million for the nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of $49.1 million. We expect to continue to incur significant expenses and increasing operating losses for the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly if and as we:

- continue to develop and conduct clinical trials of SB 9200, including our ongoing Phase 2a clinical trial in chronic HBV;
- initiate and continue research and preclinical and clinical development efforts for our other product candidates;
- seek to identify and develop additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, including clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our

financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of September 30, 2016, we had $15.6 million in cash, cash equivalents and marketable securities. We expect that our cash, cash equivalents and marketable securities as of September 30, 2016, will enable us to fund our operating expenses and capital expenditure requirements at least into the third quarter of 2017. See "—Liquidity and Capital Resources."

Financial Operations Overview

Grant revenue

We have generated revenue from grants from the NIH for the development of SB 9200. The NIH grants provided funding of $6.8 million between October 2003 and September 30, 2016. As of September 30, 2016, no additional funding remains available to us under any grant for the development of SB 9200.

Operating expenses

Our operating expenses since inception have consisted primarily of research and development expense and general and administrative costs.

Research and development

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture drug products for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Our primary focus of research and development since inception has been on the development of SB 9200. Our direct research and development expenses consist primarily of external costs, such as fees paid to investigators, consultants and CROs in connection with our preclinical studies and clinical trial and regulatory fees. We do not allocate employee-related costs and other indirect costs to specific research and development programs because our primary focus has been on the discovery and development of SB 9200. Our direct research and development expenses are not currently tracked on a program-by-program basis.

The successful development of our product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, we will generate revenues from SB 9200 or any of our other current or potential product candidates. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainties of:

- establishing an appropriate safety profile with investigational new drug, or IND, application enabling toxicology studies;
- successful enrollment in and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;

- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- a continued acceptable safety profile of the products following approval.

A change in the outcome of any of these variables with respect to any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates and pursue later stages of clinical development of other product candidates. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and administrative

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other income (expense)

Other income (expense) consists of interest income, consisting primarily of interest income earned on our cash, cash equivalents and marketable securities.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described therein may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

During the three months ended September 30, 2016, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates" in our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 6, 2016 and the notes to the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the

adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions, as an EGC, we are able to rely on certain of the exemptions and reduced reporting requirements available under the JOBS Act, including the exemption from the requirement that the auditors provide an attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earliest of the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of Operations

Comparison of the three and nine months ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three and nine months ended September 30, 2016 and 2015:

	For the Three Months Ended September 30,		Increase	For the Nine Months Ended September 30,		Increase
	2016	2015	(Decrease)	2016	2015	(Decrease)
(in thousands)						
Grant revenue	$ -	$ 260	$ (260)	$ 352	$ 841	$ (489)
Operating expenses:						
Research and development	2,723	2,101	622	11,247	4,779	6,468
General and administrative	1,452	1,566	(114)	4,136	3,695	441
Total operating expenses	4,175	3,667	508	15,383	8,474	6,909
Loss from operations	(4,175)	(3,407)	(768)	(15,031)	(7,633)	(7,398)
Other income	27	10	17	65	15	50
Net loss	$ (4,148)	$ (3,397)	$ (751)	$ (14,966)	$ (7,618)	$ (7,348)

Grant revenue. Grant revenue was $0 and $352,000 for the three and nine months ended September 30, 2016, respectively, compared to $260,000 and $841,000 for the three and nine months ended September 30, 2015, respectively. The decrease of $260,000 and $489,000 for the three and nine months ended September 30, 2016, respectively, were primarily due to the completion of our last NIH grant as of April 30, 2016.

Research and development expenses. Research and development expenses were $2.7 million for the three months ended September 30, 2016, compared to $2.1 million for the three months ended September 30, 2015. The increase of $0.6 million in research and development expenses was due primarily to a $0.3 million increase in spending on clinical trial-related activities for our ongoing Phase 2a clinical trial of SB 9200; and additional salaries, benefits and stock-based compensation of $0.3 million associated with higher headcount in the three months ended September 30, 2016.

Research and development expenses were $11.2 million for the nine months ended September 30, 2016, compared to $4.8 million for the nine months ended September 30, 2015. The increase of $6.5 million was due primarily to a $2.8 million non-cash charge for the fair value of 125,000 shares of common stock and warrants to purchase 125,000 shares of common stock issued in connection with the BioHEP license agreement in February 2016; $3.0 million in increased spending on clinical trial related activities for our ongoing Phase 2a clinical trial of SB 9200; and additional salaries, benefits and stock-based compensation of $0.7 million associated with higher headcount in the nine months ended September 30, 2016.

General and administrative expenses. General and administrative expenses were $1.5 million for the three months ended September 30, 2016, compared to $1.6 million for the three months ended September 30, 2015. The decrease of $0.1 million was primarily due to a $0.4 million decrease in severance expenses offset by $0.1 million in additional salaries, benefits and stock based compensation associated with higher headcount in the three months ended September 30, 2016 and $0.2 million in increased legal and liability insurance expenses.

General and administrative expenses were $4.1 million for the nine months ended September 30, 2016, compared to $3.7 million for the nine months ended September 30, 2015. The increase of $0.4 million was primarily due to additional salaries, benefits and stock-based compensation of $0.6 million associated with higher headcount in the nine months ended September 30, 2016, increased legal and liability insurance expenses of $0.4 million offset by a $0.4 million decrease in severance expenses and a $0.2 million decrease in expenses related to consulting activities which are now performed in-house.

Other income, net. Other income for the three and nine months ended September 30, 2016 is solely comprised of interest income. Interest income for the three and nine months ended September 30, 2016, was $27,000 and $65,000, respectively, related to the interest earned on marketable securities. Other income for the three and nine months ended September 30, 2015 is comprised of interest income of $10,000 and $15,000, respectively, primarily related to the interest earned on marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through September 30, 2016, we financed our operations from NIH funding, our initial public offering and private placements of convertible notes, common stock and warrants.

On May 11, 2016, we completed our initial public offering of 920,000 shares of common stock at a price to the public of $12.00 per share, resulting in net proceeds of approximately $10.2 million, after deducting underwriting discounts and commissions, but before deducting offering-related expenses. On June 3, 2016, we issued and sold an additional 24,900 shares of common stock at the initial public offering price of $12.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in net proceeds of approximately $275,000, after deducting underwriting discounts and commissions but before deducting offering-related expenses.

As of September 30, 2016, we had cash, cash equivalents and marketable securities totaling $15.6 million and an accumulated deficit of $49.1 million.

Cash Flows

The following table summarizes sources and uses of cash for each of the periods presented:

	For the Nine Months Ended September 30,	
	2016	2015
(in thousands)		
Net cash used in operating activities	$ (11,736)	$ (6,342)
Net cash used in investing activities	(1,927)	(8,028)
Net cash provided by financing activities	14,648	19,919
Net increase in cash and cash equivalents	$ 985	$ 5,549

Net cash used in operating activities. The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was $11.7 million and $6.3 million during the nine months ended September 30, 2016 and 2015, respectively. The increase of $5.4 million in cash used in operating activities5.4during the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 was primarily due to an increase in net loss of $7.5 million and an increase in prepaid expense, other assets, accounts payable and accrued expenses of $1.1 million, which were offset by an increase in non-cash common stock and warrant valuation expense related to the BioHEP license agreement of $2.8 million and an increase in non-cash stock based compensation of $0.3 million.

Net cash used in investing activities. Net cash used in investing activities was $1.9 million for the nine months ended September 30, 2016 compared to net cash used in investing activities of $8.0 million for the nine months ended September 30, 2015. The cash used in investing activities of $1.9 million in the nine months ended September 30, 2016 was primarily the result of $4.9 million in proceeds from the sale of marketable securities, offset by $6.7 million for the purchase of marketable securities. The cash used in investing activities of $8.0 million for the nine months ended September 30, 2015 was mainly due to the purchase of marketable securities of $7.7 million. Cash of $156,000 and $324,000 was used to purchase property and equipment during the nine months ended September 30, 2016 and 2015, respectively.

Net cash provided by financing activities. Net cash provided by financing activities was $14.6 million and $19.9 million during the nine months ended September 30, 2016 and 2015, respectively. The cash provided by financing activities in the nine months ended

September 30, 2016 was primarily the result of $11.3 million of gross proceeds received from the initial public offering of our common stock, cash of $5.3 million for the exercise of warrants in connection with the closing of the initial public offering and $0.1 million for the exercise of stock options, offset by $2.1 million underwriting discounts and offering expenses related to the initial public offering. The cash provided by financing activities in the nine months ended September 30, 2015 was primarily the result of $21.7 million of gross proceeds received from private placements of our common stock offset by $1.8 million of broker commissions paid.

Funding Requirements

We anticipate that our expenses will increase significantly if and as we continue to develop and conduct clinical trials with respect to SB 9200 product candidates; initiate and continue research, preclinical and clinical development efforts for our other product candidates and potential product candidates; maintain, expand and protect our intellectual property portfolio; establish a commercial infrastructure to support the marketing and sale of certain of our product candidates; and hire additional personnel, such as clinical, regulatory, quality control and scientific personnel. Furthermore, we expect to incur additional costs associated with operating as a public company. Specifically, we anticipate that our expenses will increase substantially if and as we:

- conduct our ongoing Phase 2 clinical program of SB 9200 for chronic HBV;
- develop SB 9200 for additional indications, including RSV, HIV latency and HDV;
- continue the research and development of our other product candidates;
- seek to leverage our SMNH platform and explore new targets in additional non-viral disease states;
- maintain, expand and protect our intellectual property portfolio;
- add key clinical, scientific, operational and financial employees; and
- enhance our management information systems and personnel, including personnel to support our product development efforts and to support our transition to a public company.

We expect that our existing cash, cash equivalents and marketable securities of $15.6 million at September 30, 2016 will enable us to fund our operating expenses and capital expenditures requirements at least into the third quarter of 2017 and to fund the Phase 2a clinical trial of SB 9200 that we initiated in chronic HBV in June 2016. However, we do not believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of SB 9200 beyond the ongoing trial, including our planned Phase 2b clinical trial of SB 9200 for chronic HBV that we plan to conduct subject to the results of the Phase 2a clinical trial, discussions with regulatory authorities and the receipt of additional funding. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of SB 9200, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- progress, timing, costs and results of preclinical studies and clinical trials of SB 9200, including our ongoing Phase 2a clinical trial and planned Phase 2b clinical trial in chronic HBV;
- initiation, progress, timing, costs and results of preclinical studies and clinical trials of SB 9200 for additional indications, including RSV, HIV latency and HDV, and of our other product candidates;
- our obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- the number and characteristics of product candidates that we discover or in-license and develop;
- the outcome, timing and cost of seeking regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of SB 9200 and any other products;
- the costs and timing of the implementation of commercial-scale manufacturing activities;

- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders'. Additional debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute our stockholders' ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2016, and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years
(in thousands)					
Operating lease commitments (1)	$ 854	$ 230	$ 513	$ 111	$ —
Total	$ 854	$ 230	$ 513	$ 111	$ —

(1) In April 2015, we entered into an amendment to extend the term of the lease for our research and development facility in Milford, Massachusetts through March 31, 2018. On March 24, 2016, we entered into a new operating lease for our headquarters in Hopkinton, Massachusetts with a lease term through May 31, 2021. The amounts in the table reflect amounts due under both leases.

In addition to the amounts shown in the above table, we have contractual obligations pursuant to our license agreement with BioHEP Technologies Ltd., or BioHEP. In January 2016, we entered into an amended and restated license agreement with BioHEP. Under the amended and restated license agreement, we have agreed to pay up to $3.5 million in development and regulatory milestone payments to BioHEP for disease(s) caused by each distinct virus for which we develop licensed product(s). BioHEP is also eligible to receive tiered royalties in the low-to-mid single-digits on net product sales of licensed products by us and our affiliates and sub licensees, and a specified share of non-royalty sublicensing revenues we and our affiliates receive from sub licensees, which share of sublicensing revenues is capped at a maximum aggregate of $2.0 million under all such sublicenses. Milestone and royalty payments associated with our license agreement with BioHEP have not been included in the above table of contractual obligations as we cannot reasonably estimate if or when they will occur.

We enter into contracts in the normal course of business with third party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We have not included our payment obligations under these contracts in the table as these contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09-*Revenue from Contracts with Customers (Topic 606)*, which will supersede nearly all existing revenue recognition guidance under U.S. generally accepted accounting principles. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In July 2015, the FASB delayed the effective date of the new standard by one year to December 15, 2017, for annual and interim reporting periods beginning after that date. In accordance with the delay, the new standard will be effective for us beginning January 1, 2018. Early adoption is permitted, but not before the original effective date of December 15, 2016. The new standard allows for the amendment to be applied either retrospectively to each prior reporting period presented or retrospectively as a cumulative-effect adjustment as of the date of adoption. In April 2016, the FASB issued ASU 2016-10—*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the implementation guidance on identifying performance obligations. We are currently evaluating the impact that the adoption of the standards may have on our consolidated financial statements and additional changes may be identified. We have not elected a transition method.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 requires management to assess an entity's ability to continue as a going concern and to provide related disclosures in certain circumstances. The requirements of ASU 2014-15 will be effective for the annual financial statement period beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact that the adoption of the standards may have on our consolidated financial statements and additional changes may be identified.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the current leasing guidance and upon adoption, will require lessees to recognize right-of-use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for our annual period beginning after December 15, 2018, and can be early adopted by applying a modified retrospective approach for leases existing at, and entered into after, the beginning of the earliest comparable period presented in the financial statements. We are currently evaluating the impact that the adoption of the standards may have on our consolidated financial statements and additional changes may be identified.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, *Compensation – Stock Compensation*, and includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The new standard is effective for our annual period ending after December 15, 2016, and for annual and interim periods thereafter, with early adoption permitted. We are currently evaluating the impact that the adoption of the standards may have on our consolidated financial statements and additional changes may be identified.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. Our cash, cash equivalents and marketable securities of $15.6 million as of September 30, 2016, consisted of cash, money market accounts and short-term marketable debt securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not be expected to have a material impact on the fair market value of our investment portfolio or on our financial condition or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of September 30, 2016, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2016, 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 become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation.

Item 1A. Risk Factors.

We operate in an industry that involves numerous risks and uncertainties. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Form 10-Q for the quarterly period ended September 30, 2016 including our financial statements and related notes included therein. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. The risks and uncertainties described below may change over time and other risks and uncertainties, including those that we do not currently consider material, may impair our business. In these circumstances, the market price of our common stock could decline.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses in the future.

We are a clinical-stage biopharmaceutical company. We have one product candidate, SB 9200, in the early stages of clinical development and all of our other product candidates are preclinical. We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2002. For the nine months ended September 30, 2016 and 2015, we reported a net loss of $14.9 million and $7.6 million, respectively. We had an accumulated deficit of $49.1 million at September 30, 2016.

We expect to continue to incur significant and increasing losses for the foreseeable future. We anticipate these losses to increase as our expenses increase, and we expect that our expenses will increase if and as we:

- continue to develop and conduct clinical trials of SB 9200, including the ongoing Phase 2a clinical trial of SB 9200 for chronic HBV that we initiated in June 2016;
- initiate and continue research and preclinical and clinical development efforts for our other product candidates;

- seek to identify and develop additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, including clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

We currently have no source of product revenue and may never become profitable.

We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales. Our ability to achieve and maintain profitability will depend upon our ability to generate revenue. We do not expect to generate significant revenue unless and until we are able to gain regulatory approval of and commercialize SB 9200 or other product candidates that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for SB 9200 or any other product candidate, we do not know when we will generate revenue from product sales, if at all. Our ability to generate revenue from product sales of SB 9200 or any other product candidate also depends on a number of factors, including our ability to:

- successfully complete development activities, including enrollment of trial participants and completion of the necessary clinical trials;
- complete and submit New Drug Applications, or NDAs, to the United States Food and Drug Administration, or FDA, and obtain regulatory approvals from the FDA for SB 9200 and our other product candidates for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities for SB 9200 and our other product candidates;
- successfully commercialize any approved products;
- manufacture or have manufactured commercial quantities of our products at acceptable cost levels;
- develop a commercial organization capable of manufacturing, sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize such products on our own;
- enter into arrangements with third parties to manufacture, market, sell and distribute our approved products in other markets; and
- obtain adequate pricing, coverage and reimbursement from third parties, including government and private payors.

In addition, because of the numerous risks and uncertainties associated with product development, including those of SB 9200 or our other product candidates, which may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for SB 9200 or any other product candidate, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of SB 9200 or any other products, we may not generate revenues that are large enough for us to become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We intend to expend our limited resources on the development of our sole clinical-stage product candidate, SB 9200, for antiviral applications and may fail to capitalize on other technologies, product candidates or other indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are focusing our resources on the development of SB 9200, which concentrates the risk of product failure on SB 9200. SB 9200 may prove to be unsafe or ineffective. Because of this concentration of resources, we may forego or delay development of other technologies, product candidates or other indications that later prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to the candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We will require additional capital to fund our operations. If we fail to obtain necessary financing, we may be forced to delay, reduce or eliminate our development and potential commercialization efforts for SB 9200.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for, SB 9200. In addition, if we obtain marketing approval for SB 9200, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We plan to continue to use our existing cash, cash equivalents and marketable securities to fund our ongoing Phase 2a clinical trial of SB 9200 for chronic HBV that we initiated in June 2016. However, we do not believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund additional development of SB 9200 beyond the Phase 2a clinical trial. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds.

Adequate additional financing may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2016 will enable us to fund our operating expenses and capital expenditure requirements at least into the third quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials of SB 9200, including our ongoing Phase 2a clinical trial in chronic HBV that we initiated in June 2016;
- initiation, progress, timing, costs and results of preclinical studies and clinical trials of our other product candidates;
- our obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- the number and characteristics of product candidates that we discover or in-license and develop;
- the outcome, timing and cost of seeking regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of SB 9200 and any other products;

- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- the costs of operating as a public company.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or SB 9200.

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of SB 9200 and our other product candidates.

If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, on favorable terms or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We have no experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable companies, products or product candidates to acquire or partners with which to form strategic alliances or collaborations, and if we enter into any such transactions, we may not be able to integrate the acquired companies, products or product candidates successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business.

To finance any acquisitions or collaborations, we may choose to issue convertible debt or equity as consideration. Any such issuance of securities would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our history of limited operations and no history of commercializing pharmaceutical products makes it difficult to evaluate the prospects for our future viability.

We were incorporated in and have been conducting operations since 2002. Our operations to date have been limited to financing and staffing our company and developing SB 9200 and our other product candidates. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had more of an operating history or a history of successfully developing and commercializing pharmaceutical products.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our future success is dependent on the successful clinical development, regulatory approval and commercialization of SB 9200, and will require significant capital resources and years of additional clinical development effort. If we are unable to develop, obtain regulatory approval for or successfully commercialize SB 9200 or experience significant delays in doing so, our business could be materially harmed.

We do not have any products that have gained regulatory approval. Currently, our only clinical-stage product candidate is SB 9200. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, to successfully commercialize SB 9200 in a timely manner. The success of SB 9200 will depend on several factors, including the following:

- successful initiation and completion of our ongoing Phase 2a clinical trial in HBV;
- successful completion of additional preclinical studies to support additional clinical trials;
- initiation and successful enrollment and completion of additional clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug products that are appropriately packaged for sale;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors following any marketing approval; and
- our ability to compete with other therapies, including therapies targeting viral hepatitis and other antiviral applications.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize SB 9200 or experience delays because of any of these factors or otherwise, our business could be substantially harmed.

We plan to conduct multiple clinical trials of SB 9200 in different indications. If patients in any of these trials experience adverse safety events, we may be required to delay, discontinue or modify all of our clinical trials of SB 9200.

The results of preclinical studies and early clinical trials may not be predictive of results in future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the results of later clinical trials and interim results of clinical trials do not necessarily predict success in such clinical trials. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies and clinical trials. The results from *in vitro* and *in vivo* preclinical studies, such as the results from our studies in animal models of chronic HBV and RSV as well as *in vitro* assays, may not translate into human efficacy.

We have conducted clinical trials of SB 9200 in patients with hepatitis C virus, or HCV. In June 2016, we initiated a Phase 2a clinical trial of SB 9200 in patients with chronic HBV. The results of our one clinical trial in patients with HCV may not be indicative of results of our Phase 2a clinical trial of SB 9200 in chronic HBV.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of SB 9200, the development timeline and regulatory approval and commercialization prospects for SB 9200, and, correspondingly, our business and financial prospects, would be negatively impacted.

The therapeutic efficacy of SB 9200 and our other product candidates is unproven in humans, and we may not be able to successfully develop and commercialize SB 9200 and our other product candidates.

SB 9200 and our other product candidates are novel compounds and their potential benefit as antiviral drugs is unproven. SB 9200 and our other product candidates may not prove to be effective against the indications for which they are being designed to act and may not demonstrate in clinical trials any or all of the pharmacological effects that have been observed in preclinical studies. As of September 30, 2016, we have only completed a single Phase 1 clinical trial of SB 9200. In that trial, we evaluated SB 9200 in 38 non-cirrhotic HCV infected patients as a monotherapy treatment for up to seven days. We conducted the Phase 1 clinical trial in Australia and New Zealand in 2013 and 2014. We expect that the dose and frequency may be different for other indications of antiviral therapy. We initiated a Phase 2a clinical trial of SB 9200 for the treatment of chronic HBV in June 2016. We expect our Phase 2a trial of SB 9200 for chronic HBV will be of longer duration and involve sequential therapy with other antiviral agents. As a result, our Phase 1 clinical trial results in HCV may not be indicative of the results of our Phase 2a clinical trial in chronic HBV.

SB 9200 and our other product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If SB 9200 or our other product candidates is associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon the development of such product candidate or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Because of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop or commercialize SB 9200 or any of our other product candidates, in which case our business will be harmed.

Clinical development of product candidates involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. Failure can occur at any time during the clinical trial process, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable.

We may experience delays in our ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on a timely basis, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or other foreign regulatory authority will not put clinical trials of SB 9200 or any other product candidates on clinical hold now or in the future. Clinical trials may be delayed, suspended or prematurely terminated or may take longer than anticipated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay or failure in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining Investigational Review Board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at a site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable study subjects to participate in a trial;

- delay or failure in study subjects completing a trial or returning for post-treatment follow-up or otherwise complying with the trial protocol;
- clinical sites and investigators deviating from the trial protocol, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for competing product candidates with the same indication;
- failure of our third-party service providers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- feedback from the FDA, the IRBs, data safety monitoring boards, or comparable foreign regulatory authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification of the protocol for the trial;
- decision by the FDA, the IRBs, comparable foreign regulatory authorities, or us, or recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects or adverse events;
- failure of a product candidate to demonstrate any benefit;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical trials;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions.

We have not submitted an investigational new drug, or IND, application to the FDA for SB 9200 or any other product candidate. We may not conduct a clinical trial in the United States until we submit an IND to the FDA. Because we are developing SB 9200 for multiple indications, we may be required to submit multiple INDs to the FDA for these indications and may not conduct a clinical trial in the United States for that indication unless we do so.

We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. If we experience delays in any preclinical or clinical trial of our product candidates, the product candidate development and approval process could be slowed down, and as a result the costs of the development and approval process may increase, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from these product candidates may be delayed. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates successfully and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. The FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, we may be required to conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before the FDA will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. Additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing such product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

We plan to develop SB 9200 for multiple indications. In order to market SB 9200 for multiple indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such indications. Regulatory approval of SB 9200 for one indication may not mean that SB 9200 will receive regulatory approval for another indication.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for any of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities, such as the European Medicines Agency, or the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

For instance, in our Phase 1 clinical trial of SB 9200 in patients with HCV, we experienced significant delays in enrollment due to competing clinical trials in patients with HCV being conducted by other biopharmaceutical companies.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to commence sales of and generate revenues from our product candidates, which could cause the value of our company to decline.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities, such as the EMA, impose similar restrictions. We may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Any inability to complete preclinical and clinical development successfully could result in additional costs to us, and impair our ability to generate revenues. Moreover, if (1) we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we, or they contemplate, (2) we are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these clinical trials or tests are unfavorable, uncertain or are only modestly favorable or (4) there are unacceptable safety concerns associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

If we experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval or commercialization of our product candidates, including:

- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we may have to delay, suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial designs or our interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates.

SB 9200 or any other product candidate may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by SB 9200 or any other product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.

Results of our trials could reveal an unacceptably high severity and prevalence of side effects. 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 SB 9200 or any other product candidates for any or all targeted indications. Study drug-related side effects could affect study subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

If SB 9200 or any of our other product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

Our commercial success depends upon attaining significant market acceptance of SB 9200 as a monotherapy or in combination with other antiviral agents or of any other product candidates, if approved, among physicians, patients, healthcare payors and others in the medical community necessary for commercial success, and the market opportunity for the product candidate may be smaller than we estimate.

Even if we obtain regulatory approval for SB 9200 or any other product candidate in chronic HBV or other indications, our product candidate may not gain market acceptance among physicians, healthcare payors, patients or the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of coverage or reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the:

- efficacy and safety of our product candidates administered with other drugs each as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which our product candidates are approved;
- potential and perceived advantages of our product candidates over alternative treatments;
- safety of our product candidates seen in a broader patient group, including its use outside the approved indications should physicians choose to prescribe for such uses;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of our product candidates as well as of competitive products;
- cost of treatment with our product candidates in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- the convenience and ease of administration of our product candidates as compared to alternative treatments;
- effectiveness of our sales and marketing efforts; and
- changes in the standard of care for the targeted indications for the product candidate.

Moreover, if SB 9200 is approved but fails to achieve market acceptance among physicians, patients, or healthcare providers are restricted, withdrawn or recalled or fail to be approved, as the case may be, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

Even if we are able to commercialize SB 9200 or any other product candidate, the product candidate may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of our product candidates for which we obtain regulatory approval. Our ability to commercialize SB 9200 or any other product candidate successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product candidate will be available from third party payors, including government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels.

Obtaining and maintaining adequate reimbursement for our product candidates, if approved, may be difficult. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. We cannot be certain if and when we will obtain an adequate level of coverage and reimbursement for our products, if they are approved, by third-party payors.

A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical drugs. Third-party payors may also seek with respect to an approved product additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations or costly pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies before covering SB 9200 or any other product candidate. We cannot be sure that coverage and reimbursement will be available for SB 9200 or any other product candidate and, if it is available, whether the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, SB 9200 or any other product candidate, if approved. If reimbursement is not available or is available only at limited levels, we may not be able to commercialize SB 9200 or any other product candidate successfully, if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to market, sell or distribute SB 9200 or any other product candidates, we may not be successful in commercializing such product candidates if and when they are approved.

We do not currently have an organization for the sale, marketing and distribution of pharmaceutical products and have no experience in the sale, marketing or distribution of pharmaceutical products. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must establish sales, marketing and distribution capabilities or make arrangements with third parties to perform these services.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales, marketing and distribution functions, we may be unable to compete successfully against these more established companies.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We expect that we will face competition with respect to SB 9200 and with respect to any other product candidates that we may seek to develop or commercialize, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing SB 9200. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We expect our current and other product candidates to face intense and increasing competition as new products enter the relevant antiviral markets and advanced technologies become available.

FDA-approved treatments for patients with chronic HBV include pegylated interferon-a, or PEG-IFN-a, products including Pegasys (PEG-IFN a-2a), marketed by Genentech, Inc., and PEG-Intron, marketed by Merck & Co., Inc., and oral antiviral agents such as the nucleoside analog Baraclude (entecavir), marketed by Bristol-Myers Squibb Company, and the nucleotide analog Viread (tenofovir), marketed by Gilead Sciences, Inc. These treatments are designed to decrease the risk of liver damage from chronic HBV by slowing down or stopping the virus from reproducing. In addition, several pharmaceutical and biotechnology companies, including Arbutus Biopharma Corp, Alnylam Pharmaceuticals, Inc., Arrowhead Research Corporation, Assembly Biosciences, Inc., Gilead Sciences, Inc. and Janssen Pharmaceuticals, Inc., are developing therapies with varying mechanisms of action to address chronic HBV, including non-nucleotide antivirals and non-interferon immune enhancers. We believe that instead of competing with certain of these therapies, SB 9200 has the potential to be used as a complementary therapy.

There are also FDA-approved vaccinations available for children and high-risk adults that protect against HBV. These vaccines are manufactured by Merck & Co., Inc. and GlaxoSmithKline Plc and are widely available in the United States (and less available in certain parts of the world), and have limited side effects. Although the vaccines are effective against HBV in non-infected individuals, they do not reverse or cure the disease in people who have already contracted the virus.

There are a variety of available antiviral therapies and supportive care products for viral diseases. Some of these other drugs are branded and subject to patent protection, some are in clinical development and not yet approved, and others are available on a generic basis. Many of the approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. These factors may make it difficult for us to achieve market acceptance at desired levels and/or in a timely manner to ensure viability of our business.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do.

Our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize SB 9200 or any other product candidates. Our competitors may also develop drugs that are safer, more effective, more convenient or less expensive than ours, and may also be more successful than us in manufacturing and marketing their products. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects or are less costly than any product candidates that we are currently developing or that we

may develop. These appreciable advantages could reduce or eliminate our commercial opportunity and render SB 9200 or any other product candidates obsolete or non-competitive.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of SB 9200 or any other product candidates.

We face an inherent risk of product liability exposure related to the testing of SB 9200 or any other product candidates by us or our investigators in human clinical trials and will face an even greater risk if we commercially sell SB 9200 or such product candidates if and after we obtain regulatory approval. Product liability claims may be brought against us by study subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling SB 9200 or such product candidates. If we cannot successfully defend ourselves against claims that SB 9200 or such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, for example:

- decreased demand for SB 9200 or such other product candidates;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize SB 9200 or such product candidates; and
- increased scrutiny and potential investigation by, among others, the FDA, the United States Department of Justice, or DOJ, the Office of Inspector General of the office of Health and Human Services, or HHS, state attorneys general, members of Congress and the public.

We currently have $10 million in product liability insurance coverage in the aggregate, which may not be adequate to cover all liabilities that we may incur.

Insurance coverage is increasingly expensive. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for any product candidate. However, we may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Like other companies, we may from time to time experience threats to our data and systems, including malware and computer virus attacks, unauthorized access, systems failures and disruptions. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data

or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of SB 9200 could be delayed.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We rely on third-party manufacturers to produce SB 9200 and expect to rely on third-party manufacturers to produce product candidates in the future. Our ability to obtain clinical supplies of SB 9200 could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our business may be harmed.

We rely on third-party research vendors, academic research institutions, CROs, and other third parties to conduct, and monitor and manage data for, our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with good laboratory practice, or GLP, and the Animal Welfare Act requirements. We and our service providers are required to comply with federal regulations and good clinical practice, or GCP, which are international standards meant to protect the rights and health of subjects that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our service providers fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot guarantee that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practices, or cGMPs. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Our service providers are not our employees, and except for remedies available to us under our agreements with such service providers, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If service providers do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize SB 9200. As a result, our results of operations and the commercial prospects for SB 9200 would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our service providers, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If our relationships with third-party vendors and other service providers are terminated, our drug development efforts could be delayed.

We rely on third-party vendors and service providers for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional third-party vendors or service providers would involve additional cost and require management time and focus. Our third-party vendors and service providers generally have the right to terminate their agreements with us under certain circumstances. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new third-party vendor or service provider commences work, and the new third-party vendor or service provider may not provide the same type or level of services as the original provider. If any of our relationships with our third-party vendors or service providers terminate, we may not be able to enter into arrangements with alternative third-party vendors or service providers or to do so on commercially reasonable terms.

We have no experience manufacturing SB 9200 or any other product candidate on a commercial scale and have no manufacturing facility. We are dependent on contract manufacturers for the manufacture of SB 9200 as well as on third parties for our supply chain and expect to rely on contract manufacturers for any other product candidates. If we experience problems with any such contract manufacturers, the manufacturing of SB 9200 or any other product candidate could be delayed.

We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on contract manufacturers to produce both drug substance and drug product required for our clinical trials. We plan to continue to rely upon contract manufacturers to manufacture commercial quantities of our products, if approved. Reliance on such third-party contractors entails risks, including:

- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We currently rely, and expect to continue to rely, on a small number of third-party contract manufacturers to supply the majority of our active pharmaceutical ingredient and required finished product for our preclinical studies and clinical trials. These contract manufacturers are typically single source suppliers to us. We do not have long-term agreements with any of these third parties. If any of our existing manufacturers become unavailable to us for any reason, we may experience a delay in identifying or qualifying replacements.

Our single source supplier of the drug substance for SB 9200 has informed us that it plans to transition away from small molecule manufacturing, but it has committed to completing our current order and supporting an orderly transition of manufacturing to another supplier over the course of 2016. We believe that the drug substance that is being manufactured by our current supplier will be sufficient to complete our ongoing Phase 2 clinical trials of SB 9200 for chronic HBV. In addition, we have been exploring alternative sources of supply. If the supply of drug substance is insufficient to complete our trials or we are unable to obtain alternative sources of supply on favorable terms, on a timely basis or at all, our business may be adversely affected.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations, delay our clinical trials and, if our products are approved for sale, result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our product candidates. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales.

If any of our product candidates are approved by any regulatory agency, we plan to enter into agreements with third-party contract manufacturers for the commercial production and distribution of those products. It may be difficult for us to reach agreement with a contract manufacturer on satisfactory terms or in a timely manner. In addition, we may face competition for access to manufacturing facilities, as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization efforts.

Third-party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States. Facilities used by our third-party manufacturers must be approved by the FDA after we submit an NDA and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to our specifications or the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate.

In addition, our manufacturers are subject to ongoing periodic inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements both prior to and following the receipt of marketing approval for any of our product candidates. Some of these inspections may be unannounced. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could adversely affect supplies of our product candidates and significantly harm our business, financial condition and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If we enter into licensing or collaboration agreements with third parties to develop, obtain regulatory approvals for and commercialize SB 9200 or any other product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product

candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

Despite our efforts, we may be unable to secure additional collaborative licensing or other arrangements that are necessary for us to further develop and commercialize SB 9200 or any other product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of SB 9200 or our other product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize SB 9200.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We, and any future collaborators, are not permitted to market SB 9200 in the United States or in other countries until we, or they, receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Product candidates in various stages of development are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for SB 9200 or any of our product candidates in the United States or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of an NDA.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that SB 9200 and our other product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Reasons that the FDA or comparable foreign regulatory authorities may not approve our product candidates, include:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent SB 9200 from being marketed abroad. Any approval we are granted in the United States would not assure approval in foreign jurisdictions.

In order to market and sell our products in the European Union and other foreign jurisdictions, including Japan, China and South Korea, we, and any future collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in the European Union, Japan, China, South Korea or another foreign country or jurisdiction, the commercial prospects of our product candidates may be significantly diminished and our business prospects could decline.

Even if we, or any future collaborators, obtain marketing approvals for SB 9200 or any other product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, importation, exportation, record keeping and reporting of safety and other post-market information for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be

consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements, and are subject to continual review. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any future collaborators, receive marketing approval for SB 9200 any other product candidate, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

Further, government agencies promulgate regulations and guidelines applicable to certain drug classes, which may include our product candidates. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes, which may include our product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the marketing approvals for SB 9200 or our other products withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any of our product candidates for which we, or any future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our product candidates for which we, or any future collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Thus, even if marketing approval of SB 9200 or another product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Violation 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 or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In addition, the holder of an approved NDA is obligated to monitor and report adverse events, and any failure of a product to meet the specifications in the NDA. Later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;

- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters asserting that we are in violation of the law;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure;
- refusal to permit us to enter into government contracts; or
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize SB 9200 or our other product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of SB 9200 or our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs; and
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals 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 product. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies, which is time-consuming and costly. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers, patients and third-party payors will 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 US federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

False Claims Laws. Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui *tam* actions, against individuals or entities for knowingly presenting, or causing to be presented to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or for making any false statements relating to healthcare matters. Similar to the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. Additionally, HIPAA, as amended by HITECH and its implementing regulations, imposes obligations on certain covered entities as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Department of Health and Human Services information related to certain payments and other transfers of value, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

FDCA. The federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; and

Analogous State and Foreign Laws. Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers. In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. 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, and our business generally, 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 these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, disgorgement, curtailment or restricting of our operations, any of which could substantially disrupt our operations and diminish our profits and future earnings. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom will recommend, purchase and/or prescribe our products, could be subject to challenge under one or more of such laws.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. For instance, the Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, the government operates hospitals, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations and similar laws and regulations established and enforced by comparable foreign

regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, incentive programs and other business arrangements. Misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a license agreement with BioHEP Technologies Ltd. under which we license certain patents and know-how to make, have made, use, sell, offer to sell and import certain product candidates, including SB 9200. We may enter into additional license agreements in the future. Our license agreement with BioHEP imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under the license agreement. Termination of these license agreements may result in our having to negotiate new or reinstated licenses with less favorable terms.

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development, such as our employees, strategic partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential information before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We may license patent rights that are valuable to our business from third parties, in which event we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties also apply to patent rights we own.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or

those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. If we or our licensors are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our compounds will result in the issuance of patents that protect our technology or products, or if any of our or our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensors' patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

If third parties initiate legal proceedings against us alleging that we are infringing their intellectual property rights, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends upon our ability to develop, manufacture, market and sell SB 9200 and any other product candidates and to use our related proprietary technologies, without infringing the intellectual property and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the United States Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. As a result, we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to SB 9200 or any other product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate.

If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court

order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing the applicable product candidate or force us to cease some of our business operations, which could materially harm our business.

Defense of claims of infringement, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Parties making claims against us may also obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our product candidates, which could materially harm our business.

Most of our competitors are larger than we are and have substantially greater resources and may be able to sustain the costs of complex patent litigation longer than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our research and development, in-license needed technology, or enter into strategic partnerships.

Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

While SB 9200 is in preclinical studies and clinical trials, we believe that the use of SB 9200 in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. If SB 9200 progresses toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that SB 9200 and the methods we employ to manufacture SB 9200, as well as the methods for its use that we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

In addition, we plan to evaluate SB 9200 in combination with other product candidates and approved products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with SB 9200. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on SB 9200 and any other product candidates throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we or our licensors have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our or our licensor's patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

The terms of our patents may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as SB 9200, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents and those licensed to us.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. We may be subject to a third party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Furthermore, an adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize medicines without infringing third-party patent rights.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results.

In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue because our patents do not cover the technology in question. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees, which could harm our business and financial results.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy in order to protect our competitive position with respect to our technology and product candidates. Trade secrets are difficult to protect, and it is possible that our trade secrets and know-how will over time be disseminated within the industry through independent development and intentional or inadvertent disclosures.

We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, strategic partners, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and intentionally or inadvertently disclose or use our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect

trade secrets. If any of our trade secrets or the equivalent knowledge, methods and know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims by third parties asserting that our licensors, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

As is common in the biotechnology and pharmaceutical industry, many of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may also have, in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates.

Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to SB 9200 but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2016, we had 19 full-time employees, of whom 10 hold Ph.D. or M.D. degrees, plus several consultants. As our development and commercialization plans and strategies develop, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place is likely not adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

Our management may need to devote a disproportionate amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our executive officers. We have entered into employment agreements with each of our executive officers. These employment agreements do not prevent such persons from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

Risks Related to Our Common Stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

Our executive officers, directors and principal stockholders, if they choose to act together, may have the ability to significantly influence all matters submitted to stockholders for approval.

As of September 30, 2016, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, beneficially own shares representing approximately 42.7% of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they may be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, may be able to significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We have broad discretion over the use of our cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the use of our cash, cash equivalents and marketable securities to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. We

intend to use our cash, cash equivalents and marketable securities to fund the clinical development of SB 9200 and our other product candidates, conduct additional research and development and for working capital and general corporate purposes. However, our use of our cash, cash equivalents and marketable securities may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and marketable securities in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of September 30, 2016, we have 7,767,981 outstanding shares of common stock, including the shares that we sold in our initial public offering. Of these shares of our common stock, 6,731,034 shares are currently subject to a 180-day lock-up following our initial public offering. These restrictions are due to expire on November 1, 2016, resulting in these shares becoming eligible for public sale without limitation on November 2, 2016 unless held by our affiliates. Moreover, holders of an aggregate of 512,500 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On June 15, 2016, we filed a registration statement registering all shares of common stock that we may issue under our equity compensation plans. As of September 30, 2016, options to purchase 718,065 shares of our common stock at a weighted average exercise price of $11.76 per share were outstanding. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the applicable lock-up agreements entered into in connection with the initial public offering.

An active trading market for our common stock may not be sustained

Our shares of common stock began trading on The NASDAQ Capital Market on May 6, 2016. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares. In addition, an inactive trading market for our common stock may impair our ability to raise capital to continue to fund our operations by selling shares.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company through 2021. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage

of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the exchange or market upon which we trade and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as regulatory and governing bodies provide new guidance. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

In prior fiscal years, we have identified material weaknesses in our internal control over financial reporting. If we identify additional weaknesses in our internal control over financial reporting in the future, such material weaknesses could affect the reliability of our consolidated financial statements and have other adverse consequences.

In the course of the preparation and external audit of our consolidated financial statements for the fiscal year ended December 31, 2014, we and our independent registered public accounting firm identified "material weaknesses" in our internal controls over financial reporting related to: (1) our financial statement close process, including both our failure to have adequate processes in place to complete our financial statement close process in a timely and accurate manner and flaws in our review controls, which were not designed with the precision necessary to detect or prevent material misstatements; and (2) our lack of sufficient personnel to account for complex transactions in accordance with generally accepted accounting principles and to properly segregate accounting duties. A material weakness in internal controls over financial reporting is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Following the identification of these control deficiencies, we took actions and measures to improve our internal control over financial reporting by hiring additional employees and consultants at various appropriate levels. We believe that we have remediated these material weaknesses.

If we discover that we have not remediated these material weakness, or we identify other material weaknesses or significant deficiencies in the future, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could cause us to fail to meet our reporting obligations or result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the securities and industry analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws that became effective upon the closing of our initial public offering may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least a majority of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the board of directors, the chairman of the board of directors, the chief executive officer or stockholders holding a majority of our issued and outstanding common stock, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Furthermore, our amended and restated bylaws that became effective upon the closing of our initial public offering specify that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased

consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development 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 could be subject to 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 pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Use of Proceeds

In May 2016, we issued and sold 920,000 shares of our common stock in our initial public offering at a price to the public of $12.00 per share, for gross proceeds of approximately $11.0 million before deducting underwriters' discounts and commissions and offering-related expenses. In addition, on June 3, 2016, we issued and sold an additional 24,900 shares of common stock at the initial public offering price of $12.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, for gross proceeds of approximately $0.3 million before deducting underwriters' discounts and commissions and offering-related expenses. All of the shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-208875), which was declared effective by the Securities and Exchange Commission, or SEC, on May 5, 2016. Dawson James Securities, Inc. acted as the sole book-running manager of the offering, and ViewTrade Securities, Inc. and Axiom Capital Management, Inc. acted as co-managers for the offering. The offering commenced on May 5, 2016 and did not terminate until the sale of all of the shares offered.

The aggregate net offering proceeds to us, after deducting underwriting discounts and commissions of $907,104 and offering expenses totaling approximately $2.0 million, were approximately $8.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associated) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

We have used the proceeds from the sale of shares of common stock in our initial public offering to fund the initiation and progress of the Phase 2a clinical trial of SB 9200 that we initiated in chronic HBV in June 2016. We have also invested $7.2 million of the net proceeds from the offering in money market accounts with future investments to be made in accordance with our investment policy. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act with the SEC on May 6, 2016.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

SIGNATURES

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

Spring Bank Pharmaceuticals, Inc.

Date: October 28, 2016

By: /s/ Jonathan Freve
Jonathan Freve
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Martin Driscoll, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Spring Bank 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(s) 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)) 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 small business issuer, 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) 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

   (c) 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 small business issuer's internal control over financial reporting; and

5. The registrant's other certifying officer(s) 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: October 28, 2016

By: /s/ Martin Driscoll
Martin Driscoll
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Freve, certify that:

1. I have reviewed this Quarterly Report on 10-Q of Spring Bank 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(s) 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)) 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) 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

   (c) 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(s) 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: October 28, 2016

By: /s/ Jonathan Freve
Jonathan Freve
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Spring Bank Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: October 28, 2016

By: /s/ Martin Driscoll
Martin Driscoll
Chief Executive officer
(Principal Executive Officer)

By: /s/ Jonathan Freve
Jonathan Freve
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)