Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014

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 001-35619

STEMLINE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0522567**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

750 Lexington Avenue
Eleventh Floor
New York, New York 10022
(Address including zip code of principal executive offices)

(646) 502-2311
(Registrant's telephone number, including area code)

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 definition 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 smaller reporting company)	Smaller reporting company ☐

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

There were 13,258,168 shares of the registrant's common stock, $0.0001 par value, outstanding as of August 11, 2014.

STEMLINE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2014

TABLE OF CONTENTS

This Quarterly Report on Form 10-Q contains trademarks and trade names of Stemline Therapeutics, Inc., including our name and logo. All other trademarks, service marks, or trade names referenced in this Quarterly Report on Form 10-Q are the property of their respective owners.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "potential," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-Q and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of our drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-Q, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our preclinical studies and clinical trials, including, site initiation, internal review board, or IRB, approval, scientific review committee, or SRC, approval, and patient accrual;
- our ability to obtain and maintain regulatory approval of our product candidates for trial initiation or marketing, and the labeling under any approval we may obtain;
- our plans to develop and commercialize our product candidates;
- the loss of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- our available cash;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to maintain the license agreements for SL-401, SL-701 and our other in-licensed product candidates;
- the ability of our product candidates to successfully perform in clinical trials;
- the successful development of our sales and marketing capabilities;
- our ability to manufacture and the performance of third-party manufacturers, clinical research organizations, or CROs, clinical trial sponsors and clinical trial investigators; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this Form 10-Q speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-Q. You should also read carefully the factors described in the "Risk Factors" section of this Form 10-Q to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Table of Contents

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements.

STEMLINE THERAPEUTICS, INC.
Balance Sheets

	June 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 21,160,428	$ 44,200,420
Short-term investments	1,042,378	—
Related party receivable	—	199,615
Prepaid expenses and other current assets	1,660,812	292,916
Total current assets	23,863,618	44,692,951
Furniture and fixtures, net	306,667	383,333
Long-term investments	47,318,347	40,204,912
Total assets	$ 71,488,632	$ 85,281,196
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,233,072	$ 5,013,808
Total current liabilities	4,233,072	5,013,808
Deferred grant revenue	500,857	643,000
Total liabilities	4,733,929	5,656,808
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2013 and June 30, 2014	—	—
Common stock $0.0001 par value, 33,750,000 shares authorized at June 30, 2014 and December 31, 2013, 13,258,168 shares issued and outstanding at June 30, 2014 and 13,095,726 shares issued and outstanding at December 31, 2013	1,326	1,310
Additional paid-in capital	113,123,849	111,032,619
Accumulated other comprehensive gain (loss)	7,919	(43,775)
Accumulated deficit	(46,378,391)	(31,365,766)
Total stockholders' equity	66,754,703	79,624,388
Total liabilities and stockholders' equity	$ 71,488,632	$ 85,281,196

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenues:				
Grant revenue	$ 71,429	—	$ 142,429	—
Operating expenses:				
Research and development	4,090,590	$ 4,084,521	11,207,446	$ 7,246,247
General and administrative	2,026,865	1,071,426	4,015,225	3,238,893
Total operating expenses	6,117,455	5,155,947	15,222,671	10,485,140
Loss from operations	(6,046,026)	(5,155,947)	(15,080,242)	(10,485,140)
Other income	632	—	632	30,649
Other expense	(11,146)	—	(19,069)	—
Interest expense	—	(297,935)	—	(505,037)
Interest income	43,842	3,244	86,054	3,244
Net loss from operations	(6,012,698)	(5,450,638)	(15,012,625)	(10,956,284)
Net loss attributable to common stockholders	$ (6,012,698)	$ (5,450,638)	$ (15,012,625)	$ (10,956,284)
Net loss attributable to common stockholders per common share:				
Basic and Diluted	$ (0.47)	$ (0.55)	$ (1.16)	$ (1.37)
Weighted-average shares outstanding:				
Basic and Diluted	12,921,898	9,837,062	12,907,931	8,014,529

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$ (6,012,698)	$ (5,450,638)	$ (15,012,625)	$ (10,956,284)
Other comprehensive gain (loss):				
Unrealized gain on investments	8,560	—	52,326	—
Reclassification adjustment for gain on investments included in net income	(632)	—	(632)	—
Other comprehensive gain (loss)	7,928	—	51,694	—
Comprehensive loss	$ (6,004,770)	$ (5,450,638)	$ (14,960,931)	$ (10,956,284)

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Statement of Stockholders' Equity
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Capital	Shares	Capital				
Balance, December 31, 2013	—	—	13,095,726	1,310	111,032,619	(43,775)	(31,365,766)	79,624,388
Restricted stock grants			144,246	14	(14)			
Forfeiture of restricted stock grants			(777)					
Issuance of common stock in connection with the exercise of stock options			18,973	2	69,146			69,148
Stock-based compensation expense					2,022,098			2,022,098
Net loss							(15,012,625)	(15,012,625)
Other comprehensive income						51,694		51,694
Balance, June 30, 2014	—	—	13,258,168	$ 1,326	$ 113,123,849	$ 7,919	$ (46,378,391)	66,754,703

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2014	2013
Cash flows from operating activities		
Net loss	$ (15,012,625)	$ (10,956,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	76,666	—
Stock-based compensation expense	2,022,098	2,861,999
Amortization of premium paid on marketable securities	137,672	
Net gain on redemption of marketable securities	(632)	
Non-cash interest expense		82,389
Mark-to-market of put option liability		(30,415)
Beneficial conversion of convertible interest		422,648
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,367,896)	(863,090)
Related party receivable	199,615	—
Accounts payable and accrued expenses	(780,736)	1,377,172
Deferred grant revenue	(142,143)	—
Net cash used in operating activities	(14,867,981)	(7,105,581)
Cash flows from investing activities		
Purchase of marketable securities	(16,246,878)	—
Redemption of marketable securities	8,005,719	—
Net cash used in investing activities	(8,241,159)	—
Cash flows from financing activities		
Proceeds from issuance of common stock, net	—	97,708,506
Proceeds from exercise of stock options	69,148	57,649
Net cash provided by financing activities	69,148	97,766,155
Net (decrease) increase in cash and cash equivalents	(23,039,992)	90,660,574
Cash and cash equivalents at beginning of period	44,200,420	2,025,338
Cash and cash equivalents at end of period	$ 21,160,428	$ 92,685,912

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Notes to Unaudited Financial Statements
June 30, 2014

1. Organization and Basis of Presentation

Organization

Stemline Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells ("CSCs") and tumor bulk. The Company's activities to date have primarily consisted of advancing its two clinical-stage programs, developing its preclinical pipeline, building its proprietary drug discovery platform, fortifying its intellectual property portfolio, identifying and acquiring additional product and technology rights and raising capital. The Company was incorporated in Delaware on August 8, 2003 and has its principal office in New York, New York.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments (including normal recurring accruals) considered necessary for fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. Operating results for the current interim period are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014 or any future periods. This Form 10-Q should be read in conjunction with the audited financial statements and accompanying notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 ("2013 Form 10-K"). The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to cover its cash flow requirements for at least the next two years.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to investments, property and equipment, accrued expenses, share-based compensation and income taxes. The estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Results may differ from these estimates due to actual outcomes differing from those on which the Company bases its assumptions.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Financial Statements included in the 2013 Form 10-K. There have been no changes to those policies.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB"), issued a comprehensive new revenue recognition Accounting Standards Update, *Revenue from Contracts with Customers (Topic 606) (ASU 2014-09).* ASU 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In June 2014, The FASB issued Accounting Standards Update ("ASU") 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 910, Consolidation.* This ASU's objective is to improve financial reporting by reducing cost and complexity associated with the incremental reporting requirements for development stage entities. The Company has previously met the conditions of being a

development stage entity and has provided the appropriate disclosures within the financial statements, including inception to date financial reporting. As a result of this ASU, all incremental reporting requirements for development stage entities including inception to date financial reporting will no longer be required to be disclosed in financial statements. The effective date of this ASU is for annual reporting periods beginning after December 15, 2014. However, early adoption is allowed and the Company has early adopted this ASU within the financial statements for the three and six months ended June 30, 2014.

3. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following at June 30, 2014 and December 31, 2013:

	June 30, 2014	December 31, 2013
Prepaid third party vendor costs	1,270,396	39,630
Prepaid insurance	284,173	43,321
Deposits	106,243	209,965
Total	$ 1,660,812	$ 292,916

4. Furniture and Fixtures

Furniture and fixtures consist of the following at June 30, 2014 and December 31, 2013:

	June 30, 2014	December 31, 2013
Office furniture and fixtures	$ 460,000	$ 460,000
Less accumulated depreciation	(153,333)	(76,667)
Furniture and fixtures, net	$ 306,667	$ 383,333

Depreciation expense was $76,666 and $0 for the six-month periods ended June 30, 2014 and 2013, respectively. Depreciation expense was $38,333 and $0 for the three-month periods ended June 30, 2014, and 2013, respectively.

5. Fair Value Measurements

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument.

Financial assets recorded at fair value on the Company's balance sheets are categorized as follows:

Level 1: Unadjusted quoted prices for identical assets in an active market.

Level 2: Quoted prices in markets that are not active or inputs that are observable either directly or indirectly for substantially the full-term of the asset. Level 2 inputs include the following:

- quoted prices for similar assets in active markets,
- quoted prices for identical or similar assets in non-active markets,
- inputs other than quoted market prices that are observable, and
- inputs that are derived principally from or corroborated by observable market data through correlation or other means.

Level 3: Prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. Level 3 inputs reflect management's own assessment about the assumptions a market participant would use in pricing the asset.

There were no transfers between levels in the fair value hierarchy during any period presented herein. The Company's financial assets and liabilities measured at fair value on a recurring basis at June 30, 2014 and December 31, 2013 consist of the following:

	June 30, 2014			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at June 30, 2014
Assets:				
Cash and cash equivalents	$ 21,160,428	$	$	$ 21,160,428
Short-term investments	1,042,378			1,042,378
Long-term investments	47,318,347			47,318,347
Total assets at fair value	$ 69,521,153	$	$	$ 69,521,153

	December 31, 2013			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2013
Assets:				
Cash and cash equivalents	$ 44,200,420	$ —	$ —	$ 44,200,420
Long-term investments	40,204,912	—	—	40,204,912
Total assets at fair value	$ 84,405,332	$ —	$ —	$ 84,405,332

The following is a summary of available-for-sale investments held by the Company at June 30, 2014 and December 31, 2013:

	June 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 19,155,473	$	$	$ 19,155,473
Short-term investments:				
Fixed-income treasury portfolio:				
Federal farm credit bank	1,042,046	332	—	1,042,378
Total Short-term investments	1,042,046	332	—	1,042,378
Long-term investments:				
Fixed-income treasury portfolio:				
Federal home loan bank	17,565,399	4,005	(6,192)	17,563,212
Federal farm credit bank	11,413,440	6,529	(929)	11,419,040
Freddie Mac	13,418,860	3,075	(1,080)	13,420,855
Fannie Mae	4,913,061	2,179	—	4,915,240
Total Long-term investments	47,310,760	15,788	(8,201)	47,318,347
Total	$ 67,508,279	$ 16,120	$ (8,201)	$ 67,516,198

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 41,441,975	$ —	$ —	$ 41,441,975
Long-term investments:				
Fixed-income treasury portfolio:				
Federal home loan bank	13,789,246	—	(14,752)	13,774,494
Federal farm credit bank	11,476,874	—	(13,701)	11,463,173
Freddie Mac	10,020,626	—	(8,340)	10,012,286
Fannie Mae	4,961,941	—	(6,982)	4,954,959
Total Long-term investments	40,248,687	—	(43,775)	40,204,912
Total	$ 81,690,662	$ —	$ (43,775)	$ 81,646,887

At June 30, 2014 and December 31, 2013, the remaining contractual maturities of available-for-sale investments classified as current on the balance sheet were less than 12 months, and the remaining contractual maturities of available-for-sale investments classified as long-term were less than two years.

There were no available-for-sale securities in a continuous unrealized loss position for greater than twelve months at June 30, 2014 and December 31, 2013.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, investments, other current assets, accounts payable and accrued expenses. Cash and cash equivalents, and long-term investments are carried at fair value (see above). Financial instruments including other assets, accounts payable and accrued expenses are carried at cost, which approximate fair value given their short-term nature.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following at June 30, 2014 December 31, 2013:

	June 30, 2014	December 31, 2013
Accrued research and development costs	$ 2,156,209	$ 1,966,360
Accrued compensation	1,095,466	2,043,704
Accrued professional fees	353,243	372,267
Short-term portion of deferred revenue	285,714	286,000
Other accrued liabilities	342,440	345,477
Total	$ 4,233,072	$ 5,013,808

7. Common Stock

At the 2013 annual meeting of stockholders held on June 19, 2013, the stockholders voted in favor of an amendment to the Company's Restated Certificate of Incorporation to increase the Company's authorized share capital by 11,250,000 shares of common stock. As of December 31, 2013, the Company was authorized to issue 33,750,000 shares of common stock.

Dividends on common stock will be paid when, and if, declared by the board of directors. Each holder of common stock is entitled to vote on all matters and is entitled to one vote for each share held. The Company will, at all times, reserve and keep available, out of its authorized but unissued shares of common stock, sufficient shares to effect the conversion of the shares of the stock options.

In connection with the Company's initial public offering ("IPO") in January 2013, the Company issued warrants to purchase up to 99,529 shares of the Company's common stock to representatives of Aegis Capital Corp., the lead underwriter in the IPO. The warrants are exercisable for cash or on a cashless basis at a price per share equal to $15.00. The term of the warrants is four years and they expire on January 28, 2018.

8. Accumulated Other Comprehensive Gain (Loss)

The change in accumulated other comprehensive gain (loss) are as follows:

	Unrealized gain (loss) on available for sale securities	Total
Balance as of December 31, 2013	$ (43,775)	$ (43,775)
Other comprehensive income before reclassifications	52,326	52,326
Amounts reclassified from accumulated other comprehensive income (loss)*	(632)	(632)
Total other comprehensive income	51,694	51,694
Balance as of June 30, 2014	$ 7,919	$ 7,919

*Amounts reclassified affect other income in the consolidated statements of income.

9. Net (Loss) Income Per Common Share

The Company accounts for and discloses net income (loss) per share using the treasury stock method. Net income (loss) per common share, or basic income (loss) per share, is computed by dividing net income (loss) by the weighted-average number of common shares outstanding. Net income (loss) per common share assuming dilutions, or diluted income (loss) per share, is computed by reflecting the potential dilution from the exercise of in-the-money stock options, non-vested restricted stock and non-vested restricted stock units.

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Basic and diluted net loss per common share calculation:				
Net loss	$ (6,012,698)	$ (5,450,638)	$ (15,012,625)	$ (10,956,284)
Basic and diluted weighted-average common shares	12,921,898	9,837,062	12,907,931	8,014,529
Basic and diluted net loss per share	$ (0.47)	$ (0.55)	$ (1.16)	$ (1.37)

The difference between basic and diluted weighted-average common shares generally results from the assumption that dilutive stock options outstanding were exercised, dilutive restricted stock has vested, outstanding warrants are issued and the conversion of convertible notes. For the six-month periods ended June 30, 2014 and 2013, the Company reported a loss from operations and therefore, all potentially dilutive stock options, restricted stock, outstanding warrants and convertible notes as of such date were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive. The total shares of stock options, restricted stock, outstanding warrants and convertible notes that could potentially dilute earnings per share in the future, but which were not included in the calculation of diluted net loss per share because their affect would have been anti-dilutive were as follows:

	Six Months Ended June 30	
	2014	2013
Restricted stock	311,403	248,869
Options outstanding	1,643,159	1,879,573
Warrants	99,529	99,529
Total	2,054,091	2,227,971

10. Revenue

In October 2013, the Company entered into an award contract (the "Agreement") with The Leukemia and Lymphoma Society ("LLS"). LLS is a national voluntary health agency which, among other activities, encourages and sponsors research relating to leukemia, lymphoma, Hodgkin's disease and myeloma to develop therapies to cure or mitigate these diseases. To further its mission, LLS provides research funding to entities that can demonstrate after LLS's review process that their proposed research projects have scientific promise to advance LLS's effort to find treatments and cures for the above diseases and their complications. Pursuant to the Agreement, LLS agreed to provide funding to the Company not to exceed $3.5 million to help fund the Company's development program related to the Company's pre-clinical and clinical product development activities. The Company received $1.0 million in October 2013, upon execution of the Agreement and could receive the additional $2.5 million based on the completion of certain milestone events. The Company has recognized approximately $0.1 million of revenue related to the Leukemia and Lymphoma Society funding for the six-month period ended June 30, 2014, which reflects six months of revenue recognized on a straight line basis, based on the Company's best estimates of work performed.

11. Income Taxes

The Company did not record an income tax provision or benefit for the six and three-month periods ended June 30, 2014 and 2013, respectively, due to the fact that the Company cannot benefit from its net operating losses. The Company has never had the ability to carry back losses to previous years to recover taxes paid and future utilization of these losses is uncertain.

The Company files income tax returns in the United States and in the State of New York. The Company is not currently being audited by the Internal Revenue Service or any state taxing jurisdiction.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their basis for income tax purposes and the tax effects of net operating loss and tax credit carryforwards.

Valuation allowances reduce deferred tax assets to the amounts that are more likely than not to be realized. As of June 30, 2014, the Company has recorded additional deferred tax assets which are fully offset by a valuation allowance. Realization of the deferred tax assets is dependent on generating sufficient taxable income in the future. At present, the likelihood of the Company being able to fully utilize its deferred income tax benefits against future income is uncertain.

12. Stock-Based Compensation

The Company's 2012 Stock Equity Incentive Plan (the "2012 Plan"), which was adopted by the board of directors and approved by the stockholders in July 2012, became effective immediately prior to the closing of the Company's initial public offering. In addition, the Company's 2004 Stock Option and Grant Plan (the "2004 Plan") was terminated effective immediately prior to the closing of the Company's initial public offering. The 1,819,839 options to purchase common stock and 34,506 restricted stock awards executed prior to the effective date of such termination remain in full force and effect pursuant to their terms and the terms of the 2004 Plan. The 2012 Plan initially authorized the Company to grant up to 1,663,727 shares of common stock to eligible employees, directors, and non-employee consultants and advisors to the Company in the form of options to purchase common stock of the Company at a price not less than the estimated fair value at the date of grant. Under the provisions of the 2012 Plan, no option will have a term in excess of 10 years.

As of June 30, 2014, there were 1,218,795 shares of common stock available for future grants under the 2012 Plan.

Total compensation cost that has been charged against operations related to the above plans was approximately $2.0 million and $2.9 million for the six-month periods ended June 30, 2014 and 2013, respectively. The Company does not recognize a tax benefit with respect to an excess stock compensation deduction until the deduction actually reduces the Company's income tax liability. No income tax benefit was recognized in the statements of operations for share-based compensation arrangements for the six-month periods ended June 30, 2014 and 2013.

The following table summarizes stock-based compensation related to the above plans by expense category for the three-month and six-month periods ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	$ 713,179	$ 422,719	$ 1,354,896	$ 1,787,127
General and administrative	366,479	154,099	667,202	1,074,872
Total	$ 1,079,658	$ 576,818	$ 2,022,098	$ 2,861,999

Stock Options

The Company grants stock options to employees, Directors and non-employee consultants, with exercise prices equal to the closing price of the underlying shares of the Company's common stock on the date that the options are granted. Options granted have a term of 10 years from the grant date. Options granted to employees generally vest over a four-year period and options granted to Directors vest in equal yearly installments over a three-year period from the date of grant. Options to Directors are granted on an annual basis and represent compensation for services performed by the board of directors. Compensation cost for stock options granted to employees and Directors is charged against operations using the straight-line attribution method between the grant date for the option and each vesting date. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost.

The weighted-average key assumptions used in determining the fair value of options granted for the six months ended June 30, 2014 and 2013 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Weighted-average volatility	87.19%	82.97%	88.90%	82.97%
Weighted-average risk-free interest rate	1.96%	1.50%	1.98%	1.50%
Weighted-average expected term in years	6.05%	6.00%	6.20%	6.00%
Dividend yield	0%	0%	0%	0%

The Company's computation of stock-price volatility is based on the volatility rates of comparable publicly held companies over a period equal to the estimated useful life of the options granted by the Company. The Company's computation of expected life was determined using the "simplified" method which is the midpoint between the vesting date and the end of the contractual term. The Company believes that it does not have sufficient reliable exercise data in order to justify the use of a method other than the "simplified" method of estimating the expected exercise term of employee stock option grants. The Company has paid no dividends to stockholders. The risk-free interest rate is based on the zero-coupon U.S. Treasury yield at the date of grant for a term equivalent to the expected term of the option.

For the six-month period ended June 30, 2014, the Company issued 18,973 shares of the Company's common stock upon the exercise of outstanding stock options and received proceeds of $69,148. There were no exercises of stock options for the six-month period ended June 30, 2013. As of June 30, 2014, there was approximately $6.7 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a remaining weighted-average period of approximately 2.8 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures.

The following table summarizes the activity related to the Company's stock options at for the six months ended June 30, 2014:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2013	1,326,486	$ 4.89		
Options granted	364,391	21.42		
Options exercised	(18,973)	3.64		
Options forfeited	(28,745)	4.86		
Outstanding at June 30, 2014	1,643,159	$ 8.57	7.29	$ 17,484,572
Options exercisable at June 30, 2014	903,585	$ 4.04	6.06	$ 12,864,431

The aggregate intrinsic value in the previous table reflects the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on June 30, 2014. The intrinsic value of the Company's stock options changes based on the closing price of the Company's common stock. The total intrinsic value of options exercised (the difference in the market price of the Company's common stock on the exercise date and the price paid by the optionee to exercise the option) was approximately $0.3 million for the six-month period ended June 30, 2014. There were no exercises of stock options for the six-month period ended June 30, 2013.

Restricted Stock

The Company grants restricted stock to its employees and Directors. Restricted stock is recorded as deferred compensation and charged against earnings on a straight-line basis over the vesting period, which ranges from one to four years in duration. Restricted stock may be granted to Directors and represents compensation for services performed on the Company's board of directors. Restricted stock awards to Directors vest in equal installments over a three-year period from the grant date. Compensation cost for restricted stock is based on the award's grant date fair value, which is the closing market price of the Company's common stock on the grant date, multiplied by the number of shares awarded.

The following table summarizes the activity related to the Company's restricted stock for the six months ended June 30, 2014:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2013	229,250	$ 17.34
Shares granted	125,663	22.90
Shares vested	(42,733)	14.22
Shares forfeited	(777)	25.05
Outstanding at June 30, 2014	311,403	$ 19.99

For the six-month period ended June 30, 2014, the Company granted 125,663 shares of restricted stock, at a weighted-average grant date fair value of $22.90 per share amounting to approximately $2.9 million in total aggregate fair value. As of June 30, 2014, approximately 311,403 shares remained unvested and there was approximately $4.8 million of unrecognized compensation cost related to restricted stock which is expected to be recognized over a remaining weighted-average period of approximately 3.1 years. The total fair value of restricted stock vested during the six-month period ended June 30, 2014 was approximately $0.6 million. There was no vesting of restricted stock for the six-month period ended June 30, 2013.

Awards Granted to Non-Employees

The Company periodically re-measures the fair value of stock-based awards issued to non-employees and records expense over the requisite service period. Total compensation cost charged against operations related to options granted to non-employees was approximately $0.1 million and $0.7 million for the six-month periods ended June 30, 2014 and 2013, respectively.

13. Commitments and Contingencies

The Company has entered into research and development agreements with third parties for the development of oncology products. These agreements require the Company to fund the development of such products and potentially make milestone payments and royalties on net sales in the future based on the Company's successful development of the products. The timing and the amount of milestone payments in the future are not certain.

Under the Company's license agreements, the Company could be required to pay up to a total of $23.3 million upon achieving certain milestones, the majority of which are due upon the achievement of late stage clinical development, regulatory approval and post-approval milestones. From Inception through June 30, 2014, the Company has paid or accrued $2.2 million in payments resulting from the execution of certain agreements, patent approvals, the initiation of sponsored research agreements, and compound development agreements. Milestone payments will also be due upon the issuance of certain patents, the initiation of certain clinical trials, the submission of regulatory applications and certain regulatory approvals, in addition to sales milestones and single-digit royalties payable on commercial sales, if any occur.

Scott and White

In June 2006, the Company entered into a research and license agreement, as amended in December 2008, March 2010 and July 2011 (collectively the "S&W Agreement"), with Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation, and its affiliate Scott and White Clinic (collectively "S&W") for the rights to SL-401 and SL-501. SL-401 is a clinical-stage targeted therapy

directed to the interleukin-3 receptor, or IL-3R, and is being developed to treat patients with hematologic cancers. SL-501 is a next generation IL-3R-targeted therapy and is in preclinical development. The Company is required to pay customary single-digit royalties on sales, if any, of new products approved utilizing the licensed compounds, and a percentage of up-front payments the Company receives from a sublicensee. The S&W Agreement will expire in its entirety upon the later of (i) the 10th anniversary of the first commercial sale of a product, or (ii) the expiration of the last issued patent claiming or covering a product. The Company may terminate the S&W Agreement at its sole discretion at any time after a specified number of days following written notice and either party may terminate for a material breach of the agreement that is not cured within a specified number of days.

University of Pittsburgh

In September 2009, the Company entered into an exclusive license agreement with the University of Pittsburgh ("UP") that covers patent rights claiming composition of a variant of the IL-13Rα2 peptide. SL-701 is an enhanced immunotherapy being developed to treat patients with advanced brain cancer (the "UP Agreement"). The Company paid UP an upfront license fee that was expensed to research and development cost for the year ended December 31, 2009. In addition to the upfront payment, the Company will be required to pay annual fees, milestones (which are contingent upon achievement of pre-defined clinical, regulatory and commercial events), and, upon regulatory approval, single-digit royalties on net sales, and a percentage of non-royalty revenue from sublicensees, which decreases if the applicable sublicense agreement is entered into after a certain clinical milestone has been met. The UP Agreement will expire in its entirety upon the expiration of the last issued patent claiming or covering the product. The Company may terminate the UP Agreement at its sole discretion at any time after a specified number of days following written notice and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days.

In March 2012, the Company entered into a non-exclusive license agreement with UP that covers patent rights claiming use of a peptide of EphA2, which the Company may use for the diagnosis, treatment or prevention of diseases and tumors of the brain. The Company paid UP an initial license fee and will be required to pay UP annual license maintenance fees until the first commercial sale of a licensed product, a customary single-digit royalty on sales, and a minimum annual royalty following the first commercial sale of a licensed product. The UP Agreement will expire in its entirety upon the expiration of the last issued patent claiming or covering the product. The Company may terminate the UP Agreement at its sole discretion at any time after a specified number of days following written notice and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days.

In March 2012, the Company also entered into a non-exclusive license agreement with UP for the right to use certain information and data contained in the INDs for the clinical trials of SL-701 that were conducted by UP. The Company may use the information and data for the development, manufacture, regulatory approval and commercialization of pharmaceutical products. The Company paid UP an initial license fee and will be required to make a payment following a specified regulatory milestone, and a percentage of non-royalty revenue received from any sublicensees. The UP Agreement will expire in its entirety in March 2032 unless earlier terminated by a party. The Company may terminate the UP Agreement at its sole discretion at any time prior to incorporating or referencing the data or UP INDs, after a specified number of days following written notice, and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days or if the IL-13Rα2 license agreement is terminated.

Other Research and Development Agreements

The Company has also licensed rights to certain technologies or intellectual property in the field of oncology. The Company is generally required to make upfront payments as well as other payments upon successful completion of preclinical, clinical, regulatory or sales milestones. In addition, these agreements generally require the Company to pay royalties on sales of the products arising from these agreements. These agreements generally permit the Company to terminate the agreement with no significant continuing obligation.

As part of the agreements discussed above, the Company has committed to make potential future milestone payments to third parties as part of its licensing agreements. Payments generally become due and payable only upon the achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, the Company has not recorded a liability on its balance sheet for any such contingencies.

Compensation Arrangements

Subsequent to the closing of the IPO, certain bonuses and salary increases in the amount of $1.0 million were paid upon approval of the board of directors and the satisfaction of certain contingencies, with an additional $0.4 million subject to the same contingencies which were paid one year after the IPO.

Contractual Agreements

In February 2013, the Company entered into a bioprocessing services agreement with a vendor for approximately $2.9 million if all services are performed under the contract. As of June 30, 2014, the contract services were performed on the initial work order and had been paid by the Company. During 2014, the Company entered into new work order agreements with this vendor totaling approximately $2.1 million, with services to be rendered on these agreements through 2015.

The Company has agreements in place with contract research organizations ("CROs") to facilitate research and clinical and data management services in connection with our clinical-stage product candidates, SL-401 and SL-701.

Lease Agreement

In July 2013, the Company entered into a leasing agreement with respect to its corporate offices at 750 Lexington Avenue, New York, New York, for a monthly rent of $50,625. The term of this lease agreement is 36 months.

The Company's future annual minimum lease payments for each of the following calendar years are as follows:

Remainder of 2014	$	303,750
2015		607,500
2016		303,750
	$	1,215,000

Rent expense charged to operations was $303,842 and $22,735 for the six-month periods ended June 30, 2014 and 2013, respectively. Rent expense charged to operations was $151,875 and $8,831 for the three-month periods ended June 30, 2014 and 2013, respectively. Rent expense is included in general and administrative expenses in the Company's Statements of Operations.

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

Unless the context requires otherwise, references in this report to "Stemline," "Company," "we," "us" and "our" refer to Stemline Therapeutics, Inc.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in our audited financial statements and notes thereto for the year ended December 31, 2013, and Management's Discussion and Analysis of Financial Condition and Results of Operation included in our 2013 Form 10-K to which the reader is directed for additional information.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells, or CSCs, and tumor bulk. We are currently developing two clinical-stage product candidates, SL-401 and SL-701.

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R, present on CSCs and tumor bulk of hematologic cancers. SL-401 has demonstrated objective clinical anticancer activity as a single-agent, including durable complete responses, or CRs, in an investigator sponsored Phase 1/2 trial involving several indications including blastic plasmacytoid dendritic cell neoplasm, or BPDCN, and relapsed or refractory acute myeloid leukemia, or AML. In particular, seven of nine evaluable BPDCN patients had objective responses (78% overall response rate), including 5 CRs. In July 2014 we opened a corporate-sponsored investigational new drug, or IND, with the U.S. Food and Drug Administration, or FDA, and opened a multicenter, open-label trial in relapsed/refractory patients with BPDCN and AML. This study is designed to accrue at least 60 patients, including a brief lead-in that transitions into a larger expansion stage in these indications. We are also planning additional open-label trials in other cancers including IL-3R+ myeloproliferative disorders.

SL-701 is an enhanced immunotherapy that activates the immune system to attack tumors. An earlier version of this therapy demonstrated objective clinical anticancer activity as a single-agent, including durable CRs and partial responses, or PRs, in investigator sponsored Phase 1/2 trials in advanced adult and pediatric brain cancers. We have since taken steps to create an enhanced version of this therapy potentially optimized for activity and commercialization. In April 2014 we opened a corporate-sponsored IND with the FDA and initiated a multicenter, open-label trial in adult patients with second-line glioblastoma multiforme, or GBM. This study is designed to accrue approximately 100 patients. We also plan to pursue a Phase 2 trial of SL-701 in pediatric patients with brainstem and non-brainstem high-grade glioma, which are also areas of unmet medical need.

We have also built a robust preclinical pipeline which includes next generation IL-3R-targeted compounds, SL-501 and SL-101, an innovative discovery platform, and an extensive intellectual property portfolio including some of the earliest patents in the CSC area.

We have devoted substantially all of our resources to developing our product candidates and our platform technology, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. We have generated minimal revenues to date, have not generated any revenues from product sales, and have funded our operations primarily through sales of common stock and convertible preferred stock and issuances of convertible debt to our investors. From inception through June 30, 2014 we have received net proceeds of $101.6 million from the sale of common stock, $12.5 million from the sale of convertible preferred stock and $0.9 million from the issuance of convertible debt.

We have never been profitable and, from inception through June 30, 2014, our net losses from operations have been $58.5 million. Our net loss from operations was $15.0 million for the six months ended June 30, 2014 and $11.0 million for the six months ended June 30, 2013. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources. 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 will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales and we have generated minimal revenues to date, all relating to a $1.0 million research funding received in October 2013 from the Leukemia and Lymphoma Society, or LLS, where we recognized revenue of $0.1 million during the six months ended June 30, 2014. In the future, we may generate revenue from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue.

If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

The following table shows our research and development expenses for the six-month and three-month periods ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Clinical (SL-401 and SL-701)	3,796,955	4,068,271	10,463,286	7,203,681
Preclinical	293,635	16,250	744,160	42,566
Total	4,090,590	4,084,521	11,207,446	7,246,247

Research and development expenses consist of costs associated with the development of our product candidates and our platform technology, which include:

- clinical trial-related costs;
- chemistry, manufacturing and controls (CMC) related costs;
- non-clinical costs;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense, and consultant costs;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, contract manufacturing organizations, or CMOs, academic institutions, and consultants;
- license fees and milestone payments related to in-licensed products and technology; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and supplies.

We expense research and development costs to operations as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received, rather than when the payments are made.

We use our employee and infrastructure resources across multiple research and development projects. We do not allocate employee-related expenses or depreciation to any particular project. The components of our research and development costs are described in more detail in “Results of Operations.”

We anticipate that our research and development expenses will increase significantly in future periods as we seek to complete development of our most advanced product candidates, SL-401 and SL-701, and continue to develop our other product candidates and our platform technology. At this time, we anticipate the majority of our research and development expense will be devoted to the development of SL-401 and SL-701.

The successful development of our product candidates is highly uncertain. At this time, other than as discussed above, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our product candidates or the period, if any, in which material net cash inflows from our product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and costs of our planned, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results;
- the potential benefits of our product candidates over other therapies;
- our ability to market and commercialize, either on our own or with strategic partners, and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- the costs, timing and outcome of regulatory approvals; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

A change in the outcome of any of these or similar variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation expense. The primary functions included in our general and administrative expenses are legal, finance, human resources, investor relations, and business development departments. Other general and administrative expenses include facility costs, insurance expenses and professional fees for consulting and accounting services.

We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased payroll, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company, among other factors.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and long-term investments. Given the current interest rate environment and that our primary investment is in 100% U.S. Treasury and Agency securities and related money market funds, we expect interest income to be minimal in future quarters.

Interest Expense

Interest expense consists primarily of cash and non-cash interest costs related to our previously outstanding debt. In addition, we capitalize costs incurred in connection with the issuance of debt. We amortize these costs over the life of our debt agreements as interest expense in our statement of operations.

Critical Accounting Policies and Estimates

To understand our financial statements, it is important to understand our critical accounting policies and estimates. We prepare our financial statements in accordance with generally accepted accounting principles, or GAAP. The preparation of financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that our accounting policies are critical to understanding our historical and future financial performance, as these policies related to the more significant areas involving management judgments and estimates.

For a discussion of our critical accounting estimates, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2013 Form 10-K. There were no material changes in our critical accounting estimates or accounting policies during the six-months ended June 30, 2014.

Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued a comprehensive new revenue recognition Accounting Standards Update, *Revenue from Contracts with Customers (Topic 606)" (ASU 2014-09)*. ASU 2014-09 provides guidance to clarify the principles for recognizing revenue. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In June 2014, The FASB issued Accounting Standards Update ("ASU") 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 910, Consolidation*. This ASU's objective is to improve financial reporting by reducing cost and complexity associated with the incremental reporting requirements for development stage entities. The Company has previously met the conditions of being a development stage entity and has provided the appropriate disclosures within the financial statements, including inception to date financial reporting. As a result of this ASU, all incremental reporting requirements for development stage entities including inception to date financial reporting will no longer be required to be disclosed in financial statements. The effective date of this ASU is for annual reporting periods beginning after December 15, 2014. However, early adoption is allowed and the Company has early adopted this ASU within the financial statements for the three and six months ended June 30, 2014.

Results of Operations

Comparison of Three Months Ended June 30, 2014 and 2013

Research and development expense. Research and development expense was flat year over year at $4.1 million for the quarters ended June 30, 2014 and June 30, 2013, respectively. We experienced an increase of $2.0 million of clinical and manufacturing development costs during the quarter as compared to the prior year. The major driver of the increased expenses during the quarter include $1.0 million of higher compensation expense relating to increased employee headcount supporting the development of our clinical programs. We also incurred $1.0 million of increased expenses relating to clinical trial preparation and recruitment activities and manufacturing development and production of drug supply. Offsetting our higher costs for the quarter was a one-time $2.0 million, in-process research and development expense relating to an assignment of intellectual property rights during the prior year.

General and administrative expense. General and administrative expense was $2.0 million for the quarter ended June 30, 2014, compared with $1.1 million for the quarter ended June 30, 2013, an increase of $0.9 million. This increase in costs was primarily attributable to $0.4 million of higher compensation expense, including non-cash stock based compensation, as a result of increased headcount to support the regulatory requirements of a public company. Additionally, the increase in expenses was due to higher costs for rent, audit fees, board of director fees and outside legal fees, each with an increase of $0.1 million during the quarter.

Interest expense. Interest expense was zero for the quarter ended June 30, 2014, compared with $0.3 million for the quarter ended June 30, 2013. The prior year interest expense related to our previously outstanding 2.45% convertible notes.

Interest income. Interest income was $43,842 for the quarter ended June 30, 2014, compared with $3,244 for the quarter ended June 30, 2013. The higher income is due to the increase in cash, cash equivalents, short-term investments and long-term investments on our balance sheet as a result of the completion of our IPO and secondary equity offering during the first half of 2013.

Comparison of Six Months Ended June 30, 2014 and 2013

Research and development expense. Research and development expense was $11.2 million for the six months ended June 30, 2014, compared with $7.2 million for the six months ended June 30, 2013, an increase of $4.0 million. The higher costs were primarily attributable to the ramp up in development activities for our SL-401 and SL-701 clinical programs. The major drivers of the increased expenses include $6.0 million of costs incurred with SL-401 and SL-701, relating to clinical trial preparation and recruitment activities and manufacturing development and production of drug supply. Partially offsetting the higher costs

was a $2.0 million, one-time in-process research and development expense relating to an assignment of intellectual property rights during the quarter ending June 30, 2013.

General and administrative expense. General and administrative expense was $4.0 million for the six months ended June 30, 2014, compared with $3.2 million for the six months ended June 30, 2013, an increase of $0.8 million. This increase was primarily attributable to higher rent costs of $0.3 million, increased audit fees of $0.2 million and higher outside legal expenses of $0.2 million. These increased costs are primarily the result of becoming a public company in 2013 and having the regulatory requirements associated with this status.

Interest expense. Interest expense was $0 for the six months ended June 30, 2014, compared with $0.5 million for the six months ended June 30, 2013. The prior year interest expense related to our previously outstanding 2.45% convertible notes.

Interest income. Interest income was $86,054 for the six months ended June 30, 2014, compared with $3,244 for the six months ended June 30, 2013. The higher income is due to the increase in cash, cash equivalents, short-term investments and long-term investments on our balance sheet as a result of the successful completion of our IPO and secondary equity offering during the first half of 2013.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations to date primarily through proceeds from sales of common stock and convertible preferred stock, and issuances of convertible debt. To date, we have not generated any revenue from the sale of products. We have incurred losses and generated negative cash flows from operations since inception.

Since inception and through June 30, 2014, we received net proceeds of $101.6 million from the sale of common stock, $12.5 million from the sale of convertible preferred stock and $0.9 million from the issuance of convertible notes.

As of June 30, 2014, our cash, cash equivalents and short and long-term investments totaled $69.5 million. We primarily invest our cash, cash equivalents, short-term investments and long-term investments in 100% U.S. Treasury and Agency securities and related money market funds, with the balance in commercial bank operating accounts. We believe that our existing cash, cash equivalents, short-term investments and long-term investments will be sufficient to fund our operations and our capital expenditures for at least the next two years.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended June 30,	
	2014	2013
Net cash used in operating activities	$ (14,867,981)	$ (7,105,581)
Net cash used in investing activities	(8,241,159)	—
Net cash provided by financing activities	69,148	97,766,155
Net increase (decrease) in cash and cash equivalents	$ (23,039,992)	$ 90,660,574

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for stock-based compensation expense, non-cash depreciation expense and changes in the components of working capital. The increased use in cash for the six months ended June 30, 2014 and 2013 was primarily the result of higher research and development expenses as we ramped up our clinical trial preparations for SL-401 and SL-701. The additional research and development costs also included CMC-related expenses for the manufacture of drug substance and drug product of our product candidates in development.

Investing activities. The net cash used in financing activities for the six months ended June 30, 2014 reflects purchases of long-term investments within our U.S. Treasury-related investment portfolio to obtain an optimum yield and minimal risk by increasing the duration on these U.S. Treasury-related investments.

Financing activities. The net cash provided by financing activities for the six months ended June 30, 2014 resulted from the exercise of stock options. The net cash provided by financing activities for the six months ended June 30, 2013 resulted from the net cash proceeds received from our initial public offering in January 2013 and secondary public offering in May 2013.

Funding Requirements

All of our product candidates are still in clinical or preclinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue to open and execute clinical trials;
- continue the research and development of our other product candidates and our platform technology;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish, either on our own or with strategic partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, fortify, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Our existing cash, cash equivalents, short-term investments and long-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next two years. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our lead product candidates;
- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the extent to which we acquire or in-license other products and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our ability to obtain government funding and operational support for our planned clinical trial of SL-701 in pediatric patients;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the

ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. Debt 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. 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 or 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

Our contractual obligations and commitments are described in more detail in our 2013 Form 10-K. As of June 30, 2014, there have been no significant changes to our contractual obligations as reported in our 2013 Form 10-K.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any relationships with any organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Tax Loss Carryforwards

As of June 30, 2014, we had federal net operating loss carryforwards of approximately $65.6 million, which are available to reduce future taxable income. We also had federal tax credits of approximately $0.6 million, which may be used to offset future tax liabilities. The net operating loss and tax credit carryforwards will expire at various dates through 2034. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service, or IRS, and state tax authorities and may become subject to an annual utilization limitation pursuant to the change in ownership rules of Internal Revenue Code, or IRC, Section 382 and 383. The amount of the annual limitation is determined based on the value of our Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. At June 30, 2014, we recorded a 100% valuation allowance against our net operating loss and tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be fully realized.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an “emerging growth company,” of which we are one, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have “opted out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and short and long-term investments of $69.5 million as of June 30, 2014 and $84.4 million as of December 31, 2013, consisting of cash, U.S. Treasury and Agency securities and U.S. Treasury-related money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term and medium-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and contract manufacturers. We may be subject to fluctuations in foreign currency rates in connection with these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of June 30, 2014 and December 31, 2013, all of our liabilities were denominated in our functional currency.

Item 4. Controls and Procedures.

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, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is 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 officer, as appropriate to allow timely decisions regarding required disclosure.

Changes to Internal Controls Over Financial Reporting

There has been no change in our internal controls over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Accounting Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition and/or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or a substantial part of your investment.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

We are heavily dependent on the success of our product candidates, SL-401 and SL-701, and we cannot provide any assurance that any of our product candidates will be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates, SL-401 and SL-701, which are advancing in clinical development. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval for, and commercialize these product candidates, which may never occur. We currently generate no revenues from our product candidates, and we may never be able to develop or commercialize a marketable drug.

Before we generate any revenues from product sales, we must complete preclinical and clinical development of one or more of our product candidates, conduct human subject research, submit clinical and manufacturing data to the FDA, qualify a third-party contract manufacturer, receive regulatory approval in one or more jurisdictions, satisfy the FDA that our contract manufacturer is capable of manufacturing the product in compliance with cGMP, build a commercial organization, make substantial investments and undertake significant marketing efforts ourselves or in partnership with others. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

We have not submitted a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, or similar market approval applications to comparable foreign authorities, for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval for trial initiation or marketing. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates in the United States, and potentially in the European Union and additional foreign countries. While the scope of regulatory review and approval is similar in other countries, to obtain separate regulatory review and approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take a substantial amount of time to complete. Its outcome is inherently uncertain. In addition, failure can occur at any time during clinical development, including after significant resources have been invested. We cannot predict whether we will encounter challenges with any of our planned clinical trials that will cause us or regulatory authorities to delay, suspend or terminate those clinical trials.

Clinical trials can be delayed or halted for many reasons, including:

- delays or failure reaching agreement on acceptable terms with prospective contract manufacturing organizations, or CMOs, contract 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;

- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;

- delays or failure in obtaining the necessary approvals from regulators, institutional review boards, or IRBs, or scientific review committees, or SRCs, in order to commence a clinical trial at a prospective trial site or to market our product candidates;
- our inability to manufacture, or obtain from third parties, adequate supply of drug substance, drug product or adjuvant therapies sufficient to complete our preclinical studies and clinical trials;
- risk of loss of drug product, adjuvants and/or other components of the product, due to third-party storage and distribution of such supplies;
- the FDA requiring alterations to any of our study designs, overall strategy or manufacturing plans;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, poor accrual, or high drop-out rates of patients in our clinical trials;
- clinical trial sites deviating from trial protocol or dropping out of a trial and our inability to add new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our product candidates during clinical trials;
- safety issues, including serious adverse events associated with our product candidates and patients' exposure to unacceptable health risks;
- receipt by a competitor of marketing approval for a product targeting an indication that one of our product candidates targets, such that we are not "first to market" with our product candidate;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or
- differing interpretations of data by the FDA or similar foreign regulatory agencies.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trial is being conducted, by the Data Safety Monitoring Board, or DSMB, if one is utilized for any such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including, among other things, failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We have not yet completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary expertise or capabilities, including adequate staffing, to successfully manage the execution and completion of any of our clinical trials, and ultimately obtain marketing approval for our product candidates in a timely manner, or at all.

If we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life-threatening diseases, in most cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival, or OS, or overall response rate, or ORR, the FDA may refuse to approve a BLA or NDA based on such intended pivotal trial. The FDA may require the completion of additional clinical trials as a condition for approving our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, which will have a negative impact on our ability to commence product sales and generate product revenues from any of our product candidates. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process and may negatively impact our ability to raise additional capital to support these increased costs. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our

product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early-stage, including investigator sponsored, clinical trials of product candidates may not be predictive of the results of subsequent later-stage, including corporate sponsored, clinical trials. Product candidates in later-stage clinical trials may fail to show the safety and efficacy results demonstrated in earlier studies despite having progressed through preclinical studies and earlier clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our clinical trial results may not be successful for these or other reasons.

This drug development risk is heightened by any changes in planned clinical trials compared to completed clinical trials. As product candidates are advanced through preclinical studies to early and later-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration and dosing, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives. For example, the results of our planned clinical trials may be adversely affected by the following anticipated changes:

- As we optimize and scale-up production of SL-401 and SL-701, there have been manufacturing, formulation, fill-finish and other process and analytical changes that are part of the optimization and scale-up necessary for producing drug substance and drug product of a quality, quantity and stability sufficient for later-stage clinical development and commercialization. Delays, including failures, in any of these steps may delay initiation and completion of clinical trials. We will also need to demonstrate comparability between newly manufactured drug substance and/or drug product relative to previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials including the need or choice to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

- We have changed the treatment regimen of SL-401 to a multi-cycle regimen, in which patients will receive more than one treatment cycle, rather than a single-cycle treatment as used in the completed clinical trial. Although we anticipate that patients receiving multiple cycles of SL-401 may derive greater clinical benefit than from a single cycle, there is a risk of toxicity or a lack of efficacy arising from multiple cycles.

- We plan to treat patients with certain indications that have not yet been treated with SL-401. These may include certain rare malignancies such as mastocytosis, hypereosinophilic syndrome, myelofibrosis, chronic myelomonocytic leukemia, hairy cell leukemia, and others, as well as multiple myeloma, or MM, and early stages of acute myeloid leukemia, or AML. In these instances, we may choose to treat patients at several different doses and multi-cycle dosing regimens to determine the optimal doses and regimens for both near-term and long-term safety and disease control in each indication.

- We may determine, based on safety and efficacy, that certain doses and regimens of SL-401 for particular indications are optimal for initial near-term therapy whereas the same, or other, doses and regimens are optimal for longer-term maintenance therapy.

- We plan to develop SL-701 as an injection administered under the skin, or subcutaneously, in our trials. The 701-Ped-G Study and 701-Adult-LGG Study used this method of delivery. The 701-Adult-RHGG Study used a different method of delivery, in which dendritic cells, which are a type of immune cell, were removed from the patient, exposed to immunogenic peptides, and then re-injected into or near a lymph node of the patient (intra/peri-nodally). Thus, our plan continues the subcutaneous injection method used in two of the previous studies and represents a change from one of the previous studies.

- We are manufacturing and formulating SL-701 as a mixture of IL-13Rα2 mutant peptide, EphA2 peptide, a new survivin mutant peptide, and a tetanus toxoid peptide. An earlier version of this immunotherapy, which included IL-13Rα2 mutant and EphA2 peptides, was mixed with additional peptides, including a different survivin peptide in the 701-Ped-G Study. We have created what we believe is an enhanced version of this immunotherapy which we call SL-701. SL-701 includes a new potentially more immunogenic mutant form of survivin which is different from the survivin peptide used in the earlier version of this immunotherapy.

- We changed the immunostimulants used with the administration of SL-701 from poly-ICLC, which was used in the earlier version, to granulocyte-macrophage-colony-stimulating factor, or GM-CSF, and imiquimod which we believe are commercially viable and state-of-the-art immunostimulants that represent a potential enhancement.

- In some of our future trials, we may combine SL-401 or SL-701 with other therapies such as chemotherapy, radiation, targeted therapy, or anti-angiogenic therapy. We have not yet clinically tested these combinations. While there do not appear to be overlapping toxicities with these combinations, there is always the risk of unforeseen toxicities. Accordingly, we plan to conduct early analyses of safety in such trials and make any appropriate adjustments, if necessary.

Any of the aforementioned, or other, changes could make the timing, including initiation, patient accrual, or results of our planned clinical trials or other future clinical trials, less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

If we experience delays in the enrollment of patients in our 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 our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. SL-401 and SL-701 are being developed in hematologic and brain cancers, respectively, both of which are orphan indications (i.e., rare diseases). SL-401 is being developed initially in BPDCN and other rare diseases, including certain myeloproliferative disorders, as well as AML, and SL-701 is being developed in adult and pediatric brain cancer. Some of these represent orphan indications for which there are very limited independently reported data on annual incidences. If the incidences of these diseases are very low, including lower than our estimates or estimates of our third-party contractors, this could significantly delay patient enrollment in any one or more of our planned clinical trials.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our common stock to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

The regulatory review and approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We may be required to undertake and complete certain additional preclinical studies to generate data related to toxicity and other data required to support the submission of a BLA or an NDA to the FDA. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Furthermore, approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- 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 or the adequacy of our right of reference to it may not be sufficient to support the submission of a BLA or 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;
- the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics we develop; 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.

This lengthy and costly review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market SL-401, SL-701, or any of our other product candidates that we may advance into and through clinical trials, which would significantly harm our business.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, we may not be able to ultimately achieve the price we intend to charge for our product candidates. Moreover, in many foreign countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our approach to the discovery and development of product candidates that target CSCs is unproven, and we do not know whether we will be able to develop any products of commercial value.

Research on CSCs is an emerging field and, consequently, there is ongoing debate regarding the importance of CSCs as an underlying cause of tumor initiation, propagation, recurrence, resistance, and metastasis. In addition, there is some debate in the scientific community regarding the defining characteristics of these cells.

Although there is general consensus that some cancer cells have tumor-initiating capacity, there also is some debate in the scientific community regarding the defining characteristics and the origin of these cells. Some believe that normal adult stem cells transform into CSCs. Others believe that non-CSC cancer cells can transform into CSCs and, therefore, a definitive CSC cannot be readily isolated or targeted. In addition, some believe that targeting CSCs should be sufficient for a positive clinical outcome, while others believe that, at times or always, targeting CSCs should be coupled with targeting tumor bulk for a positive clinical outcome.

We believe that SL-401 and SL-701 target both tumor bulk and CSCs. However, it is conceivable that SL-401, SL-701 and any other product candidates that we develop may not effectively target tumor bulk or CSCs or, even if they do, they may not have a beneficial clinical outcome. In addition, it is conceivable that our platform technology may ultimately fail to identify any commercially viable drugs to treat human patients with cancer.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives may be impaired.

Although we expect to focus a substantial amount of our efforts on the continued clinical testing and potential approval of SL-401 and SL-701, another key element of our strategy is to identify and test additional compounds that target CSCs in a variety of different types of cancer, including SL-501 and SL-101. A portion of the research that we are conducting involves new and unproven drug discovery methods, including our proprietary StemScreen® platform technology, as well as the testing of new compounds and potential new uses of existing compounds. The drug discovery that we are conducting using our StemScreen® platform technology may not be successful in identifying compounds that are useful in treating humans with cancer. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are

ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by regulatory authorities, patients, the medical community or third-party payors.

If we are unable to identify suitable compounds for preclinical and clinical development, we may not be able to obtain sufficient product revenues in future periods, which could result in significant harm to our financial position and adversely impact our stock price.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing FDA regulatory requirements, which require significant resources. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our potential strategic partners receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves any of our product candidates, the manufacturing processes, testing, packaging, labeling, storage, distribution, field alert or biological product deviation reporting, adverse event reporting, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with cGMP for commercial manufacturing and compliance with cGMP and good clinical practices, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, fines or the imposition of other civil penalties or criminal penalties.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Risks Related to Our Financial Position and Capital Requirements

We have incurred net operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability, which would depress the market price of our common stock, and could cause you to lose all or a part of your investment.

We have incurred net losses from operations from our inception through June 30, 2014 of approximately $58.5 million. We do not know whether or when we will become profitable. To date, we have not commercialized any products or generated any revenues from product sales. Our losses have resulted principally from costs incurred in development and discovery activities. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our discovery, research, development and potential commercialization activities. We believe that our existing cash and cash equivalents will be sufficient to fund our operations and our capital expenditures for at least the next two years. If our cash is insufficient to meet future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all. In addition, if we do not continue to meet our diligence obligations under our license agreements for our product candidates that we have in-licensed, including SL-401 and SL-701, we will lose our rights to develop and commercialize those product candidates.

If we do not successfully develop and obtain regulatory approval for our existing and future product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and even if we do generate product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock also could cause you to lose all or a part of your investment.

We will require additional financing to achieve our goals, and a failure to obtain this capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, most of our resources have been dedicated to the discovery, acquisition and preclinical and clinical development of our product candidates. We have expended and believe that we will continue to expend substantial resources for the development of our lead product candidates, SL-401 and SL-701, as well as our preclinical product candidates and drug discovery and acquisition efforts. These expenditures will include costs associated with general administration, facilities, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials, obtaining regulatory approvals, commercializing any products approved for sale, and costs associated with operating as a public company.

We have no significant current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we obtain approval from the FDA or other regulatory authorities, and we successfully commercialize one or more of our compounds. As the outcome of our planned and anticipated clinical trials is highly uncertain, our estimates of clinical trial costs necessary to successfully complete the development and commercialization of our product candidates may differ significantly from our actual costs. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the ability of our product candidates to progress through clinical development successfully;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost associated with securing and establishing commercialization and manufacturing capabilities for our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the economic and other terms of such agreements;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials (including patient accrual) or other research and development activities for one or more of our product candidates; or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

We will need to raise additional funds to complete our clinical trials and achieve positive cash flow.

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

We will likely seek to raise additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships 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 will be diluted, and the terms may include liquidation or other preferences that adversely affect stockholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing 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 product candidates that we would otherwise prefer to develop and market ourselves.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by an economic downturn, a volatile business environment or an unpredictable and unstable market. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to secure, more costly, and/or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon our business and clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. There is a possibility that our stock price may decline, due in part to the volatility of the stock market and the general economic downturn.

Risks Related to Our Business and Industry

We are a clinical-stage company with no approved products, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- execute product candidate development activities;
- obtain required regulatory approvals for the development and commercialization of our product candidates;

- maintain, leverage and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for our products;
- develop and maintain GMP compliant manufacturing and distribution capabilities sufficient to support the intended scope of our pre-clinical and clinical development plans and the potential commercial demand for our product(s);
- develop and maintain any strategic relationships we elect to enter into;
- satisfy our obligations under our in-license agreements; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals, manufacturing and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

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

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of product candidates. Our competitors may succeed in developing competing products before we do for the same indications we are pursuing, obtaining regulatory approval for products or gaining acceptance for the same markets that we are targeting. If we are not "first to market" with one of our product candidates, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and successfully market that product candidate as a second competitor.

We expect any product candidate that we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. For example, there are a number of biopharmaceutical companies focused on developing therapeutics that target CSCs, including Verastem, Inc., OncoMed Pharmaceuticals, Inc., Dainippon Sumitomo Pharmaceuticals, Bionomics Limited and Stem CentRx, Inc. There are also several biopharmaceutical companies that do not appear to be primarily focused on CSCs, but may be developing at least one CSC-directed compound. These companies include Astellas Pharma US, Inc., Boehringer Ingelheim GmbH, Geron Corp., GlaxoSmithKline plc, Macrogenics Inc., Micromet, Inc. (an Amgen, Inc. Company), Pfizer Inc., Roche Holding AG, Sanofi U.S. LLC, and others. Additionally, there are a number of companies working to develop new treatments for hematologic cancers, which may compete with SL-401, including Ambit Biosciences Corporation, Celator Pharmaceuticals, Inc., Celgene Corporation, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Genzyme Corporation (now a Sanofi company), Janssen Pharmaceutical Companies of Johnson and Johnson, and Sunesis Pharmaceuticals, Inc., among others. There are also a number of drugs used for the treatment of brain cancer that may compete with SL-701, including, Avastin® (Roche Holding AG), Gliadel® (Eisai Co. Ltd.), and Temodar® (Merck & Co., Inc.). There are a number of companies working to develop brain cancer therapeutics with programs in clinical testing, including Celldex Therapeutics, Inc., ImmunoCellular Therapeutics, Ltd., Northwest Biotherapeutics, Inc., Agenus, Inc., Merck & Co. Inc., Novartis AG, Roche Holding AG and others.

Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. We may not be able to compete successfully unless we successfully:

- design and develop products that are superior to other products in the market;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals; and
- collaborate with others in the design, development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management as well as other employees, consultants and scientific and medical collaborators. As of August 11, 2014, we had 20 full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. Although none of these individuals has informed us to date that he or she intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms.

In addition, 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 employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements, our business may experience serious adverse consequences.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to 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, 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, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, 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 or regulations. 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, including the imposition of significant fines or other sanctions.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, manufacturers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. The hiring, training and integration of new employees may be more difficult, costly and/or time-consuming for us because we have fewer resources than a larger organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we maintain liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, 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 and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by healthcare providers, health plans and healthcare clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- analogous state laws and regulations, such as state anti-kickback and false claims 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, and 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; and

- analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do 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 regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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 have a material adverse effect on the success of 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although 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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

Risks Related to Commercialization of Our Product Candidates

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing our product candidates.

We currently have a relatively small number of employees and do not have a sales or marketing infrastructure, and we, including our executive officers, do not have any significant sales, marketing or distribution experience. We will be opportunistic in seeking to either build our own commercial infrastructure to commercialize SL-401, SL-701 and any future product candidates if and when they are approved, or enter into licensing or collaboration agreements to assist in the future development and commercialization of such product candidates.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that SL-401 or SL-701 will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- our inability to build our own commercial infrastructure to manufacture, market and sell our product candidates; and
- our inability to build and staff, or enter a partnership to support, a commercial distribution capability.

Where and when appropriate, we may elect to utilize contract sales forces or strategic partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, including SL-401 and SL-701, among physicians and other healthcare providers, patients, third-party payors and, in the cancer market, acceptance by the major operators of cancer clinics.

Even if SL-401, SL-701 or any other product candidate that we may develop or acquire in the future obtains regulatory approval, the product may not gain market acceptance among physicians, third-party payors, patients and the medical community. For example, current cancer treatments such as chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. The degree of market acceptance of any products for which we receive approval for commercial sale depends on a number of factors, including:

- the efficacy and safety of our products, as demonstrated in clinical trials, and the degree to which our products represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which our products are approved;
- acceptance by physicians, major operators of cancer clinics and patients of our products as a safe and effective treatment;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- the continued projected growth of oncology drug markets;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our approved drugs fail to achieve market acceptance, we would not be able to generate significant revenue.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed 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 drug 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 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. 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.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from 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, decide which medications they will cover and how much they will pay for them. A primary trend in the U.S. 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 products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for 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 not be made permanent. 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 follow Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment 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.

Healthcare policy changes may have a material adverse effect on us.

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. Although the Supreme Court has upheld the ACA in the main challenge to the constitutionality of the statute and the 2012 elections maintained divided government at the federal level, Congressional efforts to repeal the ACA continue. In addition, there may be Congressional efforts to expand the Medicaid drug rebate program to the Medicare Part D program (or to provide authority for the government to negotiate drug prices under the Medicare Part D program). This adds to the uncertainty of the legislative changes enacted as part of the ACA, and we cannot predict the impact that the ACA or any other legislative or regulatory proposals will have on our business. Regardless of whether or not the ACA is repealed, we expect both government and private health plans to continue to require healthcare providers, including healthcare providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

Our therapeutic product candidates for which we intend to seek approval as biological products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable." The FDA defines an interchangeable biosimilar as a product that, in terms of safety or diminished efficacy, presents no greater risk when switching between the biosimilar and its reference product than the risk of using the reference product alone. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates, such as SL-401 or SL-701, were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama or that may be proposed by his successors, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar route and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

Risks Related to Our Dependence on Third Parties

Third parties have conducted all clinical trials of our product candidates so far, and our ability to influence the design and conduct of such trials was limited. Our current and future corporate-sponsored trials will entail additional expenses and require us to rely on additional third parties. Any failure by a third-party to meet its obligations with respect to the clinical and regulatory development of our product candidates may delay or impair our ability to obtain regulatory approval for our products.

Until April of 2014 we did not sponsor any investigational new drugs, or INDs, or any clinical trials relating to SL-401 or SL-701. Instead, faculty members at academic institutions conducted and sponsored all INDs and clinical trials relating to our drug candidates. Because the completed trials relating to our drug candidates were investigator-sponsored, we did not control the design or conduct of the previous trials, and it is possible that the FDA will not view these previous trials as providing adequate support for future clinical trials or regulatory filings, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the previous trials or safety concerns or other trial results.

In April 2014 we opened a corporate-sponsored IND with the FDA and opened a corporate-sponsored study with SL-701, and in July 2014 we opened a corporate-sponsored IND with the FDA and opened a corporate-sponsored clinical study with SL-401. We have relied on contractual arrangements with academic institutions and investigators that provide us certain information rights with respect to the completed investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the completed trials. If these obligations are breached by the investigators or institutions, or if the data prove to be inadequate then our ability to conduct our planned corporate-sponsored clinical trials may be adversely affected. Additionally, the FDA may disagree with the adequacy of our interpretation of preclinical, manufacturing, or clinical data from these clinical trials. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing, or clinical data relating to our planned trials and/or may not accept such additional data as adequate for our regulatory filings.

We rely on, and expect to continue to rely on, third-parties to monitor, support, conduct and/or oversee clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms to monitor, support, conduct and/or oversee these clinical trials, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

To date, we have relied on academic institutions, CROs, hospitals, clinics and other third-party collaborators who are outside our control to monitor, support, conduct and/or oversee preclinical and clinical studies of our product candidates. As a result, we had less control over the timing and cost of these studies and the ability to recruit trial subjects than if we had conducted these trials wholly by ourselves. As we execute our corporate-sponsored trials of SL-401 and SL-701, we will continue to engage additional third parties. Because we may lack sufficient internal staff to monitor such third parties and to interact with the FDA, we may be required to build out our internal staff and/or engage consultants for such purposes. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or

otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by contract or in accordance with regulatory requirements. If these third parties fail to meet expected deadlines, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended, delayed or terminated, and as a result we may not be able to commercialize our product candidates.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

We may seek to enter into strategic partnerships in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our products in territories outside the United States. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If we ultimately determine that entering into strategic partnerships is in our best interest but either fail to enter into, are delayed in entering into or fail to maintain such strategic partnerships:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates;
- the competitiveness of any product candidate that is commercialized could be reduced; and
- with respect to our platform technology, StemScreen®, we may not realize its potential as a means of identifying and validating new cancer therapies.

We intend to rely on third-party manufacturers to produce our clinical and preclinical product candidate supplies and we intend to rely on third-party manufacturers to produce commercial supplies of any approved product candidates. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to initiate or complete our clinical trials, commercialize our product candidates or continue to sell any products we commercialize.

We do not currently own or operate any manufacturing facilities, and we lack sufficient internal staff to produce clinical and preclinical product candidate supplies ourselves. As a result, we work with third-party contract manufacturers to produce sufficient quantities of SL-401 and SL-701 for clinical trials, preclinical testing and commercialization. If we are unable to arrange for or maintain such third-party manufacturing sources, or fail to do so on commercially reasonable terms or on a timely basis, we may not be able to successfully produce, develop, and market SL-401 or SL-701 or may be delayed in doing so.

We also expect to rely upon third parties to produce drug product required for the clinical trials and commercialization of our other product candidates, including SL-101 and SL-501. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms or on a timely basis, we may not be able to complete development of such other product candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third-party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third-party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third-party, based on its own business priorities, at a time that is costly or damaging to us. We will be dependent on

the ability of these third-party manufacturers to produce adequate supplies of drug product to support our clinical development programs and future commercialization of our product candidates. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our third-party manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we use to manufacture our drugs. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate or the material components thereof for a clinical trial, including an ongoing clinical trial, due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We are working with our contract manufacturers to optimize the manufacturing processes for SL-401 and SL-701 drug substance and drug product so that these product candidates may be routinely produced in adequate quantities of adequate quality, and at an acceptable cost, to support our planned clinical trials and ultimate commercialization. Our manufacturers may not be able to adequately demonstrate that an optimized product candidate is comparable to a previously manufactured product candidate which could cause significant delays and increased costs to our programs. In addition, our manufacturers may not be able to control batch to batch variability below an acceptable threshold, increasing the risk of batch failures, which could cause significant delays and increased costs to our programs. Our manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our drugs, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, assuming that our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing, third parties with whom we currently work may need to increase their scale of production and/or we will need to secure additional suppliers.

We rely on a single third-party to manufacture and supply our drug substance and a single third-party to manufacture and supply our drug product for each of our product candidates. Any problems experienced by our third-party manufacturers or their vendors could result in a delay or interruption in the supply of our product candidate to us until the third-party manufacturer or its vendor cures the problem or until we locate and qualify an alternative source of manufacturing and supply.

The manufacturers of our product candidates require specialized equipment and utilize complicated production processes that would be difficult, time consuming and costly to duplicate. For each of our product candidates we currently rely on a third-party manufacturers to purchase from their third-party vendors the materials necessary to produce our product candidates and manufacture our product candidates for our clinical studies. Any prolonged disruption in our third-party manufacturers vendor's ability to supply materials for our manufacturing could have a significant negative impact on our ability to manufacture products on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs and timelines and any commercialization costs. In addition, our third-party manufacturers may experience problems not related to their vendors that could also have a significant negative impact on our ability to manufacture products on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs and timelines and any commercialization costs. We may face losses related to the supply of drug substances, drug product, adjuvants and other components of the product due to third-party distribution and storage of such product. We may suffer losses as a result of business interruptions that exceed coverage under our manufacturer's insurance policies. Events beyond our control, such as natural disasters, fire, sabotage or business accidents could have a significant negative impact on our operations by disrupting our product candidate development and commercialization efforts until our third-party manufacturer can repair its facility or we can put in place alternate third-party contract manufacturers to assume this manufacturing role, which we may not be able to do on reasonable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that they can successfully transfer our manufacturing processes to produce product of equivalent quality and quantity. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to develop product candidates or produce approved products in a timely manner. Any delay or interruption in our clinical studies or in the validation and commercialization of our product candidates could negatively affect our business**.**

To the extent we elect to enter into licensing or collaboration agreements to partner our product candidates, our dependence on such relationships may adversely affect our business.

Our global commercialization strategy for certain of our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these product candidates. 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. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

Risks Related to Our Intellectual Property Rights

We could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary product candidates and technology.

Our patents and patent applications may not be sufficient to protect our products and product candidates from commercial competition. For example, we cannot obtain a composition of matter patent for SL-401 due to earlier published prior art. We have however obtained U.S. patents for certain methods of using SL-401 to treat AML and MDS. In addition, we have filed additional U.S. and foreign patent applications for the method of using SL-401 to treat AML, MDS, BPDCN, and other diseases although there can be no assurances that such patents will issue. Failure to obtain patents directed to all approved uses of SL-401 would enable a competitor to market SL-401 for such unpatented indication(s), which could lead to price erosion for sales of SL-401 for our patented indications through off-label use. Although we have licensed an issued U.S. patent directed to the composition of matter for the mutant immunogenic IL-13Rα2 peptide for use in SL-701, we do not have any foreign composition of matter patent protection. We do not expect that we will be able to obtain such protection outside the U.S. in the future although we do have foreign pending patent applications that seek to cover certain uses of this peptide. While we have a non-exclusive license to issued U.S. patents directed to methods of use for the EphA2 peptide used in SL-701, we do not have any composition of matter patent protection although we do have foreign pending patent applications that seek to cover certain uses of this peptide. While we have filed a PCT pending patent applications directed to methods of use of a new survivin mutant peptide for use in SL-701, we do not have any composition of matter patent protection. While we have patent applications pending in the United States and Canada directed to our StemScreen® technology, we currently have no issued patents covering StemScreen®.

Although we have various patent applications pending in the United States and/or abroad that we anticipate may result in additional protection for both SL-401, SL-701 and StemScreen®, there can be no assurance that any of these applications will result in an issued

patent, or that if they issue, they will provide meaningful protection for SL-401, SL-701 or StemScreen®. Our inability to obtain adequate patent protection for our product candidates or platform technology could adversely affect our business.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court.

If we were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of patentable subject matter, novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or certain aspects of our platform technology, StemScreen®. Such a loss of patent protection could have a material adverse impact on our business.

Claims that StemScreen®, our product candidates or the sale or use of our products infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our product candidates, the use of our product candidates, or our potential platform technology, StemScreen®, do not infringe third-party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future. Our failure to successfully defend against any claims that our product candidates or platform technology infringe the rights of third parties could also adversely affect our business. For example, we are aware of a third-party European patent directed to one of the peptides used in SL-701. We may need to seek a license with respect to one or more of these third-party patents in order to commercialize our products. No assurance can be given that any such licenses will be available, or that they will be available on commercially acceptable terms. Failure to obtain any required licenses could restrict our ability to commercialize our products in certain territories or subject us to patent infringement litigation, which could result in us having to cease commercialization of our products and subject us to money damages in such territories.

It is also possible that we failed to identify relevant patents or applications. Patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

In order to avoid or settle potential claims with respect to any patent rights of third parties, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or any future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing one or more of our product candidates, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. Patent litigation could also expose us to significant monetary damages. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early-stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other Company business.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

If third parties successfully assert intellectual property rights against us, we might be barred from using certain aspects of our platform technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner, in order to continue our research and development programs or to market our product(s). It is possible that the necessary

license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize certain products, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, platform technology, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

SL-401, SL-701, some of our other product candidates and our platform technology are protected by intellectual property licensed from academic institutions. If the licensors terminate the licenses or fail to prosecute patent applications or maintain or enforce the underlying patents, our competitive position, market share, and business prospects will be harmed.

We are a party to several license agreements relating to certain patents and/or patent applications owned by other institutions, upon which certain aspects of our business depend. In particular, we hold an exclusive license from Scott and White Memorial Hospital, or Scott and White, for SL-401 and three licenses, including an exclusive license and two non-exclusive licenses, from the University of Pittsburgh relating to SL-701. Our license agreement with Scott and White survives, unless earlier terminated, until the later of the expiration of the last to expire licensed patent or the date on which we owe no further payments to Scott and White. Our exclusive and our non-exclusive patent license agreements with the University of Pittsburgh survive, unless earlier terminated, until the expiration of the last to expire licensed patent, and our non-exclusive license with the University of Pittsburgh to use and reference certain clinical trial data and information survives for a term of twenty years unless earlier terminated. We also hold licenses from academic institutions relating to intellectual property underlying our SL-501 and SL-101 product candidates and our StemScreen platform technology. We expect to enter into additional license agreements as part of the development of our business. Our current or future licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In addition, in spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore seek to terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. Our licensors may also seek to terminate the license agreements if we fail to satisfy our diligence obligations and/or meet specified milestones or upon insolvency. From time to time, we have had to request extensions of our development obligations contained in some of our license agreements, and we may need to seek further extensions in the future. Although we have obtained such extensions in the past, there can be no assurance that our licensors will continue to extend the development timelines or other milestones contained in our license agreements. If these in licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, we could lose our rights to develop and commercialize the product candidates governed by the licenses and competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

We could be unsuccessful in obtaining patent protection on one or more components of our platform technology.

We believe that an important factor in our competitive position relative to other companies in the field of targeted oncology therapeutics is our proprietary innovative platform technology, StemScreen®. We believe that this platform is useful for identifying new potential product candidates. We have pending U.S. and Canadian patent applications for StemScreen®, however, there is no guarantee that any of such pending patent applications will result in issued patents, and, even if patents eventually issue, there is no certainty that the issued claims will have adequate scope to preserve our competitive position. In addition, by practicing our technology in jurisdictions where we do not have patent protection, third parties could substantially weaken our competitive position in oncology research and development.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

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 in the field of oncology. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining our Company. We take steps to protect our proprietary information, and our confidentiality agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. 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, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. 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.

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 our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or any future strategic partners 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 by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or where the applicable laws provide a safe harbor exemption from infringement liability for certain research purposes, 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.
- The patents of others may have an adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharma industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharma patents is costly, time-consuming and inherently uncertain. In addition, Congress has passed patent reform legislation which provides new limitations on attaining, maintaining and enforcing intellectual property. Further, the 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 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 the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile and our stockholders could incur substantial losses.

The trading price of our common stock may be highly volatile, and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in January 2013, the price of our common stock has ranged from $10.00 per share to $47.25 per share. 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 from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our dependence on third parties, including CROs and CMOs, clinical trial sponsors and clinical investigators;
- our ability to commercialize our product candidates, if approved;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- regulatory or legal developments in the United States and other countries;
- our ability to maintain the license agreements for SL-401, SL-701 and other in-licensed product candidates;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- 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;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;

- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and

- the other factors described in this "Risk Factors" section.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could 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 we have and intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, 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 if investors will find our common stock less attractive because we have and may continue to 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 more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Our executive officers, directors and principal stockholders maintain the ability to exert substantial influence over all matters submitted to stockholders for approval.

Our executive officers, directors and principal stockholders beneficially own shares representing approximately 51.0% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert substantial influence over 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, would exert substantial influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our Company on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, 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 corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which they 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. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;

- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from the board;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- limit who may call special stockholder meetings and the matters transacted at such meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

As a public company, we incur and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting and other requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes Oxley Act of 2002, or the Sarbanes Oxley Act, and the Dodd Frank Wall Street Reform and Protection Act, as well as rules subsequently adopted by the SEC and the NASDAQ Stock Market, or NASDAQ. These rules and regulations require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition and establish and maintain effective disclosure and financial controls and corporate governance practices. These rules and regulations are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. Our management and other personnel devote a substantial amount of time to these compliance initiatives.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

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, and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

Table of Contents

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index are included with this report.

3.1	Restated Certificate of Incorporation of Stemline Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 6, 2013 (File No.001-35619) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Stemline Therapeutics, Inc., filed as Exhibit 3.2 to Form 8-K filed on February 6, 2013 (File No. 001-35619) and incorporated herein by reference.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Comprehensive Loss, (iv) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.

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.

Date: August 14, 2014

STEMLINE THERAPEUTICS, INC.

By: /s/ Ivan Bergstein, M.D.
Ivan Bergstein, M.D.
Chairman, President and Chief Executive Officer (Principal Executive Officer)

Date: August 14, 2014

By: /s/ David G. Gionco
David G. Gionco
Vice President of Finance and Chief Accounting Officer (Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Document
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2014.
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Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ivan Bergstein, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Stemline Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2014

/s/ Ivan Bergstein, M.D.
Ivan Bergstein, M.D.
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David G. Gionco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Stemline Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2014

/s/ David G. Gionco
David G. Gionco
Chief Accounting Officer
Principal Financial and Accounting Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
STEMLINE THERAPEUTICS, INC.
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 Stemline Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Ivan Bergstein, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: August 14, 2014

/s/ Ivan Bergstein, M.D.
Ivan Bergstein, M.D.
Chief Executive Officer
Principal Executive Officer

Exhibit 32.2

STATEMENT OF CHIEF ACCOUNTING OFFICER OF
STEMLINE THERAPEUTICS, INC.
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 Stemline Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, David G. Gionco, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: August 14, 2014

/s/ David G. Gionco
David G. Gionco
Chief Accounting Officer
Principal Financial and Accounting Officer