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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, 2013

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) 502-2310
(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 12,539,031 shares of the registrant's common stock, $0.0001 par value, outstanding as of August 01, 2013.

STEMLINE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2013

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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," "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 drugs targeting cancer stem cells, 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 products, 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;
- our ability to obtain and maintain regulatory approval of our product candidates, 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;
- the successful development of our sales and marketing capabilities;
- the performance of third-party manufacturers; 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. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

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.

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Balance Sheets

(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 92,685,912	$ 2,025,338
Prepaid expenses and other current assets	1,162,179	299,089
Total current assets	93,848,091	2,324,427
Deferred financing fees	—	2,705,184
Total assets	$ 93,848,091	$ 5,029,611
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,172,723	$ 5,500,735
Total current liabilities	4,172,723	5,500,735
Convertible notes	—	2,006,881
Put option liability	—	30,415
Total liabilities	4,172,723	7,538,031
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2012 and June 30, 2013	—	—
Common stock $0.0001 par value, 33,750,000 shares authorized at June 30, 2013 and 22,500,000 shares authorized at December 31, 2012, 12,539,031 shares issued and outstanding at June 30, 2013 and 3,476,501 shares issued and outstanding at December 31, 2012	1,254	347
Additional paid-in capital	107,799,653	4,660,488
Accumulated deficit during the development stage	(18,125,539)	(7,169,255)
Total stockholders' equity/(deficit)	89,675,368	(2,508,420)
Total liabilities and stockholders' equity/(deficit)	$ 93,848,091	$ 5,029,611

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period From August 8, 2003 (Inception) to
	2013	2012	2013	2012	June 30, 2013
Operating expenses:					
Research and development	$ 4,084,521	$ 848,504	$ 7,246,247	$ 1,613,340	$ 18,691,915
General and administrative	1,071,426	983,045	3,238,893	1,372,152	12,723,689
Total operating expenses	5,155,947	1,831,549	10,485,140	2,985,492	31,415,604
Loss from operations	(5,155,947)	(1,831,549)	(10,485,140)	(2,985,492)	(31,415,604)
Other income	—	11,890	30,649	12,460	966,167
Other expense	—	—	—	(35)	(9,705)
Interest expense	(297,935)	(28,744)	(505,037)	(50,038)	(801,987)
Interest income	3,244	3,564	3,244	7,882	963,827
Net loss from operations	(5,450,638)	(1,844,839)	(10,956,284)	(3,015,223)	(30,297,302)
Less accretion of preferred stock dividends	—	—	—	—	(2,591,165)
Add discount on redemption of preferred stock	—	—	—	—	12,171,765
Net loss attributable to common stockholders	$ (5,450,638)	$ (1,844,839)	$ (10,956,284)	$ (3,015,223)	$ (20,716,702)
Net loss attributable to common stockholders per common share:					
Basic and Diluted	$ (0.55)	$ (0.54)	$ (1.37)	$ (0.88)	
Weighted-average shares outstanding:					
Basic and Diluted	9,837,062	3,441,995	8,014,529	3,441,995	

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,		Period From August 8, 2003 (Inception) to June 30, 2013
	2013	2012	
Cash flows from operating activities			
Net loss	$ (10,956,284)	$ (3,015,223)	$ (30,297,302)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,861,999	132,027	5,061,666
Non-cash interest expense	82,389	50,038	379,339
Mark to market of put option liability	(30,415)	(12,460)	(111,420)
Beneficial conversion of convertible notes	422,648	—	422,648
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(863,090)	212,285	(1,162,179)
Accounts payable and accrued expenses	1,377,172	917,115	4,172,723
Net cash used in operating activities	(7,105,581)	(1,716,218)	(21,534,525)
Cash flows from investing activities			
Purchase of marketable securities	—	—	(20,545,087)
Redemption of marketable securities	—	—	20,545,087
Net cash from investing activities	—	—	—
Cash flows from financing activities			
Proceeds from issuance of preferred stock, net	—	—	12,500,000
Redemption of preferred stock	—	—	(750,000)
Proceeds from issuance of common stock, net	97,708,506	—	101,550,788
Proceeds from exercise of stock options	57,649	—	57,649
Proceeds from issuance of convertible notes	—	322,000	862,000
Net cash provided by financing activities	97,766,155	322,000	114,220,437
Net increase (decrease) in cash and cash equivalents	90,660,574	(1,394,218)	92,685,912
Cash and cash equivalents at beginning of period	2,025,338	5,829,886	—
Cash and cash equivalents at end of period	$ 92,685,912	$ 4,435,668	$ 92,685,912
Supplemental disclosure of non-cash transactions			
Discount on redemption of preferred stock	—	—	$ 12,921,765
Issuance of common stock on redemption of preferred stock	—	—	$ 1,200,000
Accretion of preferred stock dividend	—	—	$ 2,591,165

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.

(A Development Stage Company)

Notes to Unaudited Financial Statements

June 30, 2013

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, expanding and strengthening its intellectual property portfolio, developing its proprietary drug discovery platform, identifying and acquiring additional product and technology rights and raising capital. Accordingly, the Company is considered to be in the development stage as defined in Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 915, *Development Stage Entities*. The Company was incorporated in Delaware on August 8, 2003 (Inception) 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 consolidated 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, 2013 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, 2012 ("2012 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 several years.

Initial Public Offering

On January 31, 2013 the Company completed its initial public offering (the"IPO"), selling 3,317,644 shares at an offering price of $10.00 per share. On January 29, 2013, the underwriters exercised in full their over-allotment option to purchase an additional 497,647 shares at an offering price of $10.00 per share. Aggregate gross proceeds from the IPO, including the exercise of the over-allotment option, were $38.2 million and net proceeds received after underwriting fees and offering expenses were approximately $32.3 million. Additionally, upon the closing of the IPO, certain transactions were triggered based on a successful completion of an IPO. Convertible debt of $1.4 million principal, plus accrued interest thereon, was converted into 166,769 shares of common stock. The Company recorded approximately $1.5 million of compensation expense related to certain bonuses and salary increases payable upon continued employment and the occurrence of a specified financing, including the consummation of an initial public offering. Finally, the Company recorded one-time compensation expense of approximately $1.4 million for certain options and restricted stock that fully vested upon the closing of the IPO.

Secondary Public Offering

On May 16, 2013 the Company completed a follow-on public offering (the "Secondary Offering"), selling 4,137,931 shares at an offering price of $14.50 per share. On May 22, 2013, the underwriters exercised in full their over-allotment option to purchase an additional 620,689 shares at an offering price of $14.50 per share. Aggregate gross proceeds from the Secondary, including the exercise of the over-allotment option, were $69.0 million and net proceeds received after underwriting fees and offering expenses were approximately $64.5 million.

Recently Adopted Accounting Policy

In May 2011, the Financial Accounting Standards Board issued guidance that changed the requirement for presenting "Comprehensive Income" in the financial statements. The update requires an entity to present the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The Company adopted this pronouncement and elected to present a separate statement of comprehensive income. The Company did not incur any components of comprehensive income for the periods presented and therefore did not include a statement of comprehensive income in the financial statements.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in more detail in the notes to the financial statements as set forth in the 2012 Form 10-K. However, the Company believes that the following accounting policies are the most critical to aid in fully understanding and evaluating its financial condition and results of operations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents. The Company invests its excess cash principally in a 100% U.S. Treasury Money Market Fund and the remaining balances in a major U.S. bank, and its deposits, at times, exceed federally insured limits. The Company has not experienced any losses from credit risks.

Stock-Based Compensation

The Company follows the provisions of the ASC Topic 718, *Compensation — Stock Compensation* which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and non-employee directors, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is generally recognized as an expense over the requisite service period.

The Company elected to recognize compensation cost using the straight-line attribution method for all service-based stock options. For performance-based stock options share based compensation expense is recorded using the accelerated attribution method.

For stock options granted as consideration for services rendered by non-employees, the Company recognizes expense in accordance with the requirements of ASC Topic 505-50, *Equity Based Payments to Non-Employees*. Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the vesting period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the stock options are fully vested.

Prior to becoming a public company, the board of directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of its common stock.

Due to the lack of trading history, 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.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations as follows:

	Three months Ended June 30,		Six months Ended June 30,	
	2013	2012	2013	2012
Research and development	$ 422,719	$ 67,017	$ 1,787,127	$ 91,251
General and administrative	154,099	31,726	1,074,872	40,776
Total	$ 576,818	$ 98,743	$ 2,861,999	$ 132,027

The Company had 34,507 shares of restricted common stock granted to employees at December 31, 2012 and 266,121shares of restricted common stock granted to employees at June 30, 2013. Of these shares, there were 34,507 and 248,869 unvested shares of restricted common stock at December 31, 2012 and June 30, 2013, respectively.

3. Net (Loss) Income Per Common Share

Basic and diluted net (loss) income per common share is determined by dividing net (loss) income applicable to common stockholders by the weighted average common shares outstanding during the period. For the periods where there is a net loss attributable to common stockholders, the convertible long term debt, unvested restricted shares and common stock options have been excluded from the calculation of diluted loss (income) per common stockholder because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted loss per share would be the same.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Basic and diluted net (loss) per common share calculation:				
Net loss	$ (5,450,638)	$ (1,844,839)	$ (10,956,284)	$ (3,015,223)
Basic and diluted weighted-average common shares	9,837,062	3,441,995	8,014,529	3,441,995
Basic and diluted net (loss) per share	$ (0.55)	$ (0.54)	$ (1.37)	$ (0.88)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding for the periods presented, as they would be anti-dilutive:

	Six Months Ended June 30	
	2013	2012
Restricted stock	248,869	34,507
Warrants	99,529	—
Convertible Notes	—	233,967
Options outstanding	1,879,573	1,819,839
Total	2,227,971	2,088,313

4. Fair Value Measurements

FASB Accounting Standards Codification (ASC) 820-10 “Fair Value Measurements and Disclosures” (ASC 820-10) provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Quoted prices in active markets for identical assets or liabilities. The Company’s Level 1 assets and liabilities consist of money market investments.

Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the put option liability associated with the issuance of the Company's 2.45% Convertible Notes. The fair value of the put option liability was determined utilizing a probability weighted discounted financial model based on management's assessment of the likelihood of achievement of certain outcomes.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at June 30, 2013 and December 31, 2012 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2013
Assets:				
Cash and cash equivalents	$ 92,685,912	$ —	$ —	$ 92,685,912
Total assets at fair value	$ 92,685,912	$ —	$ —	$ 92,685,912
Liabilities:				
Put Option	$ —	$ —	$ —	$ —
Total liabilities at fair value	$ —	$ —	$ —	$ —

Assets and Liabilities	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2012
Assets:				
Cash and cash equivalents	$ 2,025,338	$ —	$ —	$ 2,025,338
Total assets at fair value	$ 2,025,338	$ —	$ —	$ 2,025,338
Liabilities:				
Put Option	$ —	$ —	$ (30,415)	$ (30,415)
Total liabilities at fair value	$ —	$ —	$ (30,415)	$ (30,415)

The Company measures the put option liability at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the put option liability uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the put option liability related to updated assumptions and estimates are recognized within the statements of operations.

The put option liability may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of outcomes used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

Level 3 Disclosures

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs:

	Fair Value as of December 31, 2012	Valuation Technique	Unobservable Input	Range (Weighted Average)
Put option liability	$ 30,415	Probability-adjusted discounted cash flow	Probabilities of success	25% — 45% (35)%
			Periods in which outcomes are expected to be achieved	2013
			Discount rate	12%

The changes in fair value of the Company's Level 3 put option liability during the six months ended June 30, 2013 were as follows:

	Level 3
Balance at December 31, 2012	$ 30,415
Fair value adjustment to put option liability included in other income	(30,415)
Balance as of June 30, 2013	$ —

For the six months ended June 30, 2013, the changes in the fair value of the put option liability resulted from the expiration of the put option in conjunction with the conversion of half of the principal of the 2.45% convertible note, along with accrued interest, into common stock as a result of the IPO. The balance of the note will be due upon its maturity in February 2014. No other changes in valuation techniques or inputs occurred during the six months ended June 30, 2013. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the six months ended June 30, 2013.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	June 30, 2013	December 31, 2012
Accrued research and development costs	$ 2,896,668	$ 972,218
Accrued compensation	424,533	100,000
Accrued professional fees	548,258	4,024,234
Other liabilities	303,264	404,283
Total	$ 4,172,723	$ 5,500,735

6. Convertible Notes

On March 16, 2010, in connection with the redemption of the Series A preferred stock, the Company issued a Senior Convertible Note ("the 2.45% Convertible Note") in the amount of $1.25 million. The 2.45% Convertible Note was initially recorded at fair value of $0.90 million. The 2.45% Convertible Note and the related interest expense are due on March 16, 2015. Interest is being charged at a rate of 2.45% per annum.

Upon the occurrence of a qualified financing event as defined in the agreement, the 2.45% Convertible Note and any accrued interest are mandatorily convertible into shares of the same securities issued in the qualified financing at the same price per share used in the qualified financing. In addition, upon the occurrence of a non-qualified financing event, as defined in the agreement, the 2.45% Convertible Note and any accrued interest are convertible at the option of the holder into cash or shares (the "Put Option") of the same securities issued in the non-qualified financing event at the same price per share used in the non-qualified financing event, or the holder may elect to continue to retain the note.

The Put Option was recorded at approximately $111,000, its fair value on the date of issuance and is marked to fair value at each reporting period.

On July 26, 2012, the Company and NB Athyrium LLC, the holder of the 2.45% Convertible Notes, entered into an amendment to the 2.45% Convertible Notes pursuant to which NB Athyrium agreed to accelerate repayment of $625,000 in principal amount, plus accrued interest thereon, of such note in cash, at the time of the initial public offering, and convert the remaining $625,000 in principal amount, plus accrued interest thereon, into shares of our common stock at the initial public offering price. On November 14, 2012, the Company and NB Athyrium LLC, entered into an additional amendment to the 2.45% Convertible Notes pursuant to which NB Athyrium agreed to cancel the acceleration and defer the repayment of $625,000 in principal amount, plus accrued interest thereon, of such note in cash until February 28, 2014

As a result of the successful completion of the IPO in January 2013, $625,000 in principal amount, plus accrued interest thereon, of the 2.45% Convertible Note converted into 66,913 shares of our common stock at the initial public offering price of $10.00 per share. In April 2013, the Company and NB Athyrium LLC, the holder of the 2.45% Convertible Notes, entered into an amendment to the 2.45% Convertible Notes pursuant to which NB Athyrium agreed to convert the remaining $625,000 in principal amount, plus accrued interest thereon, into 67,198 shares of our common stock at the initial public offering price of $10.00 per share. As of June 30, 2013, all of the convertible notes obligations had been satisfied.

In January 2012, the Company issued $0.9 million of convertible notes (the "1.27% Convertible Notes") at face value for cash. As a result of the successful completion of the IPO in January 2013, the 1.27% Convertible Notes and related accrued interest were converted into 99,856 shares of our common stock at a conversion price equal to 87.5% of the initial public offering of $10.00 per share. A beneficial conversion charge of $125,000, the difference between the conversion price and the fair value of the new shares multiplied by the number of shares, was recorded to earnings with a corresponding credit to additional paid-in capital.

During the three months ended June 30, 2013 and 2012, the Company recorded interest expense of approximately $0, and $17,720, respectively, related to the amortization of the debt discount. During the six months ended June 30, 2013 and 2012, the Company recorded interest expense of approximately$76,355 and $36,071, respectively, related to the amortization of the debt discount.

7. Stock Option Plan

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 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 34,507 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, consultants and advisors to the Company in the form of options to purchase common stock in 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.

Subsequent to the closing of the IPO, certain options and restricted stock began to vest to directors, consultants and key employees. The Company recorded approximately $1.4 million of stock-based compensation expense associated with 573,424 options with a weighted average exercise price of $2.38 and 8,625 shares of restricted stock that fully vested upon consummation of an IPO. In addition, 281,895 options commenced vesting based upon the consummation of the IPO and the Company will record $1.8 million on the vesting of these options over their expected lives.

The following is a summary of stock option activity under the 2012 and 2004 Plans through June 30, 2013:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2012	**1,819,839**	**$ 2.76**		
Options granted	141,500	18.96		
Options exercised	(23,038)	2.50		
Options forfeited	(58,728)	3.24		
Outstanding at June 30, 2013	**1,879,573**	**$ 3.97**	**6.24**	**$ 37,426,040**
Options exercisable at June 30, 2013	**1,322,795**	**$ 2.96**	**5.16**	**$ 27,616,536**

The following is a summary of restricted stock activity under the 2012 and 2004 Plans through June 30, 2013:

	Restricted Stock	Aggregate Intrinsic Value
Outstanding at December 31, 2012	**34,507**	
Shares granted	231,614	
Shares forfeited	—	
Outstanding at June 30, 2013	**266,121**	**$ 6,344,325**
Vested shares at June 30, 2013	**17,252**	**$ 411,288**

In March 2013, the Company granted various consultants and advisors options to purchase an aggregate of 61,500 shares of common stock. The options were granted at an exercise price of $11.27 per share, the fair market value of the Company's common stock on the date of grant as determined by the closing price on the date of grant. The options were immediately vested.

In April 2013, the Company granted an employee an aggregate of 149,614 shares of restricted common stock. The restricted stock was granted with a fair market value of the Company's common stock on the date of grant of $13.11 per share as determined by the closing price on the date of grant. Of the 149,614 shares of restricted stock, 112,212 shares vest ratably over 5 years and 37,402 shares vest based on meeting certain market capitalization thresholds.

In June 2013, the Company granted employees and directors an aggregate of 82,000 shares of restricted common stock and options to purchase an aggregate of 80,000 shares of common stock. The restricted stock was granted with a fair market value of the Company's common stock on the date of grant of $24.88 per share as determined by the closing price on the date of grant. The restricted stock vests over 4 years and the Company will record a charge to operating expenses of approximately $2.0 million over the vesting period. The options were granted at an exercise price of $24.88 per share, the fair market value of the Company's common stock on the date of grant as determined by the closing price on the date of grant.

Total unrecognized compensation expense is $7.4 million, which will be recognized over a weighted average period of 1.5 years.

8. Common Stock

As of June 30, 2013, the Company was authorized to issue 33,750,000 shares of 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.

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. As of June 30, 2013, the Company reserved 1,352,379 shares of common stock for future issuance related to the exercise of the Company's outstanding stock options and restricted stock.

Representative's Warrants

On October 1, 2012, the Company agreed to issue to the representative of the underwriters in the IPO warrants to purchase up to 99,529 shares of the Company's common stock in the event of a successful public offering. The warrants are exercisable for cash or on a cashless basis at a price per share equal to $15.00. Based on a successful public offering in January these warrants were issued and accounted for at their cost of issuance. The Company has determined, based upon a Black-Scholes model, that the fair value of the warrants on the date of IPO was $413,146. The Company has accounted for the fair value of the warrants as a cost of issuance of common stock from the IPO resulting in a charge directly to stockholder's equity.

9. Commitments and Contingencies

License Agreements

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 $29.0 million upon achieving certain milestones, such as the initiation of clinical trials or the granting of patents. From inception through June 30, 2013, the Company has paid or accrued $1.7 million in payments resulting from the execution of certain agreements, patent approvals, the initiation of sponsor 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.

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 and payable one year after the IPO.

Contractual Agreement

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. Services under this contract are expected to be performed during 2013 and 2014.

10. Related Party Transactions

Assignment Agreement with the Company's Chief Executive Officer

On June 15, 2012, the Company entered into an assignment agreement with Dr. Bergstein. Pursuant to the assignment agreement, as amended on November 7, 2012, effective as of January 28, 2013. Dr. Bergstein assigned to the Company all of his right, title and interest in certain proprietary patent rights and related technology in exchange for $2.0 million in cash payable if the Company achieved a market capitalization of at least $200 million for a prescribed period, which it did in June 2013. The Company accounted for this transaction as an asset acquisition because it did not acquire any processes or activities in addition to the assigned rights and technology. None of the assigned patent rights and related technology has alternative future uses, nor have they reached a stage of technological feasibility. The Company recorded the entire $2.0 million purchase price to research and development expense. The assignment agreement does not contain any vesting or rescission/refund provisions.

11. Subsequent Events

The Company evaluated events that occurred subsequent to June 30, 2013 through the date the financial statements were available to be issued.

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.

Lock-up Agreements

On July 29, 2013, 1,267,428 shares previously restricted under lock-up agreements were released from their respective restrictions. As a result, we have 1,868,978 shares outstanding which remain restricted as a result of securities laws and lock-up agreements.

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, 2012, and Management's Discussion and Analysis of Financial Condition and Results of Operation included in our 2012 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 CSCs and tumor bulk, and is currently being developed for orphan indications: blastic plasmacytoid dendritic cell neoplasm, or BPDCN, a rare hematologic cancer, third-line acute myeloid leukemia, or AML, as well as additional hematologic cancers. SL-701 is a subcutaneously-delivered therapeutic cancer vaccine comprised of synthetic peptides, and is currently being developed for advanced pediatric and adult brain cancer. In completed Phase 1/2 clinical trials, both SL-401 and SL-701 have demonstrated single agent activity, including durable complete responses, or CRs, and improved overall survival, or OS, in heavily pretreated patients compared with that achieved in the past with traditional therapies. We plan to complete a pivotal Phase 2b single-arm trial of SL-401 in patients with BPDCN, with overall response rate as the primary endpoint. We also plan to complete a pivotal randomized Phase 2b clinical trial of SL-401 in patients with third-line AML with OS as the primary endpoint. In addition, we plan to advance SL-401 into Phase 2 trials of additional hematologic cancers including multiple myeloma, myelodysplastic syndrome, or MDS, and several rare hematologic malignancies. We plan to advance SL-701 into a Phase 2 clinical trial of pediatric patients with brainstem and non-brainstem glioma. In addition, we plan to advance SL-701 into a Phase 2 clinical trial of adult patients with second-line glioblastoma multiforme, or GBM. We have an extensive intellectual property portfolio, a preclinical pipeline, and an innovative discovery platform which we believe establishes us as a leader in the CSC field.

We are a development stage company. 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 not generated any revenues and, to date, have funded our operations primarily through public and private sales of common stock and private sales of convertible preferred stock and issuances of convertible debt to our investors. From inception through June 30, 2013, 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, 2013, our net losses from operations have been $30.3 million. Our net loss from operations was $11.0 million for the six months ended June 30, 2013 and $3.0 million for the six months ended June 30, 2012. 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. Further, we expect to incur additional costs associated with operating as a public company. 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.

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Financial Operations Overview

Revenue

We have not generated any revenue to date. 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. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we may recognize upon the sale of our products, to the extent that any products are successfully commercialized, and the amount and timing of fees, reimbursements, milestone and other payments received under any future licensing or collaboration arrangements. 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 months ended June 30, 2013 and 2012:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Clinical (SL-401 and SL-701)	$ 4,068,271	$ 838,054	$ 7,203,681	$ 1,574,641
Preclinical	16,250	10,450	42,566	38,699
Total	$ 4,084,521	$ 848,504	$ 7,246,247	$ 1,613,340

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

- clinical trial 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, ("CRO"), contract manufacturing organizations ("CMO"), 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. 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. As of 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, operations, finance, investor relations, and business development functions. Other general and administrative expenses include facility costs, insurance expenses and professional fees for legal, 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 and cash equivalents. Given the current interest rate environment and that our primary investment is in a 100% U.S. Treasury money market fund, 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 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. Further, in conjunction with the conversion of our convertible notes there was a beneficial conversion charge which was recorded as interest expense.

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 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 the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our significant accounting policies are described in more detail in the notes to our financial statements are set forth in our 2012 Form 10-K. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Stock-Based Compensation

We measure the fair value of stock options and other stock-based compensation issued to employees and directors on the date of grant. The fair value of equity instruments issued to non-employees is remeasured for only what vested at each reporting date. For service type awards, compensation expense is typically recognized over the requisite service period, which is the vesting period. For awards that vest or begin vesting upon achievement of a performance condition, the compensation expense is recognized beginning in the period when management has determined it is probable the performance condition will be achieved. For equity awards that have previously been revalued, any incremental increase in the fair value has been recorded as compensation expense on the date of the modification (for vested awards) or over the remaining service (vesting) period (for unvested awards). The incremental compensation cost is the excess of the fair-value-based measure of the modified award on the date of modification over the fair-value- based measure of the original award immediately before the modification. Stock-based compensation expense includes stock options and restricted stock granted to employees and non-employees and has been reported in our statements of operations as follows:

	Three months Ended June 30,		Six months Ended June 30,	
	2013	2012	2013	2012
Research and development	$ 422,719	$ 67,017	$ 1,787,127	$ 91,251
General and administrative	154,099	31,726	1,074,872	40,776
Total	$ 576,818	$ 98,743	$ 2,861,999	$ 132,027

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. As a recently public company, we do not have sufficient history to estimate the volatility of our common stock price or the expected life of our options. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies, or guideline peer group, for which the historical information is available. We will continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future. We determine the average expected life of stock options according to the "simplified method" as described in Staff Accounting Bulletin 110, which is the mid-point between the vesting date and the end of the contractual term. We determine the risk-free interest rate by reference to implied yields available from five-year and seven-year U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We estimate forfeitures based on our historical analysis of actual stock option forfeitures. The assumptions used in the Black-Scholes option-pricing model for the year ended December 31, 2012 are set forth in our 2012 Form 10-K.

The following is a summary of stock option activity under the 2012 Plan through June 30, 2013:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2012	**1,819,839**	**$ 2.76**		
Options granted	141,500	18.96		
Options exercised	(23,038)	2.50		
Options forfeited	(58,728)	3.24		
Outstanding at June 30, 2013	**1,879,573**	**$ 3.97**	**6.24**	**$ 37,426,040**
Options exercisable at June 30, 2013	**1,322,795**	**$ 2.96**	**5.16**	**$ 27,616,536**

In March 2013, we granted various consultants and advisors options to purchase an aggregate of 61,500 shares of common stock. The options were granted at an exercise price of $11.27 per share, the fair market value of our common stock on the date of grant as determined by the closing price on the date of grant. The options were immediately vested.

In April 2013, the Company granted an employee an aggregate of 149,614 shares of restricted common stock. The restricted stock was granted with a fair market value of the Company's common stock on the date of grant of $13.11 per share as determined by the closing price on the date of grant. Of the 149,614 shares of restricted stock, 112,212 shares vest ratably over 5 years and 37,402 shares vest based on meeting certain market capitalization thresholds.

In June 2013, the Company granted employees and directors an aggregate of 82,000 shares of restricted common stock and options to purchase an aggregate of 80,000 shares of common stock. The restricted stock was granted with a fair market value of the Company's common stock on the date of grant of $24.88 per share as determined by the closing price on the date of grant. The restricted stock vests over 4 years and the Company will record a charge to operating expenses of approximately $2.0 million over the vesting period. The options were granted at an exercise price of $24.88 per share, the fair market value of the Company's common stock on the date of grant as determined by the closing price on the date of grant. The options vest over 3 years.

Total unrecognized compensation expense is $7.4 million, which will be recognized over a weighted average period of 1.5 years.

Results of Operations

Comparison of Three Months Ended June 30, 2013 and 2012

Research and development expense. Research and development expense was $4.1 million for the three months ended June 30, 2013, compared with $0.8 million for the three months ended June 30, 2012, an increase of $3.3 million. This increase was primarily attributable to costs associated with increasing drug development activity and includes $0.8 million of salary and related costs including stock-based compensation and $2.0 million for in-process research and development associated with an assignment agreement with our chief executive officer.

General and administrative expense. General and administrative expense was $1.1 million for the three months ended June 30, 2013, compared with $1.0 million for the three months ended June 30, 2012. This increase was primarily attributable to increasing costs to provide support for our growing corporate and clinical activities of $0.4 million of salary and related costs including stock-based compensation.

Interest expense. Interest expense was $297,935 for the three months ended June 30, 2013, compared with $28,744 for the three months ended June 30, 2012 resulting in a $269,191 increase which was principally due to the amortization of the debt discount of the 2.45% convertible notes and due to the charge to earnings for the beneficial conversion of the 2.45% convertible notes.

Interest income. Interest income was $3,244 for the three months ended June 30, 2013, compared with $3,564 for the three months ended June 30, 2012. The $320 decrease in interest income for 2013 as compared to 2012 reflected lower returns on cash balances in 2013.

Comparison of Six Months Ended June 30, 2013 and 2012

Research and development expense. Research and development expense was $7.2 million for the six months ended June 30, 2013, compared with $1.6 million for the six months ended June 30, 2012, an increase of $5.6 million. This increase was primarily attributable to salary costs associated with increasing drug development activity and one-time IPO bonuses and related costs including stock-based compensation, $3.4 million in aggregate, and $2.0 million for in-process research and development associated with an assignment agreement with our chief executive officer.

General and administrative expense. General and administrative expense was $3.2 million for the six months ended June 30, 2013, compared with $1.4 million for the six months ended June 30, 2012. This increase was primarily attributable to increasing salary costs to provide support for our growing corporate and clinical activities, one-time IPO bonuses and related costs including stock-based compensation.

Interest expense. Interest expense was $505,037 for the six months ended June 30, 2013, compared with $50,038 for the six months ended June 30, 2012 resulting in a $454,999 increase which was principally due to the amortization of the debt discount of the 2.45% convertible notes and due to the charge to earnings for the beneficial conversion of the 2.45% convertible notes.

Interest income. Interest income was $3,244 for the six months ended June 30, 2013, compared with $7,882 for the six months ended June 30, 2012. The $4,638 decrease in interest income for 2013 as compared to 2012 reflected lower returns on cash balances in 2013.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenues and, to date, have funded our operations primarily through public and private sales of common stock and private sales of convertible preferred stock and issuances of convertible debt to our investors. From inception through June 30, 2013, 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 may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate.

As of June 30, 2013, our cash and cash equivalents totaled $92.7 million. We primarily invest our cash and cash equivalents in 100% US Treasury money market funds with the balance in commercial operating accounts. We believe that our existing cash and cash equivalents will be sufficient to fund our operations and our capital expenditures for at least several 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,	
	2013	2012
	(unaudited)	(unaudited)
Net cash used in operating activities	$ (7,105,581)	$ (1,716,218)
Net cash provided by investing activities	—	—
Net cash (used in) provided by financing activities	97,766,155	322,000
Net increase (decrease) in cash and cash equivalents	$ 90,660,574	$ (1,394,218)

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for stock-based compensation expense, non-cash interest expense and charges associated with the mark to market of the put option liability and favorable changes in the components of working capital. The cash used for the six months ended June 30, 2012 and June 30, 2013 was impacted by an increase in research and development expenses as we increased our research and development headcount, from costs associated with the development of our lead compounds SL-401 and SL-701 and costs associated with our IPO.

Financing activities. The net cash provided by financing activities for the six months ended June 30, 2013 were the net proceeds from our initial public offering in January 2013 and secondary public offering in May 2013 and the cash provided for the six months ended June 30, 2012 were due to the issuance of $0.3 million of convertible notes.

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 the ongoing clinical trials, and initiate the planned clinical trials, of our lead product candidates, SL-401 and SL-701;
- 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, 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 and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least several 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 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 your rights as 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 2012 Form 10-K. We believe that there have been no significant changes in the information presented in the table therein with the exception that in February 2013, the Company entered into a bioprocessing services agreement related to production associated with our drug development activities for approximately $2.9 million if all services are performed under the vendor's contract, in April 2013, the long-term debt obligations were converted into shares of our common stock and in July 2013, the Company entered into a leasing agreement with respect to its corporate office for a monthly rent of $50,625 with a lease term of 36 months.

Off-Balance Sheet Arrangements

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support, or engages in leasing, hedging, or research and development services on our behalf.

Tax Loss Carryforwards

As of December 31, 2012, we had federal net operating loss carryforwards of $14.7 million, which are available to reduce future taxable income. We also had federal tax credits of $0.5 million, which may be used to offset future tax liabilities. The net operating loss and tax credit carryforwards will expire at various dates through 2032. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. 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 December 31, 2012, 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. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Recently Adopted Accounting Standards

We have not recently adopted any new accounting standards. There are no recently issued accounting standards that have a material impact on us.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to "opt 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 and cash equivalents of $92.7 million as of June 30, 2013 and $2.0 million as of December 31, 2012, consisting of cash and 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 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 CMOs. 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, 2013 and December 31, 2012, all of our liabilities were denominated in our functional currency.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

As of June 30, 2013, management carried out, under the supervision and with the participation of our Chief Executive Officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and principal financial officer concluded that, as of June 30, 2013, our disclosure controls and procedures were effective.

Changes to Internal Controls Over Financial Reporting

There has been no change in 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.

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 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 two lead 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 lead product candidates, SL-401 and SL-701, which are in clinical development. Our future success depends heavily on our ability to successfully develop, obtain regulatory approval for, and commercialize these product candidates, which may never occur. We currently generate no revenues, 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 previously submitted a biologics license application, or BLA, or a new drug application or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. 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, the European Union and potentially in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory 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, depending on the stage of development, can take a substantial time period to complete. Its outcome is inherently uncertain. In addition, failure can occur at any time during clinical development. 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 CMOs, CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CMOs, 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 or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site;
- our inability to manufacture, or obtain from third parties, adequate supply of drug substance or drug product sufficient to complete our preclinical studies and clinical trials;
- the FDA requiring alterations to any of our study designs, our preclinical strategy or our manufacturing plans;
- delays in patient enrollment, and variability in the number and types of patients available for clinical trials, 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
- varying interpretations of data by the FDA and 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, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including 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, unforeseen 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 previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate, including our planned clinical trials of SL-401 and SL-701, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

In the event 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 overall response rate, the FDA may refuse to approve a BLA or NDA based on such pivotal trial. The FDA may require 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, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. 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 clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, 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 will be manufacturing, formulation and other process and analytical changes that are part of the optimization and scale-up typically necessary for producing drug substance and drug product of a quality and quantity sufficient for later stage clinical development and commercialization. Delays 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 to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

- We plan to change the treatment regimen of SL-401 to a multi-cycle treatment regimen, in which the patient receives more than one treatment cycle, rather than a single-cycle treatment as used in the completed clinical trials. Although we anticipate that patients receiving multiple cycles of SL-401 will derive even greater clinical benefit than from a single cycle, there is always the risk of an unforeseen toxicity arising from multiple cycles.

- We plan to develop SL-701 as an injection delivered under the skin, or subcutaneously, in future trials. The 701 Ped-G 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, are removed from the patient, exposed to SL-701, and then re-injected into or near a lymph node of the patient (intra/peri-nodally). Thus, our plan continues the pediatric method and represents a change in the adult method.

- We plan to manufacture and formulate SL-701 as a mixture of IL-13Rα2, EphA2 and a helper peptide. In the 701 Ped-G and 701 Adult-RHGG Studies, SL-701 (which is comprised of IL-13Rα2 and EphA2) was mixed with additional peptides, including YKL-40 and GP-100 peptides in the adult study, and survivin peptide in the pediatric study. Given the clinical anti-tumor activity observed in both trials, we believe that the IL-13Rα2 and EphA2 peptides, the common feature of both trials, represent the active components. Thus, we believe that SL-701 need not be mixed with any additional peptides for clinical activity. Accordingly, while we will continue to evaluate the scientific merit of combining SL-701 with additional peptides, we plan to advance SL-701 into future trials without additional peptides.

- We plan to change the administration regimen of SL-701 to include a more commercially available and viable adjuvant than the adjuvant used in the completed clinical trials. An adjuvant is a substance administered to a patient to potentially help enhance the patient's immune response to a vaccine.

- In some of our future trials, we may combine SL-401 or SL-701 with other therapies such as chemotherapy or anti-angiogenic therapy. We have not yet tested these combinations. In our planned clinical trial of SL-701 in adult second-line GBM, we may administer SL-701 in combination with certain therapies which may include bevacizumab (Avastin®). We may administer SL-401 in combination with certain chemotherapies. While there does not appear to be overlapping toxicities with these combinations, there is always the risk of unforeseen toxicities.

Any of these changes could make the timing, including initiation, or the results of our planned clinical trials or other future clinical trials we may initiate 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). In particular, SL-401 is being developed initially in BPDCN and AML and SL-701 is being developed in pediatric and adult brain cancer, both of which represent ultra-orphan indications for which there are very limited independently reported data on annual incidences. If the incidences of these diseases are very low, this could significantly delay patient accrual to any one or more of our 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 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 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 approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market SL-401 and SL-701, 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 products. 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 existence and importance of CSCs as an underlying cause of tumor initiation, propagation, recurrence, 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 products 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 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 a substantial amount of our efforts will focus 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. 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 likely would 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 obligations and continued regulatory review, which may result in significant additional expense. 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, 2013 of $30.3 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 several 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.

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 may require substantial additional financing to achieve our goals, and a failure to obtain this necessary 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. In particular, we have expended and believe that we will continue to expend substantial resources for the development of clinical 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 and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale. Furthermore, we expect to incur additional costs associated with operating as a public company.

We have no 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, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

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 or 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 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 of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to obtain government funding;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

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 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 may need to raise additional funds to complete the clinical development of SL-401 and SL-701 in their entirety.

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 may seek 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.

As has been widely reported, global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, 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 any strategic relationships we elect to enter into; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals 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, Dainippon Sumitomo Pharma Co. Ltd., Geron Corp., GlaxoSmithKline plc, ImmunoCellular Therapeutics, Ltd, 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 AML, which may compete with SL-401, including Ambit Biosciences Corporation, Celator Pharmaceuticals, Inc., Celgene Corporation, Clavis Pharma ASA, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Genzyme Corporation (now a Sanofi company), CSL Limited 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., 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, particularly Ivan Bergstein, M.D., our Chairman, Chief Executive Officer and President, and Eric K. Rowinsky, M.D., our Executive Vice President, Chief Medical Officer and Head of Research and Development, as well as other employees, consultants and scientific and medical collaborators. As of June 30, 2013, we had ten full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. Although none of senior management has informed us to date that he 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 and insider trading, 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 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 may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental 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 future products if and when they are approved, or enter into licensing or collaboration agreements to assist in the future development and commercialization of such products.

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 persuade 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; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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, patients, healthcare 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, healthcare 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 pay for and establish reimbursement levels. 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 rely upon 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 SL-401 and SL-701 so far, and our ability to influence the design and conduct of such trials has been limited. Our plans to assume control over the future clinical and regulatory development of such product candidates 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.

To date, we have not sponsored any clinical trials relating to SL-401 or SL-701. Instead, faculty members at academic institutions have conducted and sponsored all clinical trials relating to SL-401 and SL-701, in each case under their own INDs. Because the completed SL-401 and SL-701 clinical trials 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, 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.

While we plan to assume control of the overall clinical and regulatory development of SL-401 and SL-701 going forward, we have so far been dependent on contractual arrangements with each investigator and their respective academic institutions, and will continue to be until we assume control. Such arrangements provide us certain information rights with respect to the completed 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 compared to the first-hand knowledge we might have gained had the completed trials been corporate-sponsored trials, then our ability to design and conduct our planned corporate-sponsored clinical trials may be adversely affected. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing, or clinical data generated by these prior investigator-sponsored trials, or 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 before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

We intend to assume control over the clinical and regulatory development of SL-401 by either exercising our right under our agreement with Scott and White Memorial Hospital to have Scott and White transfer to us the existing IND for SL-401 or by filing our own IND for SL-401. We expect to either transfer the IND or file our own IND in the next twelve months. We intend to assume control over the clinical development of SL-701 by filing a corporate-sponsored IND, for which we may exercise our rights of reference under our agreements with the University of Pittsburgh with respect to the existing INDs for SL-701.

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. Once we assume control of the further clinical and regulatory development of SL-401 and SL-701, we will likely need to engage additional third parties. Because we currently lack and may lack in the future sufficient internal staff to monitor such third parties and to interact with the FDA, we will also 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 in an effort to produce sufficient quantities of SL-401 and SL-701 on a timely basis for future clinical trials, preclinical testing and commercialization. If we are unable to maintain such a third-party manufacturing source, 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. 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 have limited staffing and rely on our 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 any 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 optimizing the manufacturing processes for SL-401 and SL-701 drug substance and drug product so that these product candidates may be 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. 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 will need to increase their scale of production or we will need to secure alternate suppliers.

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 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 United States 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 products 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 the method of using SL-401 to treat AML and MDS. In addition, we have filed U.S. and foreign patent applications for the method of using SL-401 to treat AML, MDS and BPDCN, although there can be no assurances that such patents will be issued. Failure to obtain patents directed to the use of SL-401 to treat certain indication(s) 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 an issued U.S. patent directed to the composition of matter for our mutant immunogenic IL-13Rα2 peptide used in SL-701, which has been altered to make it more stimulatory to the immune system and thus designed to increase a patient's immune response to 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 the use 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. We do not expect that we will be able to obtain such protection in the future.

Although we have various patent applications pending in the U.S. and abroad that we hope will result in additional protection for both SL-401 and SL-701, there can be no assurance that any of these applications will issue into a patent, or that if they issue, they will provide meaningful protection for SL-401 and SL-701. 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 products 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 products, 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 novelty, obviousness 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 products 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 products 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 products, the use of our products, or our 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. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, 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 products, 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. 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 products, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

SL-401 and SL-701 are protected by intellectual property exclusively licensed from academic institutions. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position and market share will be harmed.

We are a party to several license agreements under which certain aspects of our business depend on patents and/or patent applications owned by other institutions. 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, from the University of Pittsburgh for 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 to clinical trial data and information survives twenty years unless terminated earlier.

We are likely to enter into additional license agreements as part of the development of our business in the future. 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 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 terminate the license agreements if we fail to meet specified milestones. If these in-licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, 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®. This platform is useful for identifying new potential product candidates. We have pending applications for StemScreen®, however, there is no guarantee that any of such pending patent applications, in the United States or elsewhere, will result in issued patents, and, even if patents eventually issue, there is no certainty that the claims in the eventual patents will have adequate scope to preserve our competitive position. Third parties might invent alternative technologies that would substitute for our platform technology while being outside the scope of the patents covering our platform technology. By successfully designing around our patented technology 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 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 products.

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

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 stockholders beneficially own shares representing approximately 38% 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 stockholder 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.

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 will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be 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.

If our stock price is volatile, our stockholders could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock, if at all. The market price for our common stock may be influenced by many factors, including:

- our ability to commercialize our product candidates, if approved;
- 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;

- 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;
- our dependence on third parties, including CROs, CMOs, clinical trial sponsors and clinical investigators;
- regulatory or legal developments in the United States and other countries;
- 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 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.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have outstanding 12,539,031shares of common stock based on the number of shares outstanding as of June 30, 2013. Of such shares 3,136,406 shares were restricted as a result of securities laws and lock-up agreements. On July 29, 2013, 1,267,428 shares previously restricted under lock-up agreements were released from their respective restrictions. As a result, we have 1,868,978 shares outstanding which remain restricted as a result of securities laws and lock-up agreements as of August 1, 2013.

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.
3.3	Certificate of Amendment of Restated Certificate of Incorporation, dated June 19, 2013.
31.1	Certification of Chief 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, 2013.
31.2	Certification of Chief Financial 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, 2013.
32.1	Certification of Chief 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, 2013.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 14, 2013.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements.*

Exhibit Index

Exhibit Number	Description of Document
3.3	Certificate of Amendment of Restated Certificate of Incorporation, dated June 19, 2013.
31.1	Certification of Chief 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, 2013.
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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, 2013

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, 2013

By: /s/ Stephen P. Hall
Stephen P. Hall
Vice President of Finance and Chief Accounting Officer (Principal Financial and Accounting Officer)

Exhibit 3.3

CERTIFICATE OF AMENDMENT OF
RESTATED CERTIFICATE OF INCORPORATION OF
STEMLINE THERAPUETICS, INC.

June 19, 2013

Stemline Therapeutics, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the Delaware General Corporation Law (the "DGCL"), does hereby certify:

FIRST: That the Board of Directors of the Corporation (the "Board"), pursuant to a unanimous written consent of the Board dated April 15, 2013, duly adopted resolutions approving an amendment to the Restated Certificate of Incorporation and declared said amendment to be advisable. The proposed amendment is as follows:

RESOLVED, the Corporation's Restated Certificate of Incorporation be amended by deleting the first paragraph of the Article Fourth and by substituting in lieu thereof the following as the amended first paragraph:

"FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is 38,750,000 shares, consisting of (i) 33,750,000 shares of Common Stock, $0.0001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $0.0001 par value per share ("Preferred Stock")."

SECOND: That said amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed by a duly authorized officer as of the date first written above.

STEMLINE THERAPEUTICS, INC.

By: /s/ Ivan Bergstein
Name: Ivan Bergstein, M.D.
Title: Chairman, President and Chief Executive Officer

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)) 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;

   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, 2013

/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, Stephen P. Hall, 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)) 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;

   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, 2013

/s/ Stephen P. Hall
Stephen P. Hall
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, 2013 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, 2013

/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, 2013 as filed with the Securities and Exchange Commission (the "Report"), I, Stephen P. Hall, 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, 2013

/s/ Stephen P. Hall
Stephen P. Hall
Chief Accounting Officer
Principal Financial and Accounting Officer