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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 September 30, 2016

OR

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

For the transition period from to

Commission File Number 001-35619

STEMLINE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if smaller reporting company)	Smaller reporting company ☐

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

There were 19,158,732 shares of the registrant's common stock, $0.0001 par value, outstanding as of November 8, 2016.

STEMLINE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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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 drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

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

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

- the success and timing of our clinical trials, including safety and efficacy of our product candidates and patient accrual, and the accuracy of data generated from our trials;
- our ability to obtain and maintain marketing approval from regulatory agencies for our products;
- our ability to obtain and maintain adequate reimbursement for our products;
- our ability to obtain the desired labeling of our products under any regulatory approval;
- our plans to develop and commercialize our products;
- our ability to successfully file and obtain timely marketing approval for one or more Biologics License Applications, or BLA, or New Drug Applications, or NDA;
- the successful development and implementation of our sales and marketing campaigns;
- 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;
- our ability to successfully compete in the potential markets for our product candidates, if commercialized;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- 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;
- market conditions in the pharmaceutical and biotechnology sectors;
- our available cash and investments;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to maintain the license agreements for SL-401, SL-701, SL-801 and our other in-licensed product candidates;
- the success and timing of our preclinical studies including IND enabling studies;
- the ability of our product candidates to successfully perform in clinical trials;
- our ability to obtain and maintain approval of our product candidates for trial initiation;
- our ability to manufacture our products, gain access to products we plan to use in combination studies and the performance of third-party manufacturers;
- the performance of our clinical research organizations, clinical trial sponsors, and clinical trial investigators; and
- our ability to successfully implement our strategy.

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

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

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

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements.

STEMLINE THERAPEUTICS, INC.
Balance Sheets

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 9,127,991	$ 13,376,196
Short-term investments	41,375,137	32,663,245
Prepaid expenses and other current assets	523,612	651,889
Total current assets	51,026,740	46,691,330
Furniture and fixtures, net	23,482	95,661
Long-term investments	23,818,645	51,428,632
Other assets	212,305	—
Total assets	$ 75,081,172	$ 98,215,623
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,917,969	$ 8,632,873
Current portion of deferred grant revenue	1,197,600	822,604
Total current liabilities	9,115,569	9,455,477
Deferred grant revenue, net of current portion	—	616,949
Other liabilities	159,975	31,241
Total liabilities	9,275,544	10,103,667
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock $0.0001 par value, 33,750,000 shares authorized at September 30, 2016 and December 31, 2015, 19,151,652 shares issued and outstanding at September 30, 2016 and 18,235,020 shares issued and outstanding at December 31, 2015	1,916	1,825
Additional paid-in capital	191,584,735	185,703,423
Accumulated other comprehensive loss	(47,512)	(153,690)
Accumulated deficit	(125,733,511)	(97,439,602)
Total stockholders' equity	65,805,628	88,111,956
Total liabilities and stockholders' equity	$ 75,081,172	$ 98,215,623

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Grant revenue	$ 299,401	$ 205,651	$ 741,953	$ 448,509
Operating expenses:				
Research and development	7,176,960	7,340,859	20,585,659	21,575,743
General and administrative	3,187,869	2,234,991	8,914,630	6,197,694
Total operating expenses	10,364,829	9,575,850	29,500,289	27,773,437
Loss from operations	(10,065,428)	(9,370,199)	(28,758,336)	(27,324,928)
Other income	1,378	—	11,736	1,609
Interest income	132,006	137,123	417,113	259,064
Net loss before income taxes	(9,932,044)	(9,233,076)	(28,329,487)	(27,064,255)
Income tax benefit	8,822	—	35,578	—
Net loss	$ (9,923,222)	$ (9,233,076)	$ (28,293,909)	$ (27,064,255)
Net loss per common share:				
Basic and Diluted	$ (0.56)	$ (0.53)	$ (1.59)	$ (1.57)
Weighted-average shares outstanding:				
Basic and Diluted	17,831,022	17,515,895	17,777,675	17,196,840

See accompanying unaudited notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (9,923,222)	$ (9,233,076)	$ (28,293,909)	$ (27,064,255)
Other comprehensive gain (loss):				
Unrealized gain (loss) on investments, net of tax	(10,975)	21,554	117,914	34,224
Reclassification adjustment for gain on investments included in net loss	(1,378)	—	(11,736)	(1,609)
Other comprehensive gain (loss)	(12,353)	21,554	106,178	32,615
Comprehensive loss	$ (9,935,575)	$ (9,211,522)	$ (28,187,731)	$ (27,031,640)

See accompanying unaudited notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Capital				
Balance, December 31, 2015	18,235,020	$ 1,825	$ 185,703,423	$ (153,690)	$ (97,439,602)	$ 88,111,956
Restricted stock grants	906,476	91	(91)	—	—	—
Forfeiture of restricted stock grants	(35,002)	(4)	4	—	—	—
Stock-based compensation expense	—	—	5,666,813	—	—	5,666,813
Employee Stock Purchase Plan compensation expense	—	—	43,258	—	—	43,258
Issuance of common stock in connection with the ESPP	11,407	1	59,953	—	—	59,954
Issuance of common stock in connection with the exercise of stock options	33,751	3	111,375	—	—	111,378
Net loss	—	—	—	—	(28,293,909)	(28,293,909)
Other comprehensive income, net of tax	—	—	—	106,178	—	106,178
Balance, September 30, 2016	19,151,652	$ 1,916	$ 191,584,735	$ (47,512)	$ (125,733,511)	$ 65,805,628

See accompanying unaudited notes.

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (28,293,909)	$ (27,064,255)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	79,306	115,000
Stock-based compensation expense	5,710,071	4,484,815
Amortization of premium paid on marketable securities	167,540	157,665
Net gain on sale of marketable securities	(11,736)	(1,609)
Income tax benefit from other comprehensive income	(35,578)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	128,277	766,103
Other assets	(212,305)	—
Accounts payable and accrued expenses	(734,024)	2,319,249
Deferred grant revenue	(241,953)	214,601
Other liabilities	128,734	—
Net cash used in operating activities	(23,315,577)	(19,008,431)
Cash flows from investing activities		
Purchase of furniture and fixtures	(7,128)	—
Purchase of marketable securities	(22,194,580)	(88,084,690)
Proceeds from redemption of marketable securities	41,097,748	38,911,353
Net cash provided by (used) in investing activities	18,896,040	(49,173,337)
Cash flows from financing activities		
Proceeds from issuance of common stock, net	59,954	64,106,372
Proceeds from exercise of stock options	111,378	354,751
Net cash provided by financing activities	171,332	64,461,123
Net decrease in cash and cash equivalents	(4,248,205)	(3,720,645)
Cash and cash equivalents at beginning of period	13,376,196	25,007,217
Cash and cash equivalents at end of period	$ 9,127,991	$ 21,286,572

See accompanying unaudited notes.

STEMLINE THERAPEUTICS, INC.
Notes to Unaudited Financial Statements
September 30, 2016

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 oncology therapeutics. The Company's activities to date have primarily consisted of advancing its clinical stage programs, developing its preclinical stage assets, fortifying its intellectual property portfolio, identifying and acquiring additional product and technology rights, and raising capital. The Company was incorporated in Delaware on August 8, 2003 and has its principal office in New York, New York.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments (including normal recurring adjustments) considered necessary for fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. Operating results for the current interim period are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016 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, 2015 ("2015 Form 10-K"). The Company believes that its existing cash, cash equivalents, short-term investments and long-term investments will be sufficient to cover its cash flow requirements for at least the next two years.

Use of Estimates

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

Reclassifications

Certain reclassifications totaling $822,604 have been made to the financial statements for the period ended December 31, 2015 to conform to the current portion of deferred revenue presentation in the financial statements for the period ended September 30, 2016. These reclassifications to adjust accounts payable and accrued expense had no impact on previously reported net loss or stockholders' equity.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Financial Statements included in the 2015 Form 10-K. There have been no changes to those policies.

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Compensation—Stock Compensation (Topic 718): Improvements To Employee Share-Based Payment Accounting, which allows for the simplification of several aspects of the accounting for share-based payment transactions. The standard is effective for interim and annual periods beginning after December 15, 2016. The Company is currently evaluating the effect that the updated standard will have on its financial statements and related disclosures.

3. Liquidity and Capital Resources

As of September 30, 2016, the Company has approximately $74.3 million in cash, cash equivalents, short and long-term investment securities. The Company primarily invests in highly liquid cash equivalents, short-term investments and long-term investments in U.S. Treasury and Agency securities and related money market funds and FDIC-insured bank certificates of deposit, with the balance in commercial bank operating accounts.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following at September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Prepaid third-party vendor costs	$ 261,304	$ 195,305
Prepaid insurance	169,551	51,623
Deposits	—	106,243
Other Receivable	92,757	298,718
Total	$ 523,612	$ 651,889

5. Furniture and Fixtures

Furniture and fixtures consist of the following at September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Office furniture and fixtures	$ 486,586	$ 479,458
Less accumulated depreciation	(463,104)	(383,797)
Furniture and fixtures, net	$ 23,482	$ 95,661

Depreciation expense was $79,306 and $115,000 for the nine-month periods ended September 30, 2016 and 2015, respectively. Depreciation expense was $952 and $38,333 for the three-month periods ended September 30, 2016 and 2015, respectively.

6. Fair Value Measurements

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

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

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

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

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

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

There were no transfers between levels in the fair value hierarchy during any period presented herein. The Company's financial assets and liabilities measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015 consist of the following:

	September 30, 2016			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at September 30, 2016
Assets:				
Cash and cash equivalents	$ 9,127,991	$ —	$ —	$ 9,127,991
Short-term investments	21,123,088	20,252,049	—	41,375,137
Long-term investments	17,994,239	5,824,406	—	23,818,645
Total assets at fair value	$ 48,245,318	$ 26,076,455	$ —	$ 74,321,773

	December 31, 2015			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2015
Assets:				
Cash and cash equivalents	$ 13,376,196	$ —	$ —	$ 13,376,196
Short-term investments	16,515,871	16,147,374	—	32,663,245
Long-term investments	37,217,727	14,210,905	—	51,428,632
Total assets at fair value	$ 67,109,794	$ 30,358,279	$ —	$ 97,468,073

The following is a summary of cash equivalents and available-for-sale investments held by the Company at September 30, 2016 and December 31, 2015:

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash:				
Cash from operating accounts	$ 2,321,486	$ —	$ —	$ 2,321,486
Cash equivalents:				
Money market funds	$ 6,806,505	$ —	$ —	$ 6,806,505
Short-term investments:				
Fixed-income treasury portfolio:				
Fannie Mae	2,109,094	288	(454)	2,108,928
Federal farm credit bank	2,061,220	2,835	—	2,064,055
Federal home loan bank	10,230,949	6,328	(1,640)	10,235,637
Freddie Mac	6,711,326	3,142	—	6,714,468
Certificate of Deposits	20,248,529	3,520	—	20,252,049
Total Short-term investments	41,361,118	16,113	(2,094)	41,375,137
Long-term investments:				
Fixed-income treasury portfolio:				
Fannie Mae	5,866,250	912	(7,149)	5,860,013
Federal farm credit bank	2,306,338	—	(890)	2,305,448
Federal home loan bank	1,906,009	1,577	—	1,907,586
Freddie Mac	7,922,837	183	(1,828)	7,921,192

	September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Certificate of Deposits	5,824,044	362	—	5,824,406
Total Long-term investments	23,825,478	3,034	(9,867)	23,818,645
Total	$ 74,314,587	$ 19,147	$ (11,961)	$ 74,321,773

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash:				
Cash from operating accounts	$ 5,462,081	$ —	$ —	$ 5,462,081
Cash equivalents:				
Money market funds	$ 7,914,115	$ —	$ —	$ 7,914,115
Short-term investments:				
Fixed-income treasury portfolio:				
Fannie Mae	2,005,785	—	(2,942)	2,002,843
Federal farm credit bank	1,076,445	—	(1,856)	1,074,589
Federal home loan bank	12,445,530	61	(9,764)	12,435,827
Freddie Mac	1,005,272	—	(2,660)	1,002,612
Certificate of Deposits	16,150,513	295	(3,434)	16,147,374
Total Short-term investments	32,683,545	356	(20,656)	32,663,245
Long-term investments:				
Fixed-income treasury portfolio:				
Fannie Mae	4,366,424	—	(15,213)	4,351,211
Federal farm credit bank	6,290,607	—	(27,957)	6,262,650
Federal home loan bank	14,113,301	—	(44,803)	14,068,498
Freddie Mac	12,576,749	—	(41,382)	12,535,367
Certificate of Deposits	14,214,941	703	(4,738)	14,210,906
Total Long-term investments	51,562,022	703	(134,093)	51,428,632
Total	$ 97,621,763	$ 1,059	$ (154,749)	$ 97,468,073

At September 30, 2016 and December 31, 2015, the remaining contractual maturities of available-for-sale investments classified as current on the balance sheet were less than 12 months, and the remaining contractual maturities of available-for-sale investments classified as long-term were less than two years.

There were no available-for-sale securities in a continuous unrealized loss position for greater than twelve months at September 30, 2016 and December 31, 2015.

Fair Value of Financial Instruments

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

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following at September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Accrued research and development costs	$ 5,811,179	$ 5,303,990
Accrued compensation	1,509,203	2,727,965
Accrued professional fees	236,752	245,329
Other accrued liabilities	360,835	355,589
Total	$ 7,917,969	$ 8,632,873

8. Common Stock

In the first quarter of 2015, the Company completed an underwritten follow-on public offering, selling 3,800,000 shares at an offering price of $15.75 per share and the underwriters exercised in full their over-allotment option to purchase an additional 553,877 shares at an offering price of $15.75 per share (the "Secondary Offering"). Aggregate gross proceeds from the Secondary Offering were $68.6 million, and net proceeds received after underwriting fees and offering expenses were approximately $64.1 million.

As of September 30, 2016 and December 31, 2015, the Company was authorized to issue 33,750,000 shares of common stock.

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

In January 2013, the Company issued warrants to purchase up to 99,529 shares of the Company's common stock. The warrants became exercisable during January 2014. The warrants are exercisable for cash or on a cashless basis at a price per share equal to $15.00. The term of the warrants is five years and they expire on January 28, 2018.

9. Accumulated Other Comprehensive Gain (Loss)

The changes in accumulated balances for each component of other comprehensive gain (loss) are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Balance at beginning of period	$ (35,159)	$ 14,061	$ (153,690)	$ 3,000
Other comprehensive income (loss) before reclassification	(17,339)	21,554	172,612	34,224
Amounts reclassified from accumulated other comprehensive income (loss)*	(1,378)	—	(11,736)	(1,609)
Income tax provision	6,364	—	(54,698)	—
Total other comprehensive income	(12,353)	21,554	106,178	32,615
Balance at end of period	$ (47,512)	$ 35,615	$ (47,512)	$ 35,615

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

10. Net (Loss) Income Per Common Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Basic and diluted net loss per common share calculation:				
Net loss	$ (9,923,222)	$ (9,233,076)	$ (28,293,909)	$ (27,064,255)
Basic and diluted weighted-average common shares	17,831,022	17,515,895	17,777,675	17,196,840
Basic and diluted net loss per share	$ (0.56)	$ (0.53)	$ (1.59)	$ (1.57)

The difference between basic and diluted weighted-average common shares generally results from the assumption that dilutive stock options outstanding were exercised, dilutive restricted stock has vested, and outstanding warrants are issued. For the nine-month periods ended September 30, 2016 and 2015, the Company reported a loss from operations and therefore, all potentially dilutive stock options, restricted stock, and outstanding warrants as of such date were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive. The total shares of stock options, restricted stock, and outstanding warrants that could potentially dilute earnings per share in the future, but which were not included in the calculation of diluted net loss per share because their affect would have been anti-dilutive were as follows:

	Nine Months Ended September 30,	
	2016	2015
Restricted stock	1,304,974	449,068
Options outstanding	3,147,545	2,145,536
Warrants	99,529	99,529
Total	4,552,048	2,694,133

11. Grant Revenue

The Company has not generated any revenue from product sales and it has generated minimal revenues to date relating to $3.0 million in research grants received from the Leukemia and Lymphoma Society, or LLS. In the future, the Company may generate revenue from product sales. In October 2013, the Company entered into an agreement with LLS, which among other activities, sponsors research relating to hematologic cancers. LLS has agreed to provide funding to the Company of up to $3.5 million based on the achievement of certain milestones. The Company could receive an additional $0.5 million based on the completion of certain additional milestone events. The Company recognized approximately $0.7 million and $0.4 million of revenue related to this funding for the nine-month periods ended September 30, 2016 and September 30, 2015, respectively, which reflects nine months of revenue recognized on a straight line basis, based on the Company's best estimates of work performed and qualifying costs incurred. The Company recognized approximately $0.3 million and $0.2 million of revenue related to this funding for the three-month periods ended September 30, 2016 and September 30, 2015, respectively. This agreement terminates when there are no longer any payment obligations.

12. Income Taxes

For the three and nine months ended September 30, 2016 the Company recognized $8,822 and $35,578, respectively, of income tax benefit as a result of the application of intraperiod tax allocation provisions of ASC 740, under which the Company is required to consider all items (including items recorded in other comprehensive income) in determining the amount of tax benefit that should be allocated to net loss. The non-cash income tax benefit was offset in full by income tax expense recorded in other comprehensive income of $54,698 and a tax provision liability of $19,120.

The Company did not record any other income tax provisions or benefits relating to its net operating losses for the nine-month periods ended September 30, 2016 and 2015, respectively, due to the fact that the Company cannot benefit from its net operating losses or other deferred tax assets. The Company has never had the ability to carry back losses to previous years to recover taxes paid and future utilization of these losses is uncertain.

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

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

Valuation allowances reduce deferred tax assets to the amounts that are more likely than not to be realized. As of September 30, 2016, the Company has recorded additional deferred tax assets which are fully offset by a valuation allowance. Realization of the deferred tax assets is dependent on generating sufficient taxable income in the future. At present, the likelihood of the Company being able to fully utilize its deferred income tax benefits against future income is uncertain.

13. Stock-Based Compensation

The Company's 2016 Stock Equity Incentive Plan (the "2016 Plan") was adopted by the board of directors and approved by the stockholders in May 2016. The 2016 Plan authorizes the Company to grant up to 1,812,932 shares of common stock to eligible employees, directors, and non-employee consultants and advisors to the Company. Under the provisions of the 2016 Plan, no option will have a term in excess of 10 years.

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

As of September 30, 2016, there were 835,431 shares of common stock available for future grants under the 2016 Plan.

Total compensation cost that has been charged against operations related to the above plans was approximately $5.7 million and $4.5 million for the nine-month periods ended September 30, 2016 and 2015, respectively. The Company does not recognize a tax benefit with respect to an excess stock compensation deduction until the deduction actually reduces the Company's income tax liability. No income tax benefit was recognized in the statements of operations for share-based compensation arrangements for the nine-month periods ended September 30, 2016 and 2015.

The following table summarizes stock-based compensation related to the above plans by expense category for the three-month and nine-month periods ended September 30, 2016 and 2015, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 1,368,932	$ 1,047,970	$ 2,536,118	$ 2,717,766
General and administrative	1,348,946	703,943	3,130,695	1,767,049
Total	$ 2,717,878	$ 1,751,913	$ 5,666,813	$ 4,484,815

Stock Options

The Company grants stock options to employees, Directors and non-employee consultants, with exercise prices equal to the closing price of the underlying shares of the Company's common stock on the date that the options are granted. Options granted, generally, have a term of 10 years from the grant date. Options granted to employees generally vest over a four-year period and options granted to Directors vest in equal yearly installments over a three-year period from the date of grant. Options to Directors are granted on an annual basis and represent compensation for services performed by the board of directors. Compensation cost for stock options granted to employees and Directors are charged against operations using the straight-line attribution method between the grant date for the option and each vesting date. The Company has also granted market based awards to an employee and an non-employee consultant in which the compensation cost will be charged against operations using the accelerated attribution method regardless of whether or not market conditions are met. The Company estimates the fair value of stock options on the grant date by applying the Black-Scholes option pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost.

The weighted-average key assumptions used in determining the fair value of options granted for the three-month and nine-month periods ended September 30, 2016 and 2015, respectively are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Weighted-average volatility	73.82%	76.00%	73.52%	78.75%
Weighted-average risk-free interest rate	1.22%	1.76%	1.56%	1.84%
Weighted-average expected term in years	5.45	6.17	6.03	6.16
Dividend yield	0%	0%	0%	0%

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

For the nine-month periods ended September 30, 2016 and September 30, 2015, the Company issued 33,751 and 86,736 shares, respectively, of the Company's common stock upon the exercise of outstanding stock options and received proceeds of $111,378 and $354,751, respectively. As of September 30, 2016, there was approximately $7.2 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a remaining weighted-average period of approximately 2.21 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures.

The following table summarizes the activity related to the Company's stock options for the nine months ended September 30, 2016:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2015	2,121,726	$ 10.74		
Options granted	1,121,686	5.24		
Options exercised	(33,751)	3.30		
Options forfeited	(62,116)	18.34		
Outstanding at September 30, 2016	3,147,545	$ 8.71	7.25	$ 13,668,456
Options exercisable at September 30, 2016	1,319,888	$ 8.35	5.29	$ 6,835,927

The aggregate intrinsic value in the previous table reflects the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the quarter ended September 30, 2016 and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on September 30, 2016. The intrinsic value of the Company's stock options changes based on the closing price of the Company's common stock.

Restricted Stock

The Company grants restricted stock to its employees, Directors, and non-employee consultants. Restricted stock is recorded as deferred compensation and charged against earnings on a straight-line basis over the vesting period, which ranges from immediate to four years in duration. The Company has also granted market based awards to an employee in which the compensation cost will be charged against operations using the accelerated attribution method regardless of whether or not market conditions are met. Restricted stock may be granted to Directors and represents compensation for services performed on the Company's board of directors. Restricted stock awards to Directors vest in equal installments over a three-year period from the grant date. Compensation cost for restricted stock is based on the award's grant date fair value, which is the closing market price of the Company's common stock on the grant date, multiplied by the number of shares awarded.

The following table summarizes the activity related to the Company's restricted stock for the nine months ended September 30, 2016:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2015	553,045	$ 13.91
Shares granted	906,476	4.84
Shares vested	(119,545)	16.63
Shares forfeited	(35,002)	10.99
Outstanding at September 30, 2016	1,304,974	$ 7.44

For the nine-month period ended September 30, 2016, the Company granted 906,476 shares of restricted stock, at a weighted-average grant date fair value of $4.84 per share amounting to approximately $4.4 million in total aggregate fair value. As of September 30, 2016, 1,304,974 shares remained unvested and there was approximately $5.7 million of unrecognized compensation cost related to restricted stock which is expected to be recognized over a remaining weighted-average period of approximately 2.56 years. The total fair value of restricted stock vested during the nine-month periods ended September 30, 2016 and September 30, 2015 was approximately $2.0 million and $1.3 million, respectively.

Awards Granted to Non-Employee Consultants

The Company grants stock options, restricted stock, and unrestricted stock to non-employee consultants. The Company periodically re-measures the fair value of stock-based awards issued to non-employees and records expense over the requisite service period. Total compensation cost charged against operations related to stock-based awards granted to non-employee consultants was approximately $0.3 million for the nine-month periods ended September 30, 2016 and 2015, respectively.

Employee Stock Purchase Plan

In September 2015, the Company adopted its 2015 Employee Stock Purchase Plan (the "2015 ESPP"). The 2015 ESPP is qualified as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended (the "IRC"). Under the 2015 ESPP, the Company will grant rights to purchase shares of common stock under the 2015 ESPP ("Rights") at prices not less than 85% of the lesser of (i) the fair value of the shares on the date of grant of such Rights or (ii) the fair value of the shares on the date such Rights are exercised. Therefore, the 2015 ESPP is considered compensatory under FASB ASC 718 since, along with other factors, it includes a purchase discount of greater than 5%. For the nine months ended September 30, 2016, the Company recorded approximately $43,258 of compensation expense, related to participation in the 2015 ESPP.

14. Commitments and Contingencies

The Company has entered into research and development agreements with third-parties for the development of oncology products and technologies. According to these agreements, the Company typically funds the development of such assets and potentially makes milestone and royalty payments based on successful development and commercialization of these assets including their net sales in the future. The timing and the amount of milestone and royalty payments in the future are not certain.

Under the Company's license agreements, upon achieving certain milestones largely consisting of late stage clinical trial events and marketing approval and sales, the Company could be required to pay up to a total of $112.9 million in future periods. From inception through September 30, 2016, the Company has paid or accrued $4.6 million in payments resulting from such agreements. Royalty payments, largely single digit, are payable on commercial sales of certain products.

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

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

Contractual Agreements

In February 2013, the Company entered into a bioprocessing services agreement with a vendor for approximately $2.9 million if all services are performed under the contract. As of December 31, 2014, the contract services were performed on the initial work order and had been paid by the Company. During 2014 through 2016, the Company entered into new work order agreements with this vendor totaling approximately $6.1 million, with services to be rendered on these agreements through 2016. The Company has received and paid for services relating to these agreements in the amount of $5.1 million.

The Company has agreements with third party service providers in connection with its clinical programs. The Company's total expenditures in the future would be approximately $7.3 million if not cancelled upon reasonable notice to the service provider and assuming the successful advancement of its programs.

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 was 36 months.

In February 2016, 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 $69,750 and a 42-month term. The term of this lease agreement commenced on July 1, 2016 and is set to expire on December 31, 2019. The aggregate minimum lease commitment over the 42 month term of the lease is approximately $2.7 million. The Company has provided the landlord with a security deposit equal to three months' rent, totaling $209,250.

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

Remainder of 2016	$	209,250
2017		837,000
2018		837,000
2019		837,000
Total minimum payments	$	2,720,250

Rent expense charged to operations was $533,305 and $455,952 for the nine-month periods ended September 30, 2016 and 2015, respectively. Rent expense is included in general and administrative expenses in the Company's Statements of Operations.

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

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in our audited financial statements and notes thereto for the year ended December 31, 2015, and Management's Discussion and Analysis of Financial Condition and Results of Operation included in our 2015 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 oncology therapeutics. We are currently developing three clinical stage product candidates, SL-401, SL-701 and SL-801.

SL-401

Patients are currently enrolling in SL-401 clinical trials in multiple indications, including a Phase 2 potentially pivotal trial in patients with blastic plasmacytoid dendritic cell neoplasm, or BPDCN. SL-401 as a single agent is also being advanced through clinical trials in acute myeloid leukemia, or AML, and myeloproliferative neoplasms, or MPN. In addition, SL-401 is being evaluated in combination with traditional therapies in a Phase 1/2 trial in patients with relapsed or refractory, or r/r, multiple myeloma.

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R (CD123). CD123 is present on a wide range of hematologic cancers including BPDCN, AML, certain MPNs, multiple myeloma, chronic myeloid leukemia, or CML, and other leukemias and lymphomas. SL-401 has demonstrated potent anti-tumor activity against a wide range of hematologic cancers in *in vitro* and *in vivo* preclinical models, including BPDCN, AML, MPN, multiple myeloma, CML, and other leukemic and lymphoid malignancies.

We are also developing SL-501, a next generation CD123-targeted therapy, which is currently in investigational new drug, or IND, enabling studies.

Previously, SL-401 was evaluated in an investigator-sponsored Phase 1/2 clinical trial in patients with advanced hematologic cancers; a trial which has since completed. In this trial, SL-401 was administered via daily intravenous infusion for up to five days, for only a single cycle, and demonstrated a manageable safety profile and anti-tumor activity, including complete responses, or CRs, largely in BPDCN but also in r/r AML (Frankel et al. Blood 124, 2014; ASH 2013 Poster #2682; ASH 2015 Poster #3795).

Currently, we are enrolling patients in the following corporate-sponsored SL-401 clinical trials in which SL-401 is administered in a multi-cycle regimen (via daily intravenous infusion for up to five days, repeated every 3-4 weeks):

- A Phase 2 potentially pivotal trial in patients with BPDCN;
- A Phase 2 trial in patients with AML in CR with minimal residual disease, or MRD;
- A Phase 2 trial in patients with advanced, high-risk MPNs; and
- A Phase 1/2 trial, in combination with pomalidomide and dexamethasone, in patients with r/r multiple myeloma.

SL-401 was granted Breakthrough Therapy Designation, or BTD, by the U.S. Food and Drug Administration, or FDA, in August 2016. In addition, SL-401 was granted Orphan Drug Designation for the treatment of BPDCN and AML from both the FDA and the European Medicines Agency, or EMA.

SL-401 in BPDCN

Patients are currently enrolling into our ongoing, Phase 2 potentially pivotal trial of SL-401 in BPDCN. The trial is a single arm, open-label, multicenter study. The two-stage trial consists of a lead-in, dose escalation stage that included BPDCN and relapsed/refractory AML patients (Stage 1) followed by an expansion stage of BPDCN patients only (Stage 2) that utilizes the dose and regimen determined in Stage 1. Stage 1 of the trial has completed and enrollment in Stage 2 is ongoing. This trial is designed to support potential registration in BPDCN and we expect input from the FDA in the near-term regarding our potential registration pathway in BPDCN.

In June 2016, our academic investigators delivered oral presentations on the Phase 2 SL-401 clinical data in BPDCN at the annual meetings of the American Society of Clinical Oncology, or ASCO, in Chicago, Illinois, and the European Hematology Association, or EHA, in Copenhagen, Denmark. The data included 24 BPDCN patients treated with SL-401, of which 19 patients were evaluable at the time. Results demonstrated a safety profile which has remained manageable over increasing treatment duration, drug exposure, and patient experience. In addition, SL-401 demonstrated high overall response rates, or ORR, in both first-line and r/r BPDCN patients. Response duration and preliminary progression-free survival, or PFS, and overall survival, or OS, data were promising and patient enrollment was ongoing.

As of July 2016, 26 adult BPDCN patients received SL-401 in a multi-cycle regimen; an additional 3 pediatric patients received SL-401 under compassionate use. SL-401's safety profile has continued to remain predictable and manageable over increasing treatment duration, drug exposure, and patient experience. SL-401 has continued to produce a high ORR (86%; 18/21) across all lines and all doses of evaluable adult patients. Data from the pediatric compassionate patients (n=3) are pending and will be reported separately. In the first-line setting at all tested doses, the ORR in evaluable adult patients is 100% (14/14), consisting of 9 CRs, 3 clinical complete responses, or CRcs (CRc defined as a CR in non-skin organs with gross reduction in cutaneous lesions and residual microscopic skin disease), and 2 partial responses, or PRs. Five of these first-line patients who experienced a major response with SL-401 (3 CR, 1 CRc, 1 PR) were subsequently bridged to stem cell transplant, or SCT, and remain progression free. Duration data continue to mature, with 75% (9/12) of evaluable first-line adult patients treated at the maximum tested dose of 12 ug/kg remaining progression free for 3^{+} to 16^{+} months (ongoing), including a patient who has been receiving SL-401 for 12^{+} months [16+ cycles] (ongoing). In the r/r setting, the ORR is >50% (4/7) in currently evaluable patients, including a r/r patient who experienced a major response while on SL-401 and was then successfully bridged to SCT and remains progression free for 4^{+} months (ongoing). OS and PFS data continue to trend favorably, and new patients are enrolling into the trial. It is our intention to present updated data from this trial at the upcoming American Society of Hematology, or ASH, conference in December 2016.

SL-401 in AML in remission with high relapse risk including minimal residual disease

We are currently enrolling AML patients in remission with MRD in a single arm, open-label, multicenter Phase 2 clinical trial. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of the clinical study are to determine 1) safety and optimal dose in this indication, 2) SL-401's ability to lessen MRD burden, and 3) whether CR duration can be extended by SL-401 relative to historical data. Stage 1 of the trial has been completed and enrollment in Stage 2 is ongoing.

SL-401 in high-risk myeloproliferative neoplasms

We are currently enrolling patients with certain advanced, high-risk MPNs, including chronic myelomonocytic leukemia, or CMML, myelofibrosis, systemic mastocytosis, and hypereosinophilic disorder, in a single arm, open-label, multicenter Phase 2 clinical trial. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of this clinical study are to determine 1) safety and optimal dose in this indication, and 2) signals of clinical activity. Stage 1 of this trial has been completed and enrollment in Stage 2 is ongoing.

SL-401 in combination with pomalidomide and dexamethasone in relapsed/refractory multiple myeloma

We are currently enrolling patients in a single arm, open-label, multicenter Phase 1/2 clinical trial evaluating SL-401 in combination with pomalidomide and dexamethasone in r/r multiple myeloma patients. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of the clinical study are to determine 1) the safety and optimal dose of SL-401 when administered in combination with pomalidomide and dexamethasone, and 2) signals of clinical activity. The trial is currently enrolling patients in Stage 1.

SL-701

SL-701 is an immunotherapy designed to activate the immune system to attack brain cancer and other malignancies. SL-701 is comprised of several synthetic peptides that correspond to targets on brain cancer cells and other malignancies, including IL-13Rα2, EphA2, and survivin. Two of these peptides are novel mutants, corresponding to IL-13Rα2 and survivin, artificially designed to be potentially immunogenic to amplify the anti-tumor immune response.

In several completed investigator-sponsored Phase 1/2 clinical trials, an earlier version of this therapy, delivered with an immunostimulant, poly-ICLC, a toll-like receptor 3, or TLR3, agonist shown to activate NK cells and CD8+ T cells, demonstrated anti-tumor activity, including several tumor shrinkages and disease stabilizations in adult and pediatric patients with high grade glioma, including glioblastoma, or GBM (Okada. J Clin Oncol. 2011, ASCO 2011 Poster#2506, AACR 2012 Poster#LB-135).

SL-701 has been granted Orphan Drug Designation by the FDA for the treatment of glioma.

SL-701 Phase 2 in Second Line GBM

In the initial stage (Stage 1) of our corporate-sponsored trial in adult patients with second-line GBM, SL-701 was administered via subcutaneous injection with the immunostimulants, GM-CSF and imiquimod. We have completed patient enrollment in this stage and patients continue to be followed for safety and efficacy. Currently, in Stage 2 of the trial, adult patients with second-line GBM are receiving SL-701 and poly-ICLC, the immunostimulant used in the previous investigator-sponsored studies. In addition, we have added bevacizumab (Avastin®) to the regimen. We expect preliminary data from this study later this year and on into next year.

SL-801

SL-801 is a structurally novel, oral, small molecule, reversible inhibitor of Exportin-1, or XPO1, a tumor-promoting nuclear transport protein. XPO1 has been shown to regulate nuclear import and export of tumor suppressor proteins and oncogenic cell growth regulators, and is overexpressed by many cancer types. Inhibition of XPO1 has been shown to restore tumor suppressor function and proper cell cycle regulation, leading to death of cancer cells. Clinically, we believe that data indicate that XPO1 is a validated target in a variety of solid and hematological cancers. SL-801 has demonstrated potent preclinical *in vitro* and *in vivo* antitumor activity against a wide array of solid and hematologic cancers. Moreover, we believe that by virtue of its relatively reversible inhibition of XPO1, SL-801 may possess a favorable therapeutic window in the clinic.

SL-801 Phase 1 — Advanced Solid Tumors

We are currently enrolling patients with advanced solid tumors in a Phase 1, dose escalation trial of SL-801. We have cleared the first three dosing cohorts, and the fourth cohort is currently open. The trial is designed to evaluate safety, establish an effective dosing regimen, as well as identify initial signals of efficacy. We also plan to initiate a Phase 1 trial in patients with advanced hematologic cancers in the future.

We have devoted substantially all of our resources to advancing our clinical stage candidates into and through clinical trials, formulating a clinical and regulatory development strategy, manufacturing our product candidates, developing our preclinical pipeline, fortifying our intellectual property portfolio, identifying and acquiring additional product and technology rights, providing general and administrative support for these operations, and raising capital. We have generated minimal revenues to date, have not generated any revenue from product sales, and have funded our operations primarily through public sales of common stock to our investors. From

inception through September 30, 2016, we raised $165.7 million primarily from the public sale of common stock relating to our 2013 Initial Public Offering, or IPO, and two subsequent secondary offerings. During the first quarter of 2015, we raised gross cash proceeds of $68.6 million ($64.1 million cash proceeds, net of expenses) from the underwritten public secondary offering and sale of 4,353,877 shares of our common stock.

We have never been profitable and our net losses from operations for the nine months ended September 30, 2016 and 2015 were $28.3 million and $27.1 million, respectively. We expect our expenses to moderately increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Accordingly, we may need additional financing to support our continuing operations. We may seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales and we have generated minimal revenues to date all relating to a $3.0 million research funding received to date from the Leukemia and Lymphoma Society, or LLS, where we recognized revenue of $0.7 million for the nine-month period ended September 30, 2016, which reflects nine months of revenue recognized on a straight line basis, based on the Company's best estimates of work performed and qualifying cost incurred. In the future, we may generate revenue from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue.

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

Research and Development Expenses

The following table shows our research and development expenses for the three-month and nine-month periods ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
SL-401	3,889,790	3,274,049	10,365,203	9,872,535
SL-701	(173,811)	1,106,562	1,806,554	2,955,219
SL-801	762,857	643,823	1,895,484	1,572,770
Personnel expenses	2,505,888	2,139,920	5,972,606	6,415,266
Other expenses	192,236	176,505	545,812	759,953
Total	7,176,960	7,340,859	20,585,659	21,575,743

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

- clinical trial costs;
- chemistry, manufacturing and controls, or CMC, related costs;
- nonclinical costs;
- regulatory expenses including Biologics License application, or BLA, related costs;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense, and consultant costs;
- third-party contract research organizations, or CROs, contract manufacturing organizations, or CMOs, academic institutions and consultants; and
- license fees and milestone payments related to in-licensed products and technology.

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 an expense 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 moderately increase in future periods as we continue to develop SL-401, SL-701, SL-801, 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, SL-701, and SL-801.

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;
- timing and results of future clinical trials;
- 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 U.S. Food and Drug Administration, or FDA, or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in future periods due to the planned build out of a commercial infrastructure to support a potential commercial product launch for SL-401 if an FDA approval for marketing is obtained.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents, short-term investments and long-term investments. Given the current interest rate market and that our primary investments are in U.S. Treasury and Agency securities and related money market funds coupled with FDIC-insured bank certificates of deposits, we expect interest income to be minimal in future quarters.

Critical Accounting Policies and Estimates

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

For a discussion of our critical accounting estimates, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2015 Form 10-K. There were no material changes in our critical accounting estimates or accounting policies during the nine months ended September 30, 2016.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, Compensation—Stock Compensation (Topic 718): Improvements To Employee Share-Based Payment Accounting, which allows for the simplification of several aspects of the accounting for share-based payment transactions. The standard is effective for interim and annual periods beginning after December 15, 2016. The Company is currently evaluating the effect that the updated standard will have on its financial statements and related disclosures.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

Research and development expense. Research and development expense was $7.2 million for the quarter ended September 30, 2016, compared with $7.3 million for the quarter ended September 30, 2015, representing a decrease of $0.1 million.

General and administrative expense. General and administrative expense was $3.2 million for the quarter ended September 30, 2016, compared with $2.2 million for the quarter ended September 30, 2015, representing an increase of $1.0 million. The increase in expense was primarily attributable to higher non-cash stock based compensation and payroll costs relating to employees.

Interest income. Interest income was $132,006 for the quarter ended September 30, 2016, compared with $137,123 for the quarter ended September 30, 2015. The slightly lower income is due to the year over year reduction in our cash, short-term investment and long-term investment balances.

Comparison of Nine Months Ended September 30, 2016 and 2015

Research and development expense. Research and development expense was $20.6 million for the nine months ended September 30, 2016, compared with $21.6 million for the nine months ended September 30, 2015, representing a decrease of $1.0 million. The lower expenses in 2016 compared to the same period in the prior year were primarily attributable to higher clinical site startup fees in the prior year.

General and administrative expense. General and administrative expense was $8.9 million for the nine months ended September 30, 2016, compared with $6.2 million for the nine months ended September 30, 2015, representing an increase of $2.7 million. The increase in expense year over year was primarily attributable to higher non-cash stock based compensation and payroll costs relating to employees.

Interest income. Interest income was $417,113 for the nine months ended September 30, 2016, compared with $259,064 for the nine months ended September 30, 2015. The higher income is due to a change in the composition of our investment portfolio to include higher yielding FDIC insured certificates of deposit.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2016, our cash, cash equivalents and short and long-term investments totaled $74.3 million. We primarily invest our cash, cash equivalents, short-term investments and long-term investments in U.S. Treasury and Agency securities and related money market funds and FDIC-insured bank certificates of deposit, with the balance in commercial bank operating accounts. We believe that our existing cash, cash equivalents, short-term investments and long-term investments including cash proceeds received from our Secondary Offering in the first quarter of 2015, will be sufficient to fund our operations and our capital expenditures for at least the next two years.

We have financed our operations to date primarily through proceeds from public sales of common stock via our 2013 IPO and two subsequent secondary offerings. To date, we have not generated any revenue from the sale of products. We have incurred losses and generated negative cash flows from operations since inception.

Since inception and through September 30, 2016, we received net proceeds of $165.7 million primarily from the public sale of common stock from our 2013 IPO and two subsequent follow-on secondary offerings. During the first quarter of 2015, we completed an underwritten follow-on public offering, selling 3,800,000 shares at an offering price of $15.75 per share and the underwriters exercised in full their over-allotment option to purchase an additional 553,877 shares at an offering price of $15.75 per share. Aggregate gross proceeds from the secondary offering were $68.6 million, and net cash proceeds received after underwriting fees and offering expenses were approximately $64.1 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2016	2015
Net cash used in operating activities	$ (23,315,577)	$ (19,008,431)
Net cash provided by/(used) in investing activities	18,896,040	(49,173,337)
Net cash provided by financing activities	171,332	64,461,123
Net (decrease) increase in cash and cash equivalents	$ (4,248,205)	$ (3,720,645)

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for stock-based compensation expense, non-cash depreciation expense and changes in the components of working capital. The net cash used in operating activities during the nine months ended September 30, 2016 and 2015 primarily resulted from research and development expenses as we ramped up our clinical activities relating to SL-401, SL-701, and SL-801. Additional research and development costs also include CMC related expenses for the manufacture of drug substance and drug product of our product candidates in development.

Investing activities. The net cash provided by and used in financing activities for the nine months ended September 30, 2016 and 2015, respectively, reflects purchases and redemptions of short-term and long-term investments within our U.S. Treasury-related investment and bank certificate of deposit portfolios, net of maturities.

Financing activities. The net cash provided by financing activities for the nine months September 30, 2016 resulted from the issuance of stock related to the 2015 Employee Stock Purchase Plan and exercise of employee stock options. The net cash provided by financing activities for the nine months ended September 30, 2015 resulted primarily from our Secondary Offering and sale of 4,353,877 shares of our common stock which generated gross cash proceeds of $68.6 million ($64.1 million cash proceeds, net of expenses).

Funding Requirements

All of our product candidates are still in clinical or preclinical development. We expect to continue to incur significant expenses and increased 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 product candidates, SL-401, SL-701 and SL-801;

- continue the research and development of our other product candidates, including SL-501, 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 manufacturing, 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 the next two years. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third-parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the progress and results of the ongoing and future clinical trials of our product candidates;
- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our product candidates now or in the future;
- 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 promotion, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our ability to obtain government funding and operational support for our planned clinical trial of SL-701 in our clinical programs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish any future collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The Company has agreements with third party service providers in connection with its clinical programs. The Company's total expenditures in the future would be approximately $7.3 million if not cancelled upon reasonable notice to the service provider and assuming the successful advancement of its programs.

Off-Balance Sheet Arrangements

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

Tax Loss Carryforwards

As of September 30, 2016, we had net operating losses of $80.2 million for both federal and state purposes, which are available to reduce future taxable income. We also had federal tax credits of approximately $14.9 million, which may be used to offset future tax liabilities. The net operating loss and tax credit carryforwards will expire at various dates through 2036. 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 utilization limitation pursuant to the change in ownership rules of Internal Revenue Code Section 382 and 383. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. At September 30, 2016, we recorded a 100% valuation allowance against our net operating loss and tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be fully realized.

Jumpstart Our Business Startups Act of 2012

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalent, short-term investments and long-term investments of $74.3 million as of September 30, 2016 and $97.5 million as of December 31, 2015, consisting of cash, U.S. Treasury and Agency securities and related money market funds and FDIC-insured bank certificates of deposit. 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 primarily in Treasury-related debt securities and bank certificates of deposit. 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 September 30, 2016 and December 31, 2015, all of our liabilities were denominated in our functional currency.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's, or SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and

procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes to Internal Controls Over Financial Reporting

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

Limitations on the Effectiveness of Controls

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

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

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

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

We are heavily dependent on the success of our clinical product candidates, SL-401, SL-701, and SL-801, and we cannot provide any assurance that any of our product candidates will be approved, commercialized, or successfully marketed in the future.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates, SL-401, SL-701 and SL-801, which we are advancing through clinical development. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize these product candidates, which may never occur. We currently generate no revenues from our product candidates, and we may never be able to develop or commercialize a marketable drug.

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

We have not submitted a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, or similar market approval applications to comparable foreign authorities, for any of our product candidates. We cannot be certain that any BLA or NDA will be filed within a specified period of time, or that any BLA or NDA will allow us to obtain or maintain marketing approval. We also cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval for trial initiation or marketing. Further, the FDA may not agree with our interpretation of the clinical safety and efficacy of our product candidates and 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. In addition, our revenues will be dependent, in part, upon the market acceptance of our products once approved. 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 may not have the resources to conduct and oversee our product development programs without assistance from third parties. In the execution of our product development programs, we may have to rely on collaborations with clinical partners as well as clinical research organizations, CROs, vendors and service providers. Failure of these entities to satisfactorily conduct clinical research or to provide the services requested by the company may negatively impact on our product development programs, including but not limited to program delays or preventing approval of our product candidates.

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

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

Clinical testing is expensive and can take a substantial amount of time to complete. Its outcome is inherently uncertain. In addition, failure can occur at any time during clinical development, including after significant resources have been invested. We cannot predict whether we will encounter challenges with any of our clinical trials that will cause us, or regulatory authorities, to delay, suspend or terminate those 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 depending on the circumstances;
- failure of our third-party contractors, including CROs and CMOs, or our investigators, to comply with regulatory requirements or otherwise meet contractual obligations in a timely manner;
- delays or failure in obtaining the necessary approvals from regulators, institutional review boards, or IRBs, or scientific review committees, or SRCs, in order to commence or continue a clinical trial or to market our product candidates;
- our inability to manufacture, or obtain from third-parties, adequate supply of drug substance, drug product or adjuvant therapies sufficient to complete our preclinical studies and clinical trials;
- risk of loss of drug product, adjuvants and/or other components of the product, due to third-party storage and distribution of such supplies;
- the FDA requiring alterations to any of our study designs, including extending a study or requiring new studies, overall strategy or manufacturing plans;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, poor accrual, or high drop-out rates of patients in our clinical trials;
- clinical trial sites deviating from trial protocol or dropping out of a trial and our inability to add new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our product candidates during clinical trials;
- safety issues, including serious adverse events associated with our product candidates and patients' exposure to unacceptable health risks;
- receipt by a competitor of marketing approval for a product targeting an indication that one of our product candidates targets, such that we are not "first to market" with our product candidate;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or
- differing interpretations of data by the FDA or similar foreign regulatory agencies.

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

We intend to have one or more interactions with the FDA in the second half of 2016 regarding our SL-401 Phase 2 potentially pivotal trial in BPDCN. If the FDA does not agree with our proposals or a mutual compromise is not reached, this trial may not be recognized as a pivotal trial, which could delay or halt our clinical trials or commercialization plans for SL-401, including requiring us to conduct additional clinical trials.

We are advancing SL-801 into and through clinical trials. There are unknown risks with respect to dosing, administration, pharmacokinetics, bioavailability, safety and efficacy that we expect we will learn about during clinical development.

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

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

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

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

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

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

- As we optimize and scale-up production of SL-401, SL-701 and SL-801, there have been manufacturing, formulation, fill-finish and other process and analytical changes that are part of the optimization and scale-up necessary for producing drug substance and drug product of a quality, quantity and stability sufficient for later stage clinical development and commercialization. Delays, including failures, in any of these steps may delay initiation and completion of clinical trials. We may also need to demonstrate comparability between newly manufactured drug substance and/or drug product relative to previously manufactured drug substance and/or drug product. Demonstrating comparability may cause us to incur additional costs or delay initiation or completion of our clinical trials including the need or choice to initiate a dose escalation study and, if unsuccessful, could require us to complete additional preclinical or clinical studies of our product candidates.

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

- We are, or may in the future be, treating patients with certain diseases or conditions that have not been previously treated with SL-401. In these instances, we may choose to treat patients at several different doses and use multi-cycle dosing regimens to determine the optimal doses and schedules for both near-term and long-term safety and disease control in each indication.

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

- We are developing SL-701 as an injection administered under the skin, or subcutaneously, in our trials. Two previous investigator-sponsored trials utilizing an earlier version of SL-701 used this method of delivery. Another previous investigator-sponsored trial utilizing an earlier version of SL-701 used a different method of delivery, in which dendritic cells, which are a type of immune cell, were removed from the patient, exposed to immunogenic peptides, and then re-injected into or near a lymph node of the patient (intra/peri-nodally). Our plan continues the subcutaneous injection method used in two of the previous studies and represents a change from one of the previous studies.

- We are manufacturing and formulating SL-701 as a mixture of IL-13Rα2 mutant peptide, EphA2 peptide, a new survivin mutant peptide, and a tetanus toxoid peptide. An earlier version of this immunotherapy, which included IL-13Rα2 mutant and EphA2 peptides, was mixed with additional peptides in previous studies, including a different survivin peptide in some studies.

- In the initial stage of our SL-701 corporate-sponsored trial we used granulocyte-macrophage-colony-stimulating factor, or GM-CSF, and imiquimod as the immunostimulants. In the current stage of our SL-701 trial, we are using poly-ICLC as the immunostimulant, which was the immunostimulant used, along with an earlier version of SL-701, in the previous investigator-sponsored study.

- In some of our current or future trials, we may combine SL-401, SL-701, or SL-801 with other therapies such as chemotherapy, radiation, targeted therapy, or anti-angiogenic therapy. We may not have yet clinically tested these combinations. While there do not appear to be overlapping toxicities with these combinations, there is always the risk of unforeseen toxicities. We are currently combining SL-401 with pomalidomide in myeloma and SL-701 with bevacizumab and immunostimulants in brain cancer.

Any of the aforementioned, or other, changes could make the timing, including initiation, patient accrual, or results of our clinical trials or other future clinical trials, less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay or suspend completion of our clinical trials, delay or prevent 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 continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. SL-401 and SL-701 are being developed in hematologic and brain cancers, respectively, both of which are orphan indications (i.e., rare diseases). SL-401 is being developed initially in BPDCN and other rare diseases, including certain myeloproliferative disorders, as well as AML, and SL-701 is being developed in adult and pediatric brain cancer. Some of these represent orphan indications for which there are very limited independently reported data on annual incidences. If the incidences of these diseases are very low, including lower than our estimates or estimates of our third-party contractors, this could significantly delay patient enrollment in any one or more of our ongoing or future clinical trials. SL-801 is being developed in a number of advanced solid tumors, some of which may be orphan indications.

Further, 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.

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We may be required to undertake and complete certain additional preclinical or clinical studies to generate data related to toxicity and other data required to support the submission of an IND or a BLA or an NDA to the FDA or comparable foreign authorities. 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 alone or in combination with any adjuvant, immunostimulant including poly-ICLC, or other agents with which we may combine our drug 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, conduct or findings of our clinical trials;
- the FDA may identify protocol deviations or data quality or integrity concerns with our preclinical or 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 FDA may not accept our definition of response or our criteria for other endpoints for evaluation of patient efficacy and potential marketing approval;
- the data collected from clinical trials of our product candidates or the adequacy of our right of reference to it may not be sufficient to support the submission of a BLA or an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics we develop; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy and costly review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market SL-401, SL-701, SL-801, or any of our other product candidates that we may advance into and through clinical trials, which would significantly harm our business.

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

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

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

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

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

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

Although we expect to focus a substantial amount of our efforts on the continued clinical testing and potential approval of SL-401, SL-701, and SL-801, another key element of our strategy is to identify and test additional compounds. A portion of the research that we are conducting involves new and unproven drug discovery methods, including our proprietary StemScreen® platform technology, as well as the testing of new compounds and potential new uses of existing compounds. The drug discovery that we are conducting using our StemScreen® platform technology may not be successful in identifying compounds that are useful in treating humans with cancer. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

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

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

Any regulatory approvals that we or our potential strategic partners receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, may contain product contraindications, warnings, or precautions that limit use of our product candidates or may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of our product candidates. 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 compliance 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. In addition, any regulatory approvals will trigger compliance with the Federal Physician Payment Sunshine Act reporting requirements or related state marketing disclosure laws. 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 September 30, 2016 of approximately $137.9 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, cash equivalents, short-term investments and long-term investments including the cash proceeds received from our Secondary Offering during the first quarter of 2015, will be sufficient to fund our operations and our capital expenditures for at least the next two years. If our cash is insufficient to meet future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third-parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all. In addition, if we do not continue to meet our diligence obligations under our license agreements for our product candidates that we have in-licensed, including SL-401, SL-701, and SL-801, we will lose our rights to develop and commercialize those product candidates.

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

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

Since our inception, most of our resources have been dedicated to the discovery, acquisition and preclinical and clinical development of our product candidates. We have expended and believe that we may continue to expend substantial resources for the development of SL-401, SL-701, and SL-801, as well as other product candidates and drug discovery and acquisition efforts. These expenditures will include costs associated with general administration, facilities, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials, obtaining regulatory approvals, commercializing any products approved for sale, and costs associated with operating as a public company.

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

Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the ability of our product candidates to progress through clinical development successfully;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost associated with securing and establishing commercialization and manufacturing capabilities for our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the economic and other terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

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

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

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

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

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

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

There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by an economic downturn, a volatile business environment or an unpredictable and unstable market. If equity and credit markets deteriorate, it may make any necessary equity, debt, or other financing more difficult to secure, more costly, more dilutive, and less favorable to existing shareholders. 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, defend, leverage and expand our intellectual property portfolio;
- build and maintain sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners should our products obtain market approval;
- gain market acceptance for our products should they obtain market approval;
- develop and maintain cGMP compliant manufacturing and distribution capabilities sufficient to support the intended scope of our pre-clinical and clinical development plans and the potential commercial demand for our product(s);
- develop and maintain any strategic relationships we elect to enter into;
- satisfy our obligations under our license and other agreements; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals, manufacturing and commercialization.

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

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

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

We expect any product candidate that we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. For example, there are a number of biopharmaceutical companies focused on developing therapeutics that target CSCs, including Verastem, Inc., OncoMed Pharmaceuticals, Inc., Sumitomo Dainippon Pharma Co. Ltd., Bionomics Limited and Stemcentrx, Inc. There are also several biopharmaceutical companies that do not appear to be primarily focused on CSCs, but may be developing at least one CSC-directed compound. These companies include Astellas Pharma US, Inc., Boehringer Ingelheim GmbH, Geron Corp., GlaxoSmithKline plc, Macrogenics Inc., Micromet, Inc. (an Amgen, Inc. company), Pfizer Inc., Roche Holding AG, Sanofi U.S. LLC, and others. Additionally, there are a number of companies working to develop new treatments, which may compete with SL-401 and SL-801, including AbbVie, Agios, Inc., Ambit Biosciences Corporation (now a Daiichi Sankyo company), Amgen, Astex Pharmaceuticals (now an Otsuka Pharmaceutical company), Celator Pharmaceuticals, Inc., Celgene Corporation, Cellectis, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Genmab, Genzyme Corporation (now a Sanofi company) Immunogen, Janssen Pharmaceutical Companies of Johnson and Johnson, Karyopharm Therapeutics, Inc., Novartis AG, Seattle Genetics, Inc., and Sunesis Pharmaceuticals, Inc., Xencor, 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 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 Agenus Inc., Bristol-Myers Squibb, Inc., Cortice Biosciences, Inc., Celldex Therapeutics, Inc., CytRx Corporation, GenSpera, Inc., GlaxoSmithKline plc., ImmunoCellular Therapeutics, Ltd., Northwest Biotherapeutics, 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. In addition, many are farther along in their clinical development programs. We may not be able to compete unless we successfully:

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

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management as well as other employees, consultants and scientific and medical collaborators. As of November 8, 2016, we had 28 full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. Although none of these individuals has informed us to date that he or she intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, completion of our ongoing and future clinical trials or the commercialization of our product candidates.

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

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, clinical study, 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 and inability to enroll future clinical trial participants;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

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

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

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by healthcare providers, health plans and healthcare clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and

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

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

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

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

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

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

Risks Related to Commercialization of Our Product Candidates

If we are unable to establish or implement our own sales, marketing and distribution capabilities in a timely matter 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, SL-801, and any future product candidates if and when they are approved, or enter into licensing or collaboration agreements to assist in the future development and commercialization of such product candidates.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that SL-401, SL-701, and/or SL-801 will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians to prescribe any future products;

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

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

If we do not establish sales, marketing and distribution capabilities successfully and in compliance with legal and regulatory requirements, 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, SL-701, and SL-801, among physicians and other healthcare providers, patients, third-party payors and, in the cancer market, acceptance by the operators of major cancer clinics.

Even if SL-401, SL-701, SL-801, or any other product candidate that we may develop or acquire in the future obtains regulatory approval, the product may not gain market acceptance among physicians, third-party payors, patients and the medical community. For example, current cancer treatments such as chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. The degree of market acceptance of any products for which we receive approval for commercial sale depends on a number of factors, including:

- the efficacy and safety of our products, as demonstrated in clinical trials, and the degree to which our products represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which our products are approved;
- acceptance by physicians, operators of major cancer clinics and patients of our products as a safe and effective treatment;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-parties and government authorities;
- the continued projected growth of oncology drug markets;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

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

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, recently passed legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and how much they will pay for them. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

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

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

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the statute in 2012. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. While other challenges remain to portions of the ACA, these two cases were generally viewed as the only existential threats to the statute that have been raised so far. Proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been presented to Congress in 2016, including by the current Administration, but implementation likely will be challenging in light of strong opposition to these proposals as well as the current political climate. The Administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has proposed to test alternative payment methodologies for drugs covered under the Part B program. In general, 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 changed or modified by Congress or the Supreme Court, 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 receive marketing approval by the FDA as a biological product under a BLA, such an approved product(s) 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 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 initial clinical trials of our product candidates in the past, and our ability to influence the design and conduct of such trials was limited. Our current and future corporate-sponsored trials will also require us to rely on various 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.

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

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

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

We rely 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 have 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. In our corporate sponsored trials of SL-401, SL-701 and SL-801, we have continued to engage various third-parties. 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 rely on third-party manufacturers to produce and supply our clinical and preclinical product candidates and we intend to rely on third-party manufacturers to produce commercial supplies of any approved products. 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 products or continue to sell any products we commercialize.

We do not currently own or operate any manufacturing facilities, and we lack sufficient internal staff and infrastructure to produce clinical and preclinical product candidate supplies ourselves. As a result, we work with third-party CMOs to produce SL-401, SL-701, and SL-801 in acceptable quality and quantity for our ongoing and future clinical trials. If we are unable to maintain such third-party manufacturing sources, or fail to do so on commercially reasonable terms or on a timely basis, we may not be able to successfully produce, develop, and market SL-401, SL-701, and/or SL-801, or may be delayed in doing so. We purchase and plan to purchase immunostimulants used with SL-701 from third-parties. Whereas GM-CSF and Imiquimod are commercially available products, poly-ICLC (Hiltonol®) is a development stage candidate and not commercially available. We do not have a right to manufacture poly-ICLC directly or through third-party CMOs and are dependent on the distributor of poly-ICLC for clinical supply.

We also expect to rely upon third-parties to produce drug product required for the clinical trials and commercialization of our other product candidates, including SL-501, a targeted therapy directed to CD123 in preclinical development.. 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 of acceptable quality in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

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

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

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

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

can successfully transfer our manufacturing processes to produce product of equivalent quality and quantity. FDA approval of the new manufacturer may also be required. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to develop product candidates or produce approved products in a timely manner. Any delay or interruption in our clinical studies or in the development, validation and commercialization of our product candidates could negatively affect our business**.**

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

Our global commercialization strategy for certain of our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing to collaborate under the terms provided is not in our best interest, and we may terminate such 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 that issued or allowed patents will not later be found to be invalid and/or unenforceable. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary product candidates and technology.

Our patents and patent applications may not be sufficient to protect our products and product candidates from commercial competition. For example, we cannot obtain a composition of matter patent for SL-401 due to earlier published prior art. We have however obtained U.S. and foreign patents for certain methods of using SL-401 to treat AML, BPDCN, and myelodysplastic syndrome, or MDS. In addition, we have filed additional U.S. and foreign patent applications for the method of using SL-401 to treat AML, MDS, BPDCN, and other diseases although there can be no assurances that such patents will issue. Failure to obtain patents directed to all approved uses of SL-401 would enable a competitor to market SL-401 for such unpatented indication(s), which could lead to price erosion for sales of SL-401 for our patented indications through off-label use. With respect to SL-701, although we have licensed an issued U.S. patent directed to the composition of matter for the mutant immunogenic IL-13Rα2 peptide, 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, including an issued patent in Australia, that seek to cover certain uses of this peptide. While we have a non-exclusive license to issued U.S. patents directed to methods of use for the EphA2 peptide, we do not have any composition of matter patent protection although we do have rights to foreign pending patent applications that seek to cover certain uses of this peptide. While we have filed U.S. and foreign patent applications directed to methods of use of a new survivin mutant peptide for use in SL-701, we do not have any composition of matter patent protection. With respect to SL-801, we licensed issued

patent in the U.S. and abroad directed to composition of matter for the SL-801 compound. While we have patent applications pending in the United States and Canada directed to our StemScreen® technology, we currently have no issued patents covering StemScreen®. Although we have various patent applications pending in the United States and abroad that we anticipate may result in additional protection for SL-401, SL-701, SL-801 and StemScreen®, there can be no assurance that any of these applications will result in an issued patent, or that if they issue, they will provide additional meaningful protection for these assets. Our inability to obtain adequate patent protection for our product candidates or platform technology could adversely affect our business.

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

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

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

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

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

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

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

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

If third-parties successfully assert intellectual property rights against us, we might be barred from using certain aspects of our platform technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a

plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner, in order to continue our research and development programs or to market our product(s). It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize certain products, or both.

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

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

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

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

SL-401, SL-701, SL-801, some of our other product candidates and our platform technologies are protected by intellectual property licensed from third-parties including academic institutions. If the licensors terminate the licenses or fail to prosecute patent applications or maintain or enforce the underlying patents, our competitive position, market share, and business prospects will be harmed.

We are a party to several license agreements relating to certain patents and patent applications owned by third-parties, upon which certain aspects of our business depend. In particular, we hold an exclusive license from Scott and White Memorial Hospital, or Scott and White, for SL-401 and SL-501 and three licenses, including an exclusive license and two non-exclusive licenses, from the University of Pittsburgh relating to SL-701. Our license agreement with Scott and White survives, unless earlier terminated, until the later of the expiration of the last to expire licensed patent or the date on which we owe no further payments to Scott and White. Our exclusive and our non-exclusive patent license agreements with the University of Pittsburgh survive, unless earlier terminated, until the expiration of the last to expire licensed patent, and our non-exclusive license with the University of Pittsburgh to use and reference certain clinical trial data and information survives for a term of twenty years unless earlier terminated. We hold an exclusive license from CanBas, Ltd. for SL-801 in all worldwide territories other than Japan, Korea, Taiwan, and China. The agreement with CanBas, Ltd. survives until the later of ten years following the first commercial sale of each product in each country; the date upon which there are no more valid claims; or the expiration or termination of the last regulatory exclusivity period, after which our license becomes fully paid, irrevocable, perpetual, non-exclusive and royalty-free. We also hold licenses from academic institutions relating to intellectual property underlying other product candidates and our StemScreen® platform technology. We expect to enter into additional license agreements as part of the development of our business. Our current or future licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In addition, in spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore seek to terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. Our licensors may also seek to terminate the license agreements if we fail to satisfy our diligence obligations and/or meet specified milestones or upon insolvency. From time to time, we have had to request extensions of our development obligations contained in some of our license agreements, and we may need to seek further extensions in the future. Although we have obtained such extensions in the past, there can be no assurance that our licensors will continue to extend the development timelines or other milestones contained in our license agreements. If these in licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, we could lose our rights to develop and commercialize the product candidates governed by the licenses and competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

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

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

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

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

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors.

Enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

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

- Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.

- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

- Our competitors might conduct research and development activities in countries where we do not have patent rights, or where the applicable laws provide a safe harbor exemption from infringement liability for certain research purposes, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- We may not develop additional proprietary technologies that are patentable.

- The patents of others may have an adverse effect on our business.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharma industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharma patents is costly, time-consuming and inherently uncertain. In addition, Congress has passed patent reform legislation which provides new limitations on attaining, maintaining and enforcing intellectual property. Further, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to Our Common Stock

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

The market price of our common stock may be highly volatile, and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in January 2013, the price of our common stock has ranged from $3.88 per share to $47.25 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;

- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- our dependence on third-parties, including clinical research organizations and contract manufacturing organizations, trial sites, clinical trial sponsors and clinical investigators;

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

- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;

- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;

- regulatory or legal developments in the United States and other countries;

- our ability to maintain the license agreements for our product candidates;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key scientific or management personnel;

- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we have and intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we have and may continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC.

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

Our executive officers, directors and principal stockholders beneficially own shares representing approximately 42.4% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert substantial influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would exert substantial influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which they might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call special stockholder meetings and the matters transacted at such meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

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

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

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

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

Cash dividends on our capital stock in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business, and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

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 of Stemline Therapeutics, Inc., filed as Exhibit 3.3 to Form 10-Q on August 14, 2013 (File No. 001-35691) and incorporated herein by reference.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
32.2	Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Comprehensive Loss, (iv) Statements of Stockholders' Equity, (v) Statements of Cash Flows, and (vi) the Notes to Financial Statements.

SIGNATURES

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

Date: November 8, 2016

STEMLINE THERAPEUTICS, INC.

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

Date: November 8, 2016

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

EXHIBIT INDEX

Exhibit Number	Description of Document
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 8, 2016.
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Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2016

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

Exhibit 31.2

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

I, David G. Gionco, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2016

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

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
STEMLINE THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Stemline Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016 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: November 8, 2016

/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 September 30, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, David G. Gionco, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: November 8, 2016

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