Current Agreements

Dealdoc

IPO for $33 million

Stemline Therapeutics

Jan 28 2013

IPO for $33 million

Companies:	Stemline Therapeutics
Announcement date:	Jan 28 2013
Value, US$m:	38 : sum of IPO

- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Announcement date:	Jan 28 2013
Type:	IPO » IPO>Completed
Industry sectors:	Biotech
Therapy areas:	Oncology

Financials

Value, US$m:	38 : sum of IPO

Termsheet

Stemline Therapeutics announced that it has filed a registration statement with the Securities and Exchange Commission for a proposed initial public offering of its common stock.

The offering size and the estimated price range of the offering have not yet been determined.

All shares proposed to be included in the offering will be sold by Stemline.

Oppenheimer & Co. Inc. and JMP Securities LLC are acting as joint book-running managers for the offering.

Press Release

29 January 2013

Stemline Therapeutics, Inc. Announces Exercise of Over-Allotment Option

NEW YORK, Jan. 29, 2013 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing oncology therapeutics that target both cancer stem cells (CSCs) and tumor bulk, today announced the exercise in full of the over-allotment option granted to the representative of the underwriters by Stemline with respect to the purchase of 497,647 shares of common stock at a public offering price of $10.00 per share, less underwriting discounts and commissions. The over-allotment option is being exercised in connection with Stemline's previously announced initial public offering of 3,317,644 shares of common stock. As a result of the exercise of the over-allotment option, the total gross proceeds to Stemline from the offering will be $38,152,910, before deducting underwriting discounts and commissions and other offering expenses.

Aegis Capital Corp. is acting as sole book-running manager for the offering.

Feltl and Company, Inc. and Sunrise Securities Corp. are acting as co-managers for the offering.

A registration statement relating to these securities was declared effective by the Securities and Exchange Commission on January 28, 2013.

This offering is being made only by means of a prospectus. Copies of the prospectus relating to this offering may be obtained by contacting Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Stemline:

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics that target both cancer stem cells (CSCs) as well as the tumor bulk. Among Stemline's drug candidates are SL-401 and SL-701, both of which have demonstrated clinical activity, including durable complete responses (CRs), and an overall survival (OS) benefit versus historical controls in Phase 1/2 studies of advanced cancer patients.

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28 January 2013

Stemline Therapeutics, Inc. Announces Pricing of Initial Public Offering of 3,317,644 Shares of Common Stock

NEW YORK, Jan. 28, 2013 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc., a clinical-stage biopharmaceutical company developing oncology therapeutics that target both cancer stem cells (CSCs) and tumor bulk, today announced the pricing of its initial public offering of 3,317,644 shares of its common stock offered at a price to the public of $10.00 per share. The gross proceeds to Stemline from the initial public offering are expected to be $33,176,440, before underwriting discounts and commissions and other offering expenses. Stemline has granted the representative of the underwriters a 45-day option to purchase up to 497,647 additional shares of common stock from Stemline to cover over-allotments, if any. The shares are expected to begin trading on the NASDAQ Capital Market under the symbol "STML" on January 29, 2013. The offering is expected to close on January 31, 2013, subject to customary closing conditions.

Aegis Capital Corp. is acting as sole book-running manager for the offering.

Feltl and Company, Inc. and Sunrise Securities Corp. are acting as co-managers for the offering.

A registration statement relating to these securities was declared effective by the Securities and Exchange Commission on January 28, 2013.

This offering is being made only by means of a prospectus. Copies of the prospectus relating to this offering may be obtained by contacting Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: prospectus@aegiscap.com.

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About Stemline:

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics that target both cancer stem cells (CSCs) as well as the tumor bulk. Among Stemline's drug candidates are SL-401 and SL-701, both of which have demonstrated clinical activity, including durable complete responses (CRs), and an overall survival (OS) benefit versus historical controls in Phase 1/2 studies of advanced cancer patients.

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3 April 2012

Stemline Therapeutics, Inc. Files Registration Statement for Proposed Initial Public Offering

NEW YORK, April 3, 2012 /PRNewswire via COMTEX/ -- Stemline Therapeutics, Inc., a clinical-stage biopharmaceutical company developing oncology therapeutics that target both cancer stem cells (CSCs) and tumor bulk, announced today that it has filed a registration statement with the Securities and Exchange Commission for a proposed initial public offering of its common stock. The offering size and the estimated price range of the offering have not yet been determined. All shares proposed to be included in the offering will be sold by Stemline.

Oppenheimer & Co. Inc. and JMP Securities LLC are acting as joint book-running managers for the offering.

A registration statement relating to these securities has been filed with the Securities and Exchange Commission, but has not yet become effective. These securities may not be sold and offers to buy may not be accepted prior to the time the registration statement becomes effective. This press release shall not constitute an offer to sell or a solicitation of an offer to buy, and there shall not be any sale of these securities in any state in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state.

The offering will be made only by means of a prospectus. When available, copies of the preliminary prospectus relating to and describing the terms of this offering may be obtained by contacting Oppenheimer & Co. Inc., Attention: Syndicate Prospectus Department, 85 Broad Street, 26th Floor, New York, NY, 10004, (212) 667-8563, EquityProspectus@opco.com, or JMP Securities LLC, Attention: Prospectus Department, 600 Montgomery Street, Suite 1100, San Francisco, California 94111, (415) 835-8985.

Filing Data

Not available.

Contract

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

STEMLINE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of

incorporation or organization) 2834

(Primary Standard Industrial

Classification Code Number) 45-0522567

(I.R.S. Employer

Identification Number)

750 Lexington Avenue

Sixth Floor

New York, New York 10022

(646) 502-2310

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Ivan Bergstein, M.D.

Chairman, President and Chief Executive Officer

Stemline Therapeutics, Inc.

750 Lexington Avenue

Sixth Floor

New York, New York 10022

(646) 502-2310

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Chrysler Center

666 Third Avenue

New York, New York 10017

(212) 935-3000

Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer ý

(Do not check if a

smaller reporting company) Smaller reporting company o

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(1)	AMOUNT OF REGISTRATION FEE(2)
Common Stock, $0.0001 Par Value Per Share	$50,000,000	$5,730

(1)

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2)

Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus Subject to Completion April 2, 2012

shares

GRAPHIC

Common Stock

This is the initial public offering of our common stock. No public market currently exists for our common stock. We are offering all of the shares of common stock offered by this prospectus. We expect the public offering price to be between $ and $ per share.

We are applying to list our common stock on the NASDAQ Global Market under the symbol "STML."

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock in "Risk Factors" beginning on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Per Share Total

Public offering price

$ $

Underwriting discounts and commissions

$ $

Proceeds to Stemline, before expenses

$ $

The underwriters may also purchase up to an additional shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $ and our total proceeds, after deducting underwriting discounts and commissions but before expenses, will be $.

The underwriters are offering the common stock as set forth under "Underwriting." Delivery of the shares will be made on or about , 2012.

Oppenheimer & Co. JMP Securities

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We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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Prospectus Summary

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors" section and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells, or CSCs, and tumor bulk. We believe that we are developing the most clinically advanced pipeline of anti-CSC therapeutics and that we hold a broad portfolio of CSC-focused intellectual property, establishing us as a leader in the CSC field. Among the therapeutic candidates in our portfolio, we are currently developing two clinical-stage product candidates, SL-401 and SL-701, for which we hold global marketing rights. The lead indication for SL-401, a biologic-drug conjugate, is acute myeloid leukemia, or AML. The lead indications for SL-701, a synthetic peptide vaccine, are pediatric and adult brain cancer. In completed Phase 1/2 clinical trials, both SL-401 and SL-701 have demonstrated single agent activity, including durable complete responses, or CRs, and longer overall survival, or OS, in patients compared with that achieved in the past with traditional therapies. We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult relapsed or refractory AML patients who failed two previous treatments (i.e. third-line AML) with OS as the primary endpoint. We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat pediatric patients with newly diagnosed brain stem glioma, or BSG. In addition, we plan to advance SL-701 into a randomized Phase 2b clinical trial in adult patients with glioblastoma, or GBM, who failed one previous treatment (i.e. second-line GBM) with a development plan designed to culminate in registration. We have a proprietary discovery platform, StemScreen®, for the discovery of novel CSC-targeted compounds, from which we have discovered or validated several of our clinical and preclinical product candidates and which we believe may be instrumental in the discovery of additional new therapies targeting a wide range of cancer types.

The field of CSCs is a new area of cancer biology with the potential to fundamentally alter the approach to oncology drug development. CSCs have been identified in virtually all major tumor types, including leukemia and cancers of the brain, breast, colon, prostate and pancreas. CSCs are the highly malignant "seeds" of a tumor that self-renew and generate more mature cells that comprise the bulk of the tumor, or "the tumor bulk." As such, we believe that CSCs are responsible for tumor initiation, propagation, and metastasis. Many of the characteristics of CSCs, such as their slow growth, presence of multi-drug resistance proteins, anti-cell death mechanisms, and upregulated DNA repair machinery, may enable CSCs to resist therapeutic agents traditionally used to treat cancer. Further, while standard therapies may initially shrink tumors by targeting the tumor bulk, which excludes CSCs, there is a large body of evidence indicating that treatment failure, tumor relapse and poor survival are largely the result of the failure of conventional cancer treatments to eradicate CSCs. Accordingly, we believe that targeting CSCs, in addition to the tumor bulk, may represent a major advance in the fight against cancer. This premise has formed the basis of our drug development strategy, as illustrated below.

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GRAPHIC

Since our inception in 2003, we have leveraged our knowledge of CSCs to anticipate and establish a leadership position in this new field of oncology. During this time, we have developed or strategically in-licensed key intellectual property, built and validated a drug discovery platform and developed clinically active drug candidates. We believe that our early and comprehensive effort to develop a new generation of oncology therapeutics that target CSCs as well as the tumor bulk provides us with a significant competitive advantage.

Our most advanced product candidates are SL-401 and SL-701.

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SL-401 is a clinically active biologic-drug conjugate comprised of human interleukin-3 (IL-3) genetically linked to a truncated version of diphtheria toxin. SL-401 targets the IL-3 receptor, or IL-3R, which is overexpressed on both the CSCs and tumor bulk of multiple hematologic cancers, including AML. In contrast, IL-3R is not expressed on normal bone marrow stem cells that form the components of blood. SL-401 demonstrated single agent anti-tumor activity in a completed Phase 1/2 clinical trial of 76 patients with advanced hematologic cancers, including 57 patients with relapsed or refractory AML. With only a single cycle of treatment, SL-401 induced either a reduction in leukemia blasts (i.e., tumor bulk) or disease stabilization in 47% (27/57) of relapsed or refractory AML patients. This included two durable CRs, seven partial responses, or PRs, and improved OS of the 34 most heavily pre-treated AML patients by more than two-fold compared with historical data. In future trials, we intend to administer multiple cycles of SL-401, which we believe may further increase its efficacy with respect to both clinical response and survival. Importantly, SL-401 was not toxic to the bone marrow, which was predicted based on the absence of IL-3R on normal bone marrow stem cells, and is a key differentiating feature relative to many other hematologic cancer therapies. The lack of overlapping toxicities between SL-401 and traditional therapeutics indicates that SL-401 may be combined with standard therapeutic regimens used in early stages of AML. The Phase 1/2 clinical trial, completed for relapsed or refractory AML patients, is still open for patients with advanced myelodysplastic syndrome, or MDS, and chronic myeloid leukemia, or CML.

We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult AML patients as a third-line multiple cycle treatment with OS as the primary endpoint. In addition, we plan to evaluate SL-401 as consolidation and/or maintenance therapy in patients with AML who are in CR following chemotherapy but have a high risk of disease recurrence, as well as in first- and/or second-line AML in combination with chemotherapy, and potentially in certain lymphoid and plasma cell cancers.

In February 2011, SL-401 received Orphan Drug designation from the FDA for the treatment of AML. We hold an exclusive worldwide license with respect to SL-401.

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SL-701 is a clinically active synthetic peptide vaccine that targets several epitopes on CSCs and tumor bulk of brain cancer. In two completed Phase 1/2 clinical trials, SL-701 demonstrated single agent anti-tumor activity in pediatric patients with newly diagnosed brainstem glioma, or BSG, and other high-grade gliomas, or HGGs, and in adult patients with refractory or recurrent GBM, and other HGGs. SL-701 induced tumor shrinkage or disease stabilization in 84% (16/19) of patients in the pediatric study, and 59% (13/22) of patients in the adult study. This includes two CRs and five PRs. Seven of ten pediatric patients with newly diagnosed BSG treated with SL-701 survived past the historical median of 9.6 months, including three children who have survived for periods in excess of 50% greater than the historical median survival. Additionally, the OS of adult patients with recurrent or refractory GBM and other HGGs who were treated with SL-701 was increased compared with historical results for similar patients treated with a wide range of therapies.

We plan to advance SL-701 into a pivotal Phase 2b clinical trial for the treatment of pediatric patients with newly diagnosed BSG. We also plan to initiate a randomized Phase 2b clinical trial in adult second-line GBM, with a development plan designed to culminate in registration. There are also clinical trials currently open for pediatric and adult patients with low-grade glioma, or LGG.

We hold an exclusive worldwide license with respect to SL-701.

We have developed a proprietary discovery platform, StemScreen®, for the identification of novel CSC-targeted compounds. StemScreen® contrasts with traditional drug discovery methods that have been designed to identify compounds that target tumor bulk, not CSCs. StemScreen® includes a cell-based assay that can track CSCs in their natural state during high throughput screening. We believe this approach represents a major technological advance because not only is it CSC-focused and high throughput, but it also does not require artificial manipulation to create CSC-like cells as other systems do. We have utilized StemScreen® to discover a number of our product candidates. We believe that this platform may be instrumental in the discovery of new compounds targeting a wide range of cancer types.

Our intellectual property portfolio includes 13 issued patents and more than 30 pending patent applications in the United States and abroad. This portfolio includes owned and exclusively in-licensed intellectual property that we believe is early and broad with respect to the use of CSC-directed therapeutics and diagnostics (including companion diagnostics), as well as drug discovery.

Management

We are led by a team with extensive experience in managing biopharmaceutical companies and in oncology drug development, including:

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Our Chairman, Chief Executive Officer and President, Ivan Bergstein, M.D., founded Stemline in 2003. He was previously Medical Director of Access Oncology Inc., a private clinical stage oncology-focused biotechnology company. Prior to that, Dr. Bergstein was a biopharmaceuticals analyst in the financial sector. He previously completed a residency and fellowship in internal medicine and hematology-oncology at the New

York Presbyterian Hospital – Weill Medical College of Cornell University.

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Our Chief Medical Officer and Head of Research and Development, Eric K. Rowinsky, M.D., was previously the Chief Medical Officer for ImClone Systems, Inc. Dr. Rowinsky has more than 25 years of experience managing clinical trials and developing drugs in oncology, including leading the FDA approval of Erbitux® for head and neck and colorectal cancers. Dr. Rowinsky currently serves on the Board of Directors of Biogen Idec Inc., as well as several other public biopharmaceutical companies.

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Strategy

Our goal is to maintain and fortify a leadership position in the discovery, acquisition and development of novel oncology therapies that target CSCs. The fundamental components of our business strategy to achieve this goal include the following:

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Be the first anti-CSC-focused company to commercialize a CSC-directed oncology drug. As the most clinically advanced anti-CSC-focused company, we aim to fortify our leadership position and be the first to commercialize a CSC-directed oncology drug.

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Develop and commercialize SL-401 in multiple hematological cancers. We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial with OS as the primary endpoint to treat adult AML patients as a third-line treatment, which is an unmet medical need, as well as pursue other indications in parallel. The SL-401 target, IL-3R, is expressed on a wide variety of hematologic cancers including other forms of leukemia, such as CML, MDS, and acute lymphoid leukemia, as well as lymphomas, such as Hodgkin's disease and multiple myeloma. Accordingly, we believe that SL-401 should be active in multiple hematologic cancers. These indications could represent significant market opportunities for SL-401.

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Develop and commercialize SL-701 in multiple brain cancers. We plan to advance SL-701 into a pivotal Phase 2b clinical trial for the treatment of pediatric patients with newly diagnosed BSG. If successful, we plan to submit a Biologics License Application, or BLA, to the FDA as a basis for marketing approval of SL-701. We also plan to initiate a randomized Phase 2b clinical trial in adult second-line GBM, with a development plan designed to culminate in registration.

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Leverage our proprietary drug discovery platform, StemScreen®, to identify new therapeutics. We intend to utilize our proprietary discovery platform to identify new CSC-targeted drug candidates. We may conduct some of these efforts internally and/or leverage our platform to forge strategic collaborations. We have utilized StemScreen® to identify a number of preclinical drug candidates and may initiate IND-enabling studies either alone or in collaboration with strategic partners.

•

Develop commercialization capabilities in North America and Europe. We believe that the infrastructure required to commercialize our oncology products is relatively limited, which may make it cost-effective for us to internally develop a marketing effort and sales force. If SL-401 and SL-701 are approved by the FDA and other regulatory authorities for first use, we plan to commercialize these products ourselves in North America and Europe through direct sales and distribution. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous.

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Continue to both leverage and fortify our CSC intellectual property portfolio. We believe we have a strong intellectual property position relating to the development and commercialization of CSC-targeted therapeutics, diagnostics, and drug discovery. We plan to continue to leverage this portfolio to create value. In addition to fortifying our existing intellectual property position, we intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

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Clinical Pipeline

The following table summarizes key information about our two most advanced product candidates:

GRAPHIC

Abbreviations:

Acute myeloid leukemia (AML); Myelodysplastic syndrome (MDS); Chronic myeloid leukemia (CML); Tyrosine-kinase inhibitor (TKI); Complete Response (CR); High-grade glioma (HGG); Low-grade glioma (LGG); Brainstem glioma (BSG); Glioblastoma (GBM).

Risks Associated with our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus beginning on page 9. In particular:

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We currently have no commercial products, and we have not received regulatory approval for any of our product candidates.

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We are heavily dependent on the success of our two lead product candidates, SL-401 and SL-701. Positive results in the completed Phase 1/2 clinical trials of SL-401 and SL-701 may not be predictive of the results in our planned Phase 2b clinical trials of SL-401 and SL-701. Our clinical trials may not be successful. If we are unable to obtain required regulatory approvals of, commercialize, obtain or maintain patent protection for or gain sufficient market acceptance by physicians, patients and healthcare payors of our product candidates, or experience significant delays in doing so, our business will be materially harmed and our ability to generate revenue will be materially impaired.

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Our approach to the discovery and development of product candidates that target CSCs is unproven. Research on CSCs is an emerging field and, consequently, there is ongoing debate regarding the existence and importance of CSCs as an underlying cause of tumor initiation, propagation, recurrence and metastasis, as well as the defining characteristics and origins of CSCs. To date, we do not believe that any drugs have been successfully developed to target CSCs for the treatment of cancer.

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We will require substantial additional financing, in addition to the net proceeds of this offering, to achieve our goals. A failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

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We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do. We expect any product candidate that we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. Many of our potential competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. If we are not able to compete effectively against our competitors, our business will not grow and our financial condition and operations will suffer.

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Our inability to obtain adequate patent protection for our product candidates or platform technology or 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. In addition, SL-401 and SL-701 are protected by patents exclusively licensed from third parties. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position will be materially harmed. Any challenges relating to our intellectual property may require us to spend a substantial amount of time and money to resolve.

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We have incurred net operating losses since our inception and, to date, we have not generated any revenues. We expect to incur net operating losses for the foreseeable future and may never achieve or maintain profitability.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in August 2003. Our principal executive offices are located at 750 Lexington Avenue, Sixth Floor, New York, New York 10022 and our telephone number is (646) 502-2310. Our website address is www.stemline.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

In this prospectus, unless otherwise stated or the context otherwise requires, references to "Stemline," "we," "us," "our" and similar references refer to Stemline Therapeutics, Inc. The Stemline name and logo and StemScreen® are our trademarks. The other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

This prospectus 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.

The Offering

Common stock offered by us

shares

Common stock to be outstanding after this offering

shares

Over-allotment option

The underwriters have an option for a period of 30 days to purchase up to additional shares of our common stock to cover over-allotments.

Use of proceeds

We intend to use the net proceeds from this offering for clinical development of SL-401 and SL-701 and other general corporate purposes.

Risk factors

You should read the "Risk Factors" section starting on page 9 of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market Symbol

STML

The number of shares of our common stock outstanding after this offering is based on 1,917,995 actual shares of our common stock outstanding as of March 20, 2012 and (i) additional shares of our common stock issuable upon the assumed conversion of $1,250,000 in principal amount, together with any accrued and unpaid interest, of our 2.45% senior convertible promissory note due 2015, or senior convertible note due 2015, upon the closing of this offering, and (ii) additional shares of our common stock issuable upon the automatic conversion of $0.9 million in aggregate principal amount, together with any accrued and unpaid interest, of our 1.27% convertible promissory notes due 2017, or convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

The number of shares of our common stock outstanding after this offering excludes:

- 1,026,498 shares of our common stock issuable upon the exercise of stock options outstanding as of March 20, 2012 at a weighted-average exercise price of $5.01 per share; and
- 205,769 additional shares of our common stock available for future issuance as of March 20, 2012 under our Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

Unless otherwise indicated, all information in this prospectus assumes:

- the (i) conversion of all outstanding principal amounts on our senior convertible note due 2015 upon the closing of this offering into shares of our common stock and (ii) automatic conversion of all outstanding principal amounts on our convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering into shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering);
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock to cover over-allotments; and
- the amendment and restatement of our amended and restated certificate of incorporation and the amendment and restatement of our bylaws upon the closing of this offering.

In addition, unless otherwise indicated, all information in this prospectus gives effect to the -for- forward stock split of our common stock that was effected on , 2012.

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Summary Financial Information

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statements of operations data for the years ended December 31, 2009, 2010 and 2011 and the balance sheet data as of December 31, 2011 from our audited financial statements included in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Year Ended December 31,			Period from August 8, 2003 (inception) to December 31, 2011
2009	2010	2011	
Statement of operations data:			
Operating expenses:			
Research and development	$ 1,520,225	$ 1,800,507	$ 2,045,253	$ 11,076,403
General and administrative	560,896	459,333	671,801	3,386,488
Total operating expenses	2,081,121	2,259,840	2,717,054	14,462,891
Loss from operations	(2,081,121			

)

(2,259,840

)

(2,717,054

)

(14,462,891

)

Other income:

102,257 484,905 46,673 633,834

Other expense

– – (9,670) (9,670)

Interest expense

– (69,493) (98,643) (178,185)

Interest income

201,088 43,045 24,068 950,676

Net loss

$ (1,777,776) $ (1,801,383) $ (2,754,626) $ (13,066,236)

Less: accretion of preferred stock dividends

(1,100,107) (239,720) – (2,591,165)

Add: discount on redemption of preferred stock

– 12,171,765 – 12,171,765

Net (loss) / income attributable to common stockholders

$ (2,877,883) $ 10,130,662 $ (2,754,626) $ (3,485,636)

Net (loss) / income attributable to common stockholders per common share:

Basic

$ (1.45)

Diluted

$ (1.45)

Weighted average number of common shares:

Basic

1,904,774

Diluted

1,904,774

As of

December 31, 2011

Balance sheet data:

Cash and cash equivalents

$ 5,829,886

Total assets

6,453,096

Long-term liabilities

1,665,346

Deficit accumulated during development stage

(894,473)

Total stockholders' equity

3,205,340

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Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment.

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

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

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

Before we generate any revenues from product sales, we must complete preclinical and clinical development of one or more of our product candidates, obtain manufacturing supply, receive regulatory approval in one or more jurisdictions, build a commercial organization, make substantial investments and undertake significant marketing efforts ourselves or in partnership with others. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

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

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

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

Clinical testing is expensive and, depending on the stage of development, can take a substantial time period to complete. Its outcome is inherently uncertain. In addition, failure can occur at any time

during clinical development. Moreover, regulatory and administrative delays may adversely affect our clinical development plans and jeopardize our ability to attain product approval, commence product sales and generate revenues.

Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- drug product or drug substance storage and distribution;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate that meet specifications for use in clinical trials.

The FDA may require alterations to any of our study designs, our preclinical strategy or our manufacturing plans. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing, or clinical data relating to, or generated by the prior investigator-sponsored trials involving our lead product candidates and our interpretation of preclinical, manufacturing, or clinical data from these clinical trials or require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials. The FDA may not accept our additional preclinical, manufacturing, or clinical data as adequate to initiate our planned trials.

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

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trial is being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in

the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any

clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

•

As we optimize and scale-up production of SL-401 and SL-701, there will be manufacturing, formulation and other process and analytical changes that are part of the optimization and scale-up typically necessary for producing drug substance and drug product of a quality and quantity sufficient for later stage clinical development and commercialization. We will need to demonstrate comparability between newly manufactured drug substance and/or drug product relative to previously manufactured drug substance and/or drug product.

•

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

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We plan to develop SL-701 as a direct subcutaneous injection in future trials. The 701 Ped-G Study used this method of delivery. The 701 Adult-RHGG Study used a different method of delivery, consisting of delivering SL-701 ex vivo to patient-harvested dendritic cells that were then re-injected intra/peri-nodally back into the patient. Thus, our plan continues the pediatric method and represents a change in the adult method.

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We plan to manufacture and formulate SL-701 as a mixture of IL-13Ra2, EphA2 and a helper peptide. In the 701 Ped-G and 701 Adult-RHGG Studies, SL-701 (which is comprised of IL-13Ra2 and EphA2) was mixed with additional peptides, including YKL-40 and GP-100 peptides in the adult study, and survivin peptide in the pediatric study. Given the clinical anti-tumor activity observed in both trials, we believe that the IL-13Ra2 and EphA2 peptides, the common feature of both trials, represent the active components. Thus, we believe that SL-701 need not be mixed with

any additional peptides for clinical activity. Accordingly, while we will continue to evaluate the scientific merit of combining SL-701 with additional peptides, we plan to advance SL-701 into future trials without additional peptides.

•

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

Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

Additionally, we plan to assume control of the overall clinical and regulatory development of SL-401 and SL-701, which were both previously managed by investigators under their own INDs. This transition may include (i) a change to corporate-sponsored INDs which may entail transferring, referring to, or relying on the investigator-sponsored INDs and/or filing our own INDs; (ii) our enhanced corporate oversight and management of quality control and data collection activities for studies conducted under investigator-sponsored INDs; or (iii) a continuation of certain investigator-sponsored studies without our corporate oversight. Because the completed SL-401 and SL-701 clinical trials were investigator-sponsored, we did not control the previous trials' design or conduct. It is possible that the FDA will not view these previous trials as providing adequate support for our planned clinical trials for any one or more reasons, including elements of the design or execution of the previous trials. Also, we are dependent on contractual arrangements with each investigator and their respective academic institutions, which provide us certain information rights with respect to the completed trials, including access to and the ability to use the data, including for our own regulatory filings, resulting from the completed trials. If these obligations are breached by the investigators or institutions, the data prove to be inadequate compared to the first-hand knowledge we might have gained had the completed trials been corporate-sponsored trials, or the FDA disagrees with the adequacy of our right of reference to such data, then our ability to design and conduct our planned corporate-sponsored clinical trials may be adversely affected.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

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 the Company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

•

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

•

we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

•

the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

•

the data collected from clinical trials of our product candidates or the adequacy of our right of reference to it may not be sufficient to support the submission of a BLA or an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

•

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

•

the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics we develop; and

•

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy and costly approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market SL-401 and SL-701, which would significantly harm our business.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label

that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, we may not be able to ultimately achieve the price we intend to charge for our products. Moreover, in many foreign countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

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

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

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

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

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of SL-401 and SL-701, another key element of our strategy is to identify and test additional compounds that target CSCs in a variety of different types of cancer. A significant 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:

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the research methodology used may not be successful in identifying potential product candidates;

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competitors may develop alternatives that render our product candidates obsolete;

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a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

•

a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

•

a product candidate may not be accepted as safe and effective by regulatory authorities, patients, the medical community or third-party payors.

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

Any failure or delay in completing clinical trials for our product candidates may prevent us from obtaining regulatory approval or commercializing product candidates on a timely basis, or at all, which would require us to incur additional costs and delay receipt of any product revenue.

We cannot predict whether we will encounter challenges with any of the planned clinical trials that will cause us or regulatory authorities to delay, suspend or terminate those clinical trials. The completion of clinical trials for product candidates may be delayed or halted for many reasons, including:

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delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;

•

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

•

delays or failure in obtaining the necessary approvals from regulators or institutional review boards in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;

•

our inability to manufacture, or obtain from third parties, adequate supply of drug product sufficient to complete our preclinical studies and clinical trials;

•

delays in patient enrollment, and variability in the number and types of patients available for clinical trials, or high drop-out rates of patients in our clinical trials;

•

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;

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governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or

•

varying interpretations of data by the FDA and similar foreign regulatory agencies.

Additionally, we have not previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate, including our planned clinical trials of SL-401 and SL-701, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

Significant clinical trial delays, including any caused by any of the foregoing factors, could 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. Our product

development costs also will increase if we experience delays in completing clinical trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue the development of any product candidate that is affected or the development of any of our other product candidates.

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

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

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restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, 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 or the imposition of civil 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 since our inception of $13.1 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.

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

Since our inception, most of our resources have been dedicated to the discovery, acquisition and preclinical and clinical development of our product candidates. In particular, we have expended and believe that we will continue to expend substantial resources for the foreseeable future developing our clinical candidates, SL-401 and SL-701, as well as our preclinical product candidates and drug discovery and acquisition efforts. These expenditures will include costs associated with research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

At December 31, 2011, we had $5.8 million of cash and cash equivalents. Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory note in its report on our financial statements as of and for the year ended December 31, 2011 with respect to this uncertainty. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we obtain approval from the FDA or other regulatory authorities and we successfully commercialize one or more of our compounds. Accordingly, our ability to continue as a going concern will require us to seek alternative financing to fund our operations. However, because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or

strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

•

the number and characteristics of the product candidates we pursue;

•

the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;

•

the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

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•

the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;

•

the cost of manufacturing our product candidates and any products we successfully commercialize;

•

our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

•

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

•

the timing, receipt and amount of sales of, or royalties on, our future products, if any.

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

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delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for one or more of our product candidates; or

•

delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

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

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

As has been widely reported, global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult to secure, more costly, and/or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon our business and

clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. There is a possibility that our stock price may decline, due in part to the volatility of the stock market and the general economic downturn.

Risks Related to Our Business and Industry

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

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

- execute product candidate development activities;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- maintain, leverage and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for our products;
- develop and maintain any strategic relationships we elect to enter into; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals and commercialization.

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

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

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

We expect any product candidate that we commercialize will compete with products from other companies in the biotechnology and pharmaceutical industries. For example, there are a number of biopharmaceutical companies focused on developing therapeutics that target CSCs, including Boston Biomedical, Inc., Eclipse Therapeutics, Inc., OncoMed Pharmaceuticals, Inc. and Verastem, Inc. There are also several biopharmaceutical companies that do not appear to be primarily focused on CSCs, but may be developing at least one CSC-directed compound. These companies include Astellas Pharma US, Inc., Boehringer Ingelheim GmbH, Dainippon Sumitomo Pharma Co. Ltd., Geron Corp.,

GlaxoSmithKline plc, ImmunoCellular Therapeutics, Ltd, Macrogenics Inc., Micromet, Inc. (an Amgen, Inc. Company), Pfizer Inc., Roche Holding AG, Sanofi U.S. LLC, and others. Additionally, there are a number of companies working to develop new treatments for AML, which may compete with SL-401, including Ambit Biosciences Corporation, Celator Pharmaceuticals, Inc., Celgene Corporation, Clavis Pharma ASA, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Genzyme Corporation (now a Sanofi company), and Sunesis Pharmaceuticals, Inc., among others. There are also a number of drugs used for the treatment of brain cancer that may compete with SL-701, including, Avastin® (Roche Holding AG), Gliadel® (Eisai Co. Ltd.), and Temodar® (Merck & Co., Inc.). There are a number of companies working to develop brain cancer therapeutics with programs in clinical testing including Celldex Therapeutics, Inc., ImmunoCellular Therapeutics, Ltd., Merck & Co. Inc., Novartis AG, Roche Holding AG and others.

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

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design and develop products that are superior to other products in the market;

•

attract qualified scientific, medical, sales and marketing and commercial personnel;

•

obtain patent and/or other proprietary protection for our processes and product candidates;

•

obtain required regulatory approvals; and

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collaborate with others in the design, development and commercialization of new products.

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly Ivan Bergstein, M.D., our Chairman, Chief Executive Officer and President, and Eric K. Rowinsky, M.D., our Executive Vice President, Chief Medical Officer and Head of Research and Development, as well as other employees, consultants and scientific and medical collaborators. As of March 9, 2012, we had seven 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 intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care 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.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. Despite the adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

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

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

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

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

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;

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

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $5.0 million in the aggregate. Although we maintain such 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

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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, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false

statement to avoid, decrease or conceal an obligation to pay money to the federal government;

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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 health care providers, health plans and health care clearinghouses, and also 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;

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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;

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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;

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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 health care providers or marketing expenditures; and

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

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

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

•

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

•

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

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

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

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

Even if SL-401, SL-701 or any other product candidate that we may develop or acquire in the future obtains regulatory approval, the product may not gain market acceptance among physicians, health care 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:

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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;

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the clinical indications for which our products are approved;

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acceptance by physicians, major operators of cancer clinics and patients of our products as a safe and effective treatment;

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

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

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

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

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

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made

permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, 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 D program. ACA is currently being challenged in the courts, and there are also Congressional efforts to repeal ACA. This adds to the uncertainty of the legislative changes enacted as part of ACA, and we cannot predict the impact that ACA or any other legislative or regulatory proposals will have on our business. Regardless of whether or not the ACA is overturned or repealed, we expect both government and private health plans to continue to require healthcare providers, including healthcare providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

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

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. 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 and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates, such as SL-401 or SL-701, were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama, 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

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:

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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;

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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;

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the competitiveness of any product candidate that is commercialized could be reduced; and

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with respect to our platform technology, StemScreen®, we may not realize its potential as a means of identifying and validating new cancer therapies.

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

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

We also expect to rely upon third parties to produce drug product required for the clinical trials and commercialization of our other product candidates. If we are unable to arrange for third-party

manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such other product candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. We will be dependent on the ability of these third-party manufacturers to produce adequate supplies of drug product to support our clinical development programs and future commercialization of our product candidates. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We have limited staffing and rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we use to manufacture

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

We are optimizing the manufacturing processes for SL-401 and SL-701 drug substance and drug product so that these product candidates may be produced in adequate quantities of adequate quality, and at an acceptable cost, to support our planned clinical trials and ultimate commercialization. Our manufacturers may not be able to 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, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

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, and expect to continue to 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 conducted these trials wholly by ourselves. 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.

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

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

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

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to

such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

Risks Related to Our Intellectual Property Rights

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

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

Our patents and patent applications may not be sufficient to protect our products and product candidates from commercial competition. For example, we cannot obtain a composition of matter patent for SL-401 due to earlier published prior art. We have obtained a U.S. patent for the method of using SL-401 to treat MDS. In addition, we have filed U.S. and foreign patent applications for the method of using SL-401 to treat MDS and AML, our lead indication, although there can be no assurances that such patents will be issued over the prior art. Failure to obtain patents directed to the use of SL-401 to treat AML (or any other indication) would enable a competitor to market SL-401 for such unpatented indication(s), which could lead to price erosion for sales of SL-401 for our patented indications through off-label use. Although we have an issued U.S. patent directed to the composition of matter for our mutant immunogenic IL-13Ra2 peptide used in SL-701, we do not have any foreign composition of matter patent protection. We do not expect that we will be able to obtain such protection outside the U.S. in the future. Although we have a non-exclusive license to issued U.S. patents directed to methods of use for the EphA2 peptide used in SL-701, we do not have any composition of matter patent protection. We do not expect that we will be able to obtain such protection in the future.

Although we have various patent applications pending in the U.S. and abroad that we hope will result in additional protection for both SL-401 and SL-701, there can be no assurance that any of these applications will issue into a patent, or that if they issue, they will provide meaningful protection for SL-401 and SL-701. Our inability to obtain adequate patent protection for our product candidates or platform technology could adversely affect our business.

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

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot

be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology, StemScreen®. Such a loss of patent protection could have a material adverse impact on our business.

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

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

It is also possible that we failed to identify relevant patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

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

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

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

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

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

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

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

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

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

We are a party to several license agreements under which certain aspects of our business depend on patents and/or patent applications owned by other institutions. In particular, we hold exclusive licenses from Scott and White Memorial Hospital, or Scott and White, for SL-401 and three licenses, including an exclusive license, from the University of Pittsburgh for SL-701. Our license agreement with Scott and White survives, unless earlier terminated, until the later of the expiration of the last to expire licensed patent or the date on which we owe no further payments to Scott and White. Our exclusive and our non-exclusive patent license agreements with the University of Pittsburgh survive, unless earlier terminated, until the expiration of the last to expire licensed patent, and our non-exclusive license to

clinical trial data and information survives twenty years unless terminated earlier. We are likely to enter into additional license agreements as part of the development of our business in the future. Our licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In addition, in spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. Our licensors may also terminate the license agreements if we fail to meet specified milestones. If these in-licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

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

We believe that an important factor in our competitive position relative to other companies in the field of targeted oncology therapeutics is our proprietary innovative platform technology, StemScreen®. This platform is useful for identifying new potential product candidates. We have pending applications for StemScreen®, however, there is no guarantee that any of such pending patent applications, in the United States or elsewhere, will result in issued patents, and, even if patents eventually issue, there is no certainty that the claims in the eventual patents will have adequate scope to preserve our competitive position. Third parties might invent alternative technologies that would substitute for our platform technology while being outside the scope of the patents covering our platform technology. By successfully designing around our patented technology third parties could substantially weaken our competitive position in oncology research and development.

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

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

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the

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outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

•

Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

•

We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.

•

We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions.

•

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.

•

It is possible that our pending patent applications will not lead to issued patents.

•

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

•

Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

•

We may not develop additional proprietary technologies that are patentable.

•

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharma industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharma patents is costly, time-consuming and inherently uncertain. In addition, Congress may pass patent reform legislation. 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 and this Offering

After this offering, our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately % of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to control 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 control 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 that will become effective upon the closing of this offering 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. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

•

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

•

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

•

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

•

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

•

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

•

limit who may call stockholder meetings;

•

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

•

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

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

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the book value of your shares.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our stock but will own only approximately % of our common stock outstanding after this offering. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

We do not know whether a market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering, there has been no public market for our common stock. Although we are applying to have our common stock listed on the NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all. The initial public offering price for our common stock will be determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price for our common stock after this offering. The initial public offering price may vary from the market price of our common stock after the offering. As a result of these and other factors, you may not be able to sell your shares of our common stock at or above the initial public offering price or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be 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 will 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. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

- our ability to commercialize our product candidates, if approved;
- results from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;

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

•

our dependence on third parties, including CROs, clinical trial sponsors and clinical investigators;

•

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

•

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

•

the recruitment or departure of key scientific or management personnel;

•

the level of expenses related to any of our product candidates or clinical development programs;

•

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

•

variations in our financial results or those of companies that are perceived to be similar to us;

•

sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;

•

changes in the structure of healthcare payment systems;

•

market conditions in the pharmaceutical and biotechnology sectors;

•

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

•

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of March 20, 2012. This includes the shares that we are selling in this offering, which may be resold in the

public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the "Shares Eligible for Future Sale" section of this prospectus. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

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. Securities and industry analysts do not currently, and may never, publish research on our Company. If no or too few securities or industry analysts commence coverage of our Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, 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.

Special Note Regarding Forward-Looking Statements

This prospectus 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 prospectus and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drugs targeting cancer stem cells, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, 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 prospectus. 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 prospectus, they may not be predictive of results or developments in future periods.

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

- the success and timing of our preclinical studies and clinical trials;

- our ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans to develop and commercialize our product candidates;
- the loss of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- our use of the proceeds from this offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain and maintain intellectual property protection for our product candidates;

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- the successful development of our sales and marketing capabilities;
- the performance of third-party manufacturers; and
- our ability to successfully implement our strategy.

Any forward-looking statements that we make in this prospectus 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 prospectus. You should also read carefully the factors described in the "Risk Factors" section of this prospectus 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 prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

This prospectus 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.

Use of Proceeds

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $, assuming an initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds from this offering by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for clinical development of SL-401 and SL-701 and other general corporate purposes:

- SL-401. We plan to advance SL-401 into a randomized Phase 2b clinical trial to treat adult AML patients as a third-line treatment. Our current estimate for the cost associated with completing the trial is approximately $.
- SL-701. We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat pediatric patients with newly diagnosed BSG. We also plan to initiate a randomized Phase 2b clinical trial of SL-701 in adult second-line GBM. Our current estimate for the aggregate cost associated with completing these trials is approximately $.
- The remaining proceeds will be used to fund working capital, capital expenditures and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2011:

- on an actual basis;
- on a pro forma basis to give effect to:
- a -for- forward stock split of our common stock to be effected prior to the closing of this offering;
-

the issuance of shares of our common stock upon the closing of this offering as a result of the conversion of our senior convertible note due 2015 in the principal amount of $1.25 million we issued on March 16, 2010, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and assuming the conversion occurs on , 2012 (the expected closing date of this offering); and

•

the issuance of shares of our common stock upon the closing of this offering as a result of the automatic conversion and/or cancellation of our convertible notes due 2017 in the aggregate principal amount of $0.9 million that we issued in December 2011 and January 2012, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

•

on a pro forma as adjusted basis to give further effect to the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with "Selected Financial Data," our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

As of December 31, 2011

Actual Pro Forma Pro Forma as

Adjusted(1)

Cash and cash equivalents

$ 5,829,886 $ $

Long-term liabilities

1,665,345

Common stock, $0.0001 par value, 3,000,000 shares authorized and 1,904,774 shares issued and outstanding, actual; and shares authorized and shares issued and outstanding, pro forma; shares authorized and shares issued and outstanding, pro forma as adjusted

191

Additional paid-in capital

4,099,622

Accumulated deficit

(894,473)

Total stockholders' equity

3,205,340

Total capitalization

$ 959,201 $ $

(1)

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

The table above does not include:

•

682,380 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2011 at a weighted-average exercise price of $4.53 per share; and

•

21,429 additional shares of our common stock available for future issuance as of December 31, 2011 under our Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this initial public offering.

Our historical net tangible book value as of December 31, 2011 was $(2,805,341), or $(1.47) per share of our common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

Our pro forma net tangible book value as of December 31, 2011 was $, or $ per share of our common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the pro forma number of shares of our common stock outstanding after giving effect to (i) the assumed conversion of all principal and accrued and unpaid interest on our senior convertible note due 2015 upon the closing of this offering into shares of our common stock and (ii) the automatic conversion of all principal and accrued and unpaid interest on our convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering into shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

After giving effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2011 would have been $, or $ per share. This represents an immediate increase in pro forma net tangible book value per share of $ to existing stockholders and immediate dilution of $ in pro forma net tangible book value per share to new investors purchasing common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis.

Assumed Initial Public Offering Price Per Share

$

Historical Net Tangible Book Value Per Share as of December 31, 2011

$ (2,805,341)

Increase Attributable to the Conversion of Convertible Notes

Pro Forma Net Tangible Book Value Per Share as Of December 31, 2011

Increase in Net Tangible Book Value Per Share Attributable To New Investors

Pro Forma Net Tangible Book Value Per Share After This Offering

Dilution Per Share to New Investors

$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) our pro forma net tangible book value by approximately $, our pro forma net tangible book

value per share by approximately and dilution per share to new investors by approximately

$, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their over-allotment option or if any additional shares are issued in connection with outstanding options, you will experience further dilution.

The following table summarizes, on a pro forma basis as of December 31, 2011, the total number of shares purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

Shares purchased Total consideration

Average Price

Per Share

Number Percentage Amount Percentage

Existing stockholders

% $ % $

New investors

Total

100 % $ 100 %

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table above is based on shares of our common stock outstanding as of December 31, 2011 and (i) additional shares of our common stock issuable upon the assumed conversion of all principal and accrued and unpaid interest on our senior convertible note due 2015, upon the closing of this offering, and (ii) additional shares of our common stock issuable upon the automatic conversion of all principal and accrued and unpaid interest on our convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

The table above excludes:

•

682,380 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2011 at a weighted-average exercise price of $4.53 per share; and

•

21,429 additional shares of our common stock available for future issuance as of December 31, 2011 under our Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

If the underwriters exercise their over-allotment option in full, the following will occur:

•

the percentage of shares of our common stock held by existing stockholders will decrease to approximately % of the total number of shares of our common stock outstanding after this offering; and

•

the number of shares of our common stock held by new investors will increase to , or approximately % of the total number of shares of our common stock outstanding after this offering.

Selected Financial Data

You should read the following selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statements of operations data for the years ended December 31, 2009, 2010 and 2011 and the balance sheet data as of December 31, 2010 and 2011 from our audited financial statement included in this prospectus. We have derived the statements of operations data for the years ended December 31, 2007 and 2008 and the balance sheet data as of December 31, 2007, 2008 and 2009 from our financial statements not included in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Year Ended December 31, Period from

August 8, 2003

(inception) to

December 31, 2011

2007 2008 2009 2010 2011

(unaudited)

(unaudited)

Statement of operations data:

Revenue

$ – $ – $ – $ – $ – $ –

Operating expenses:

Research and development

$ 1,540,831 $ 1,850,702 $ 1,520,225 $ 1,800,507 $ 2,045,253 $ 11,076,403

General and administrative

201,306 345,984 560,896 459,333 671,801 3,386,488

Total operating expenses

1,742,137 2,196,686 2,081,121 2,259,840 2,717,054 14,462,891

Loss from operations

(1,742,137) (2,196,686) (2,081,121) (2,259,840) (2,717,054) (14,462,891)

Other income:

– – 102,257 484,905 46,673 633,834

Other expense

– – – – (9,670) (9,670)

Interest expense

(10,043) – – (69,493) (98,643) (178,185)

Interest income

180,425 376,578 201,088 43,045 24,068 950,676

Net loss

$ (1,571,755) $ (1,820,108) $ (1,777,776) $ (1,801,383) $ (2,754,626) $ (13,066,236)

Less: accretion of preferred stock dividends

(230,137) (1,021,201) (1,100,107) (239,720) – (2,591,165)

Add: discount on redemption of preferred stock

– – – 12,171,765 – 12,171,165

Net (loss) / income attributable to common stockholders

$ (1,801,892) $ (2,841,309) $ (2,877,883) $ 10,130,662 $ (2,754,626) $ (3,485,636)

Net (loss) / income attributable to common stockholders per common share:

Basic

$ (1.45)

Diluted

$ (1.45)

Weighted average number of common shares:

Basic

1,904,774

Diluted

1,904,774

As of December 31,

2007 2008 2009 2010 2011

(unaudited)

(unaudited)

Balance sheet data:

Cash and cash equivalents

$ 3,446,709 $ 2,196,881 $ 9,236,395 $ 7,226,366 $ 5,829,886

Total assets

12,555,854 10,856,476 9,329,341 7,502,912 6,453,096

Long-term liabilities

– – – 1,017,033 1,665,346

Deficit/earnings accumulated during development stage

4,912,345 6,732,453 8,510,229 1,860,153 (894,473)

Total stockholders' (deficit)/equity

(657,938) (3,355,509) (6,162,215) 5,851,561 3,205,340

Management's Discussion and Analysis of Financial Condition

and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells, or CSCs, and tumor bulk. We believe that we are developing the most clinically advanced pipeline of anti-CSC therapeutics and that we hold a broad portfolio of CSC-focused intellectual property, establishing us as a leader in the CSC field. Among the therapeutic candidates in our portfolio, we are currently developing two clinical-stage product candidates, SL-401 and SL-701, for which we hold global marketing rights. The lead indication for SL-401, a biologic-drug conjugate, is acute myeloid leukemia, or AML. The lead indications for SL-701, a synthetic peptide vaccine, are pediatric and adult brain cancer. In completed Phase 1/2 clinical trials, both SL-401 and SL-701 have demonstrated single agent activity, including durable complete responses, or CRs, and longer overall survival, or OS, for patients compared with that achieved in the past with traditional therapies. We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult relapsed or refractory AML patients who failed two previous treatments (i.e., third-line AML) with OS as the primary endpoint. We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat pediatric patients with newly diagnosed brain stem glioma, or BSG. In addition, we plan to advance SL-701 into a randomized Phase 2b clinical trial in adult second-line glioblastoma, or GBM, with a development plan designed to culminate in registration. We have developed a proprietary discovery platform, StemScreen®, for the discovery of novel CSC-targeted compounds, from which we have discovered several of our product candidates and which we believe may be instrumental in the discovery of additional new therapies targeting a wide range of cancer types.

We are a development stage company. Since our inception in 2003, we have devoted substantially all of our resources to developing our product candidates and our platform technology, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. We have not generated any revenues and, to date, have funded our operations primarily through sales of common stock and convertible preferred stock and issuances of convertible debt to our investors. From inception through December 31, 2011, we have received net proceeds of $3.8 million from the sale of common stock, $12.5 million from the sale of convertible preferred stock and $0.5 million from the issuance of convertible debt.

We have never been profitable and, from inception to date, our losses from operations have been $13.1 million. Our net loss from operations was $2.8 million for the year ended December 31, 2011, $1.8 million for the year ended December 31, 2010 and $1.8 million for the year ended December 31, 2009. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Furthermore, upon the closing of

this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Obligations Related to the License and Development of SL-401 and SL-701

SL-401

In June 2006, we entered into a research and license agreement with Scott and White Memorial Hospital, or Scott and White, for SL-401. Under the agreement, as amended, Scott and White granted us an exclusive, royalty-bearing, worldwide license under certain patent rights, know-how

and materials to research, develop, make, have made, formulate, use, sell, offer to sell and import SL-401 and any products containing or comprising such compound in finished dosage pharmaceutical form, for the diagnosis, prophylaxis and/or treatment of any disease or condition in humans or animals.

Pursuant to the research and license agreement, we are required to pay Scott and White royalties based on adjusted gross sales, by us or our sublicensees, of products containing the licensed compound for a period of ten years following the first commercial sale of each product in each country. The royalty rates for each product are in the single digits and tiered based on our annual sales.

We paid Scott and White fees totaling $0.7 million for its conduct of the research program through December 31, 2011. Under the agreement, we are obligated to pay up to an additional $150,000 in quarterly installments of less than $20,000 unless we terminate the research program prior to its expiration.

SL-701

In September 2009, we entered into an exclusive license agreement with the University of Pittsburgh, or the University, for the composition of matter, and use with other components, of an active ingredient of SL-701, our brain cancer vaccine candidate. Under the agreement, the University granted us an exclusive worldwide license under certain patent rights to make, have made, use, sell and import such active ingredient as a component of brain cancer vaccines.

We paid the University an initial license fee and will pay the University annual license maintenance fees until the net sales of a licensed product exceed a specified threshold amount. We must pay the University a single digit royalty as a percentage of net sales of licensed products by us or any sublicensees, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize the licensed products. We must also pay a minimum annual royalty following the first commercial sale of a licensed product, but only to the extent the minimum annual royalty amount is greater than the annual royalty otherwise due. We also must pay the University a percentage of non-royalty revenue we receive from our sublicensees, which decreases if we enter into the applicable sublicense agreement after a certain clinical milestone has been met. We also must make certain one-time payments of up to approximately $4.1 million to the University upon the achievement of specific regulatory and commercial milestone events.

In March 2012, we entered into a non-exclusive license agreement with the University for the use of another active ingredient of SL-701. Under the agreement, the University has granted us a non-exclusive worldwide license under certain patent rights to use this other active ingredient in or

packaged with vaccines we may develop and own or exclusively control, including SL-701, for the diagnosis, treatment or prevention of diseases and tumors of the brain in human patients.

We are obligated to pay the University an initial license fee, and will pay the University annual license maintenance fees until the net sales of a licensed product exceed a specified threshold amount. We must also pay the University a single digit royalty as a percentage of net sales of licensed products by us or any sublicensees, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize the licensed products. We must also pay a minimum annual royalty following the first commercial sale of a licensed product, but only to the extent the minimum annual royalty amount is greater than the annual royalty otherwise due.

In March 2012, we also entered into a non-exclusive license agreement with the University under which we acquired a non-exclusive, worldwide license to use certain know-how information and data that is contained in the INDs covering the clinical trials of SL-701 that were conducted by the University for the development, manufacture, regulatory approval and commercialization of pharmaceutical products.

We are obligated to pay the University an initial license fee and have agreed to make certain payments following specified regulatory milestones. We also must pay the University a percentage of non-royalty revenue we receive from our sublicensees.

Financial Operations Overview

Revenue

We have not generated any revenue to date. In the future, we may generate revenue from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of payments that we may recognize upon the sale of our products, to the extent that any products are successfully commercialized, and the amount and timing of fees, reimbursements, milestone and other payments received under any future licensing or collaboration arrangements. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

The following table shows our research and development expenses for the years ended December 31, 2009, 2010 and 2011:

2009 2010 2011

Clinical (SL-401 and SL-701)

$ 1,486,170 $ 1,697,736 $ 1,982,368

Preclinical

34,055 102,771 62,885

Total

$ 1,520,225 $ 1,800,507 $ 2,045,253

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

•

clinical trial costs;

•

patent-related legal costs;

•

employee-related expenses, including salaries, benefits, travel and stock-based compensation expense, and consultant costs;

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•

external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, contract manufacturing organizations, or CMOs, academic institutions, and consultants;

•

license fees and milestone payments related to in-licensed products and technology; and

•

facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and supplies.

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

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

We anticipate that our research and development expenses will increase significantly in future periods as we seek to complete development of our most advanced product candidates, SL-401 and SL-701, and continue to develop our other product candidates and our platform technology. The clinical development and regulatory strategies for our lead product candidates are as follows:

•

SL-401. We plan to advance SL-401 into a randomized Phase 2b clinical trial to treat adult AML patients as a third-line treatment. Our current estimate for the cost associated with completing the trial is approximately $.

•

SL-701. We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat pediatric patients with newly diagnosed brainstem glioma, or BSG. We also plan to initiate a randomized Phase 2b clinical trial of SL-701 in adult second-line glioblastoma, or GBM. Our current estimate for the aggregate cost associated with completing these trials is approximately $.

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

•

the scope, rate of progress and costs of our planned, as well as any additional, clinical trials and other research and development activities;

•

future clinical trial results;

•

the potential benefits of our product candidates over other therapies;

•

our ability to market and commercialize, either on our own or with strategic partners, and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;

•

the costs, timing and outcome of regulatory approvals; and

•

the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

A change in the outcome of any of these or similar variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation expense, operations, finance and business development functions. Other general and administrative expenses include facility costs, insurance expenses and professional fees for legal, consulting and accounting services.

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

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Interest Expense

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

Critical Accounting Policies and Estimates

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

Our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this prospectus. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The

majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include fees paid to CROs, consultants and other third party organizations in connection with research and development activities and administrative activities for which we have not yet been invoiced.

We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period.

Income Taxes

We use the liability method of accounting for income taxes as set forth in the authoritative guidance for income taxes. Under this method, we recognize deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the respective carrying amounts and tax bases of our assets and liabilities.

We continue to assess the realizability of our deferred tax assets, which primarily consist of net operating loss, or NOL, carry-forwards. In assessing the realizability of these deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. We establish valuation allowances when necessary to reduce deferred tax assets to the amounts expected to be realized. The factors used to assess the likelihood of realization include our latest forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. As of December 31, 2011 and 2010, our deferred tax assets had full valuation allowances on them as we did not have sufficient positive evidence to recognize such deferred tax assets at that time.

The Internal Revenue Code of 1986, as amended (the "Code"), provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the Code) that could limit the Company's ability to utilize these carryforwards, At this time, the Company has not completed a study to assess whether an ownership change under section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation, due to the costs and complexities associated with such a study. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financing transactions. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

If any of our products are approved for commercial sale and we start to realize profitability, we may determine that there is sufficient positive evidence to support a reversal of, or decrease in, the valuation allowance. If we were to reverse all or some part of our valuation allowance, our financial

statements in the period of reversal would likely reflect an increase in assets on our balance sheet and a corresponding tax benefit to our statement of operations in the amount of the reversal.

As of December 31, 2011, we had U.S. federal net operating loss carryforwards of $10.9 million and research and development credits of $0.4 million which expire in 2023 through 2031.

We adopted Accounting Standards Codification (ASC) 740-10, Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109, on January 1, 2007. We analyzed our tax position in all jurisdictions where we are required to file an income tax return and concluded that we do not have any material unrecognized tax benefits. We filed a U.S. income tax return as well as returns for any state jurisdiction in which we are authorized to conduct business. Our policy is to recognize interest and penalties accrued on any unrecognized tax benefit within the provision for income taxes on the statement of operations. We have no interest or penalties accrued for any unrecognized tax benefits for any periods presented.

Our annual provision for income taxes and the determination of the resulting deferred tax assets and liabilities involve a significant amount of management judgment. Management's judgments, assumptions and estimates relative to the current provision for income taxes take into account current tax laws, our interpretation of current tax laws and possible outcomes of current and future audits conducted by foreign and domestic tax authorities. We operate within federal, state and international taxing jurisdictions and are subject to audit in these jurisdictions. These audits can involve complex issues that may require an extended period of time to resolve.

Stock-Based Compensation

In accordance with ASC 718, Stock Compensation, we account for stock options issued to employees using a fair-value-based method, under which we measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant-date fair value of the award. The resulting cost is recognized for the awards expected to vest over the period during which an employee is required to provide service in exchange for the award, usually the vesting period.

In accordance with ASC 505-50, Equity-Based Payments to Non-Employees, we account for stock options issued to non-employees on a fair-value-based method as well; however, the fair value of the options granted to non-employees is remeasured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as income or loss during the period the related services are rendered.

The fair value of the stock options issued to employees and non-employees was estimated at each grant date using the Black-Scholes option-pricing model. One of the inputs to this model is the estimate of the fair value of the underlying common stock on the date of grant. The other inputs include an estimate of the expected volatility of the stock price, an option's expected term, the risk-free interest rate over the option's expected term, the option's exercise price, and our expectations regarding dividends.

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

Year Ended December 31,

2010 2011

Research and development

$ 50,311 $ 79,955

General and administrative

30,224 28,450

Total

$ 80,535 $ 108,405

We do not have a history of market prices for our common stock because our stock is not publicly traded. We utilized the observable data for a group of public peer companies that grant options with substantially similar terms to assist in developing our volatility assumption. We derived our expected term assumption based on the simplified method, if applicable, which results in an expected term based on the midpoint between the vesting date and the contractual term of an option. The simplified method was chosen because we have limited historical option exercise experience because our Company was privately held. The expected term for options issued to non-employees was determined based on the

contractual term of the awards. The weighted-average risk-free interest rate was based on a zero coupon U.S. Treasury instrument whose term was consistent with the expected life of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield was assumed to be zero.

A summary of the significant assumptions used to estimate the fair value of employee and non-employee equity awards for the years ended December 31, 2011 and 2010 is as follows:

Year Ended December 31,

2010 2011

Expected term

6.02 6.26

Risk-free interest rate

2.78 % 2.66 %

Volatility

74.5 % 72.9 %

Dividend yield

0 % 0 %

If factors change and we employ different assumptions, stock-based compensation cost on future awards may differ significantly from what we have recorded in the past. Higher volatility and longer expected terms result in an increase to stock-based compensation determined at the date of grant. Future stock-based compensation cost and unrecognized stock-based compensation will increase to the extent that we grant additional equity awards to employees or we assume unvested equity awards in connection with acquisitions. If there are any modifications of the underlying unvested securities, we may be required to accelerate any remaining unearned stock-based compensation cost or incur incremental cost. Stock-based compensation cost affects our research and development, and selling, general, and administrative expenses.

Assuming a fair value of our common stock of $5.61 at December 31, 2011, the aggregate intrinsic value of the vested and unvested options to purchase shares of our common stock outstanding as of December 31, 2011, was $1.2 million.

We estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior, and other factors. Changes in the estimated forfeiture rate can have a significant effect on reported stock-based compensation expense, because the cumulative effect of adjusting the rate for all expense amortization is recognized in the period the forfeiture estimate is changed. The effect of forfeiture adjustments during 2011 and 2010 was insignificant.

Significant Factors, Assumptions, and Methodologies Used in Estimating Fair Value of Common Stock

On March 26, 2009 our board of directors engaged in a review of the Company's valuation. The board of directors considered the status of the Company's product pipeline, the Company's StemScreen® platform for identifying novel compounds that target and kill CSCs, the asset value of the Company (comprised of intellectual property rights and current cash on hand), the present value of future cash flows of the Company as a clinical and development stage company, the Company's capital structure (including the repurchase during 2010 of all of its outstanding preferred stock and the removal of the corresponding liquidation preference), and the Company's acquisition potential. The board of directors

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also considered additional factors, including the Company's existing licensing and research agreements, intellectual property, funding prospects, the funding prospects and valuations of similar companies, the ability of the management team and the Company's access to financing. Based on the foregoing review, the board of directors determined that the per share value of the Company's common stock was equal to $4.00 on March 26, 2009.

We also performed a valuation to estimate the fair value of our common stock for the options granted during the 12-month period ended December 31, 2011. The per share exercise price, fair value of underlying shares and fair value of the option awards as of the respective dates of valuation are as follows:

Date of Grant Number of Options

Granted Exercise Price per Share

of Common Stock Fair Value of

Underlying Share of

Common Stock Grant Date Fair Value

per Option Award

March 8, 2011

124,000 $ 5.27 $ 5.61 $ 3.81

The exercise prices for options granted were set by our board of directors, the members of which have extensive experience in the life sciences industry, based on the group's determination of the fair market value of our common stock at the time of the grants. The board of directors considered the status of the Company's product pipeline and the progress since the last valuation date, the Company's StemScreen® platform for identifying novel compounds that target and kill CSCs, the asset value of the Company (comprised of intellectual property rights and current cash on hand, which was less than the previous valuation), the present value of future cash flows of the Company as a clinical and development stage company, the Company's capital structure (including the repurchase during 2010 of all of its outstanding preferred stock and the removal of the corresponding liquidation preference), the valuation of comparable companies and the Company's acquisition potential. The board of directors also considered additional factors, including the Company's existing licensing and research agreements, intellectual property, funding prospects, the funding prospects and valuations of similar companies, the growth prospects of the biopharmaceutical industry in general and oncology companies focused on CSC targets specifically, expected regulatory and commercial hurdles to commercializing or licensing the Company's clinical candidates, the ability of the management team and the Company's access to financing. Based on the foregoing review, the board of directors determined that the fair market value of the common stock underlying options to purchase 124,000 shares granted on March 8, 2011 was determined to be $5.27 per share at the time of grant.

However, in connection with the preparation of the financial statements for a public offering, we performed a retrospective determination of fair value for financial reporting purposes of our common stock underlying stock options utilizing a combination of valuation methods described in the AICPA Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid, using a more sophisticated method to determine fair market value.

Determining the fair value of the common stock of a private enterprise requires complex and subjective judgments. Our retrospective estimate of enterprise value at March 31, 2010, March 31, 2011 and January 30, 2012 used results from both the income approach and the market approach.

Under the income approach, our enterprise value was based on the present value of our forecasted operating results. Our revenue forecasts were based on our estimates of expected annual growth rates following the anticipated commercial launch of our lead product candidates SL-401 and SL-701. Estimated operating expenses were based on our internal assumptions, including continuing research, development activities for SL-401 and SL-701 and other clinical and preclinical product candidates and our platform technology, and preparation and ongoing support for the commercialization of our lead product candidates. The assumptions underlying the estimates are consistent with our business plan. The risks associated with achieving our forecasts were assessed in selecting the appropriate discount rates, which were approximately 25%.

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Under the market approach, our estimated enterprise value was developed based on a comparison of pre-money initial public offering, or IPO, values of recent biotechnology and emerging pharmaceutical companies at a similar stage of development to ours.

Once our enterprise value was established, the enterprise value was allocated to the different classes of equity instruments. Our board of directors engaged in a retrospective review during which we used the probability weighted expected returns, or PWER, method to allocate our enterprise value to our common stock. Under the PWER method, the value of common stock is estimated based upon an analysis of future values for the enterprise assuming various future outcomes. In our retrospective review, the future outcomes included three scenarios: (i) we become a public company, (ii) we merge with or are acquired by another company, and (iii) we sell our intellectual property and other assets. We used a low probability assumption for an IPO when valuing our 2011 grants, and this percentage was expected to increase over time as we continue to have discussions with our investment bankers and continue to increase as we prepared for an IPO. An increase in the probability assessment for an IPO increases the value ascribed to our common stock while a decrease in that probability has the opposite effect on the value ascribed to our common stock.

Estimated future and present values for the common stock were calculated using assumptions including:

•

our expected pre-IPO valuation;

•

a risk-adjusted discount rate associated with the IPO scenario;

•

the liquidation preferences of our redeemable convertible preferred stock;

•

the appropriate discount for lack of marketability assuming we remain a private company;

•

the expected probability of completing an IPO versus remaining a private company or completing a merger or acquisition; and

•

the estimated timing of a potential IPO.

The retrospective fair value of our common stock on March 31, 2010 was determined based on the following factors: the outlook of the oncology market at such time and the likelihood of completing an IPO or merger or sale transaction, offset by general market conditions. Relying primarily on the PWER method, the retrospective fair value of our common stock on March 31, 2010 was determined to be $5.34 per share.

The retrospective fair values of our common stock increased throughout 2010 and into 2011. The increases in the fair value of the common stock took into account changes in the following factors: the improved outlook in the oncology market in general and oncology companies focused on CSC targets specifically, the advancement of our product candidates, the increased likelihood of completing an IPO or merger or sale transaction and the improvement in general market conditions. Relying primarily on the PWER method, the retrospective fair value of our common stock on March 31, 2011 was determined to be $5.61 per share.

The fair value of our common stock was estimated again as of January 30, 2012. The fair value of the common stock on that date took into account changes in the following factors:

•

the presentation of SL-401 data at the annual American Society of Hematology (ASH) conference;

•

the presentation of SL-701 data at the American Society for Clinical Oncology (ASCO) conference;

•

the improvement of general market conditions, which increased the probability of an IPO; and

•

the advancement of discussions with investment bankers and the drafting of a prospectus for an IPO.

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Based on the foregoing factors, and relying primarily on the PWER method, the fair value of our common stock on January 30, 2012 was determined to be $5.97 per share.

On February 29, 2012, March 5, 2012 and March 9, 2012 we issued equity awards with an exercise price of $5.97 per share, which our board of directors determined to be equal to the fair market value of our common stock on the date of grant. At the time these awards were granted, there remained substantial uncertainty regarding the regulatory pathway for our product candidates and the likelihood of a successful initial public offering. Specifically, at the time these awards were granted no significant events had occurred regarding our product candidates or prospects of completing a successful initial public offering to impact the retrospective valuation that had been set as of January 30, 2012.

In addition, at the time these awards were made, our underwriters had not yet communicated to us the proposed price range for this initial public offering. Based on these and other factors, including concern over whether the public equity markets would be receptive to pre-commercial biotechnology companies such as ours, and in light of the challenges that similarly situated companies have experienced in recent months in

completing their own proposed initial public offerings, our board of directors determined that the fair market value of our common stock at the time these awards were granted was equal to $5.97 per share.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, the time to completing an IPO or other liquidity event, and the timing of and probability of successful completion of our clinical trials as well as determinations of the appropriate valuation methods. If we had made different assumptions, our share-based compensation expense could have been significantly different.

We recorded stock-based compensation of $80,535 and $108,405 during 2010 and 2011. Included in these amounts was employee stock-based compensation of $59,000 and $95,411, respectively. In future periods, we expect stock-based compensation to increase, due in part to our existing unrecognized stock-based compensation and as we issue additional stock-based awards to continue to attract and retain employees. As of December 31, 2011 and 2010, we had $1.1 million and $0.9 million of unrecognized stock-based compensation costs related to equity instruments previously granted, which are expected to be recognized over an average period of 1.54 years for 2010 and 3.18 years for 2011. Included in the unrecognized stock-based compensation amounts above, there are performance-based equity awards granted to employees that will vest upon the consummation of the initial public offering and will result in the immediate recognition of $1.0 million in compensation expense. Additionally, there are performance-based equity awards granted to non-employees that will vest upon the consummation of this offering and will result in the immediate recognition of $ million in expenses, assuming an offering price of $.

Valuation models require the input of highly subjective assumptions. Because our common stock has characteristics significantly different from that of publicly traded common stock and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable, single measure of the fair value of our common stock. The foregoing valuation methodologies are not the only valuation methodologies available and will not be used to value our common stock once this offering is complete. We cannot make assurances as to any particular valuation for our stock. Accordingly, investors are cautioned not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

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Results of Operations

Comparison of Years Ended December 31, 2011 and 2010

Research and development expense. Research and development expense was $2.0 million for the year ended December 31, 2011, compared with $1.8 million for the year ended December 31, 2010, an increase of $0.2 million or 14%. This increase was primarily attributable to increased costs pertaining to the continued development of our lead compound SL-401, including $0.2 million of consulting fees and $0.1 million of salary and related costs including stock-based compensation, partially offset by a decrease of $0.1 million of patent-related costs.

General and administrative expense. General and administrative expense was $0.7 million for the year ended December 31, 2011, compared with $0.5 million for the year ended December 31, 2010. This increase was primarily attributable to $0.2 million of corporate legal fees and professional fees.

Interest income. Interest income was $24,068 for the year ended December 31, 2011, compared with $43,045 for the year ended December 31, 2010. The $18,977 decrease in interest income for 2011 as compared to 2010 reflected lower cash balances in 2011.

Other income. Other income was $46,673 for the year ended December 31, 2011, compared with $484,905 for the year ended December 31, 2010. The $438,232 decrease in other income for 2011 as compared to 2010 was due to $244,479 of income associated with the receipt of the Qualified Therapeutic Discovery grant program from the federal government and the receipt of $218,556 from the Biotechnology Tax Credit from the City of New York received during calendar year 2010.

Other expense. Other expense was $9,670 for the year ended December 31, 2011, compared with none for the year ended December 31, 2010. The $9,670 increase in other expense for 2011 was attributed to the mark to market of the Put option liability.

Interest Expense. Interest expense was $98,643 for the year ended December 31, 2011, compared with $69,493 for the year ended December 31, 2010. The $29,150 increase for 2011 was attributable to the 2.45% convertible notes outstanding for the full calendar year versus nine months during the calendar year 2010.

Comparison of Years Ended December 31, 2010 and 2009

Research and development expense. Research and development expense was $1.8 million for the year ended December 31, 2010, compared with $1.5 million for the year ended December 31, 2009, an increase of $0.3 million or 18%. This increase was primarily attributable to $0.2 million in salary and related costs including stock-based compensation resulting from an increase in staffing and a $0.1 million increase associated with continued development of our lead compounds.

General and administrative expense. General and administrative expense was $0.5 million for the year ended December 31, 2010, compared with $0.6 million for the year ended December 31, 2009. This decrease of $0.1 million was primarily attributable to a $0.1 million net decrease in legal and professional fees.

Interest Expense. Interest expense was $69,493 for the year ended December 31, 2010, compared with none for the year ended December 31, 2009. The $69,493 increase for 2010 was attributable to the 2.45% convertible notes outstanding for nine months during the calendar year 2010.

Interest income. Interest income was $43,045 for the year ended December 31, 2010, compared with $201,088 for the year ended December 31, 2009. The $158,043 decrease in interest income for 2010 as compared to 2009 reflected lower cash balances in 2010.

Other income. Other income was $484,905 for the year ended December 31, 2010, compared with $102,257 for the year ended December 31, 2009. The $382,648 increase in other income for 2010 as compared to 2009 was primarily due to $244,479 of income associated with the receipt of the Qualified Therapeutic Discovery grant program from the federal government and the receipt of $218,556 of other income from the Biotechnology Tax Credit from the City of New York received during calendar year 2010.

Liquidity and Capital Resources

Sources of Liquidity

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

Through December 31, 2011, we received net proceeds of $3.8 million from the sale of common stock and $12.5 million from the sale of convertible preferred stock and $0.5 million from the issuance of convertible notes. In January 2012, we received net proceeds of $0.4 million through the issuance of convertible notes.

As of December 31, 2011, our cash, cash equivalents and marketable securities totaled $5.8 million. We primarily invest our cash and cash equivalents in commercial savings accounts. We believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, will be sufficient to fund our operations and our capital expenditures for at least the next 12 months.

We will also incur costs as a public company that we have not previously incurred, including, but not limited to, costs and expenses for directors fees, increased personnel costs, increased directors and officers insurance premiums, audit and legal fees, investor relations fees, expenses for compliance with the Sarbanes-Oxley Act of 2002 and rules implemented by the SEC and The NASDAQ Stock Market, LLC and various other costs. We cannot currently estimate how much these costs will be.

Cash Flows

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

Year Ended December 31,

2009 2010 2011

Net cash used in operating activities

$ (1,560,717) $ (1,862,600) $ (1,936,480)

Net cash provided by investing activities

8,600,231 – –

Net cash used by financing activities

– (147,429) 540,000

Net increase (decrease) in cash and cash equivalents

7,039,514 (2,010,029) (1,396,480)

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and favorable changes in the components of working capital. The net cash used in operating activities decreased in 2009, increased in 2010 and decreased in 2011 mainly due to the timing of payments to our suppliers in connection with supply and research agreements associated with the continued

development of our product candidates. The cash used for the years ended December 31, 2010 and December 31, 2011 was also impacted by an increase in research and development expenses as we increased our research and development headcount.

Investing activities. The cash provided by investing activities for the year ended December 31, 2009 was due to the sale of marketable securities, primarily certificates of deposit.

Financing activities. The cash used by financing activities for the year ended December 31, 2010 was due to the payment of $0.8 million in connection with the redemption of our Series A preferred stock offset by the receipt of $0.6 million of proceeds from the private placement of our common stock. The net cash provided by financing activities for the year ended December 31, 2011 was due to the issuance of $0.5 million of convertible notes.

Funding Requirements

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

•

continue the ongoing clinical trials, and initiate the planned clinical trials, of our lead product candidates, SL-401 and SL-701;

•

continue the research and development of our other product candidates and our platform technology;

•

seek to identify additional product candidates;

•

acquire or in-license other products and technologies;

•

seek marketing approvals for our product candidates that successfully complete clinical trials;

•

establish, either on our own or with strategic partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;

•

maintain, leverage and expand our intellectual property portfolio;

•

add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

•

the progress and results of the clinical trials of our lead product candidates;

•

the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our other product candidates;

•

the extent to which we acquire or in-license other products and technologies;

•

the costs, timing and outcome of regulatory review of our product candidates;

•

the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

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•

revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

•

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and

•

our ability to establish any future collaboration arrangements on favorable terms, if at all.

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

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2011:

Total Less Than

1 Year 1 to 3

Years 3 to 5

Years More Than

5 Years(3)

Long-term debt obligations(1)

$ 1,843,726 — — 1,303,594 $ 540,132

Operating lease obligations

$ 12,246 $ 12,246 $ — $ — $ —

License agreements(2)

$ 804,025 $ 159,300 $ 269,525 $ 273,900 $ 101,300

Total:

$ 2,659,997 $ 171,546 $ 269,525 $ 1,577,494 $ 641,432

(1)

Included in the "3 to 5 Years" column is all of the outstanding principal amount, as of December 31, 2011, of our senior convertible note due 2015, which equals $1,250,000 in principal amount plus accrued interest. Upon the consummation of this offering, the holder of the senior convertible note may, at such holder's election, choose instead to accelerate repayment of such note in full or in part in cash, or may convert such note into shares of our common stock at the initial public offering price. Included in the "More Than 5 Years" column is all of the currently outstanding principal amount of our convertible notes due 2017, which equals approximately $540,000 plus accrued interest. See Note 6 to the Financial Statements appearing at the end of this prospectus. Upon the consummation of this offering, the convertible notes due 2017 automatically convert into shares of our common stock at 87.5% of the initial public offering price.

(2)

We have executed several license agreements, as discussed in Note 10 to the financial statements appearing at the end of this prospectus and in more detail in the section titled "Business — License and Research Agreements." Other than the payments noted in the table above, milestone and royalty payments associated with licensing have not been included as management cannot reasonably estimate if or when they will occur. These arrangements include the following:

•

Under a research and license agreement with Scott and White Memorial Hospital for SL-401, we are required to pay royalties on annual sales of licensed products.

•

Under three separate license agreements with The University of Pittsburgh, we are required to make aggregate development and regulatory milestone payments associated with SL-701 and pay royalties on net sales of licensed products.

•

Under an exclusive patent and non-exclusive know-how license agreement with the Cambridge University Technical Services Limited, related to our StemScreen® platform technology, we are required to make milestone payments upon specified regulatory events and pay royalties on sales of licensed products.

(3)

Certain contractual payment obligations will extend beyond five years until certain specified milestones are achieved. For purposes of this calculation, we have assumed that these payment obligations have only been made in the sixth year, however these payments would continue each subsequent year until the specified milestones are achieved.

Off-Balance Sheet Arrangements

During the years ended December 31, 2011, 2010 and 2009, we did not 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 December 31, 2011, we had federal net operating loss carryforwards of $10.9 million, which are available to reduce future taxable income. We also had federal tax credits of $0.4 million, which may be used to offset future tax liabilities. The net operating loss and tax credit carryforwards will expire at various dates through 2029. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our Company

immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. At December 31, 2011, we recorded a 100% valuation allowance against our net operating loss and tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of $7.2 million as of December 31, 2010 and $5.8 million as of December 31, 2011, consisting of cash and money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and contract manufacturers. We may be subject to fluctuations in foreign currency rates in connection with these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2011, all of our liabilities were denominated in our functional currency.

Recently Adopted Accounting Standards

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

Business

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells, or CSCs, and tumor bulk. We believe that we are developing the most clinically advanced pipeline of anti-CSC therapeutics and that we hold a broad portfolio of CSC-focused intellectual property, establishing us as a leader in the CSC field. Among the therapeutic candidates in our portfolio, we are currently developing two clinical-stage product candidates, SL-401 and SL-701, for which we hold global marketing rights. The lead indication for SL-401, a biologic-drug conjugate, is acute myeloid leukemia, or AML. The lead indications for SL-701, a synthetic peptide vaccine, are pediatric and adult brain cancer. In completed Phase 1/2 clinical trials, both SL-401 and SL-701 have demonstrated single agent activity, including durable complete responses, or CRs, and longer overall survival, or OS, in patients compared with that achieved in the past with traditional therapies. We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult relapsed or refractory AML patients who failed two previous treatments (i.e. third-line AML) with OS as the primary endpoint. We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat pediatric patients with newly diagnosed brain stem glioma, or BSG. In addition, we plan to advance SL-701 into a randomized Phase 2b clinical trial in adult recurrent or refractory glioblastoma, or GBM, with a development plan designed to culminate in registration. We have a proprietary discovery platform, StemScreen®, for the discovery of novel CSC-targeted compounds, from which we have discovered or validated several of our clinical and preclinical product candidates and which we believe may be instrumental in the discovery of additional new therapies targeting a wide range of cancer types.

The field of CSCs is a new area of cancer biology with the potential to fundamentally alter the approach to oncology drug development. CSCs have been identified in virtually all major tumor types, including leukemia and cancers of the brain, breast, colon, prostate and pancreas. CSCs are the highly malignant "seeds" of a tumor that self-renew and generate more mature cells that comprise the bulk of the tumor, or "the tumor bulk." As such, we believe that CSCs are responsible for tumor initiation, propagation, and metastasis. Many of the characteristics of CSCs, such as their slow growth, presence of multi-drug resistance proteins, anti-cell death mechanisms, and upregulated DNA repair machinery, may enable CSCs to resist therapeutic agents traditionally used to treat cancer. Further, while standard therapies may initially shrink tumors by targeting the tumor bulk, which excludes CSCs, there is a large body of evidence indicating that treatment failure, tumor relapse and poor survival are largely the result of the failure of conventional cancer treatments to eradicate CSCs. Accordingly, we believe that targeting CSCs, in addition to the tumor bulk, may represent a major advance in the fight against cancer. This premise has formed the basis of our drug development strategy, as illustrated below.

GRAPHIC

Since our inception in 2003, we have leveraged our knowledge of CSCs to anticipate and establish a leadership position in this new field of oncology. During this time, we have developed or strategically in-licensed key intellectual property, built and validated a drug discovery platform

and developed clinically active drug candidates. We believe that our early and comprehensive effort to develop a new generation of oncology therapeutics that target CSCs as well as the tumor bulk provides us with a significant competitive advantage.

Our most advanced product candidates are SL-401 and SL-701.

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SL-401 is a clinically active biologic-drug conjugate comprised of human interleukin-3 (IL-3) genetically linked to a truncated version of diphtheria toxin. SL-401 targets the IL-3 receptor, or IL-3R, which is overexpressed on both the CSCs and tumor bulk of multiple hematologic cancers, including AML. In contrast, IL-3R is not expressed on normal bone marrow stem cells that form the components of blood. SL-401 demonstrated single agent anti-tumor activity in a completed Phase 1/2 clinical trial of 76 patients with advanced hematologic cancers, including 57 patients with relapsed or refractory AML. With only a single cycle of treatment, SL-401 induced either a reduction in leukemia blasts (i.e. tumor bulk) or disease stabilization in 47% (27/57) of relapsed or refractory AML patients. This included two durable CRs, seven PRs, many of which were clinically meaningful, and improved OS of the 34 most heavily pre-treated AML patients by more than two-fold compared with historical data. Of note, we intend to administer multiple cycles of SL-401 in future trials, which we believe may further increase its efficacy with respect to both clinical response and survival. Importantly, SL-401 was not toxic to the bone marrow, which was predicted based on the absence of IL-3R on normal bone marrow stem cells, and is a key differentiating feature relative to many other hematologic cancer therapies. The lack of overlapping toxicities between SL-401 and traditional therapeutics indicates that SL-401 may be combined with standard therapeutic regimens used in early stages of AML. The Phase 1/2 clinical trial, completed for relapsed or refractory AML patients, is still open for patients with myelodysplastic syndrome, or MDS, and chronic myeloid leukemia, or CML.

We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult AML patients as a third-line multiple cycle treatment with OS as the primary endpoint. In addition, we plan to evaluate SL-401 as consolidation and/or maintenance therapy in patients with AML who are in CR following chemotherapy but have a high risk of disease recurrence, as well as in first- and/or second-line AML in combination with chemotherapy, and potentially in certain lymphoid and plasma cell cancers.

In February 2011, SL-401 received Orphan Drug designation from the FDA for the treatment of AML. We hold an exclusive worldwide license with respect to SL-401.

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SL-701 is a clinically active synthetic peptide vaccine that targets several epitopes on CSCs and tumor bulk of brain cancer. In two completed Phase 1/2 clinical trials, SL-701 demonstrated single agent anti-tumor activity in pediatric patients with newly diagnosed brainstem glioma, or BSG, and other high-grade gliomas, or HGGs, and in adult patients with refractory or recurrent GBM, and other HGGs. SL-701 induced tumor shrinkage or disease stabilization in 84% (16/19) of patients in the pediatric study, and 59% (13/22) of patients in the adult study. This includes two CRs and five PRs. Seven of ten pediatric patients with newly diagnosed BSG treated with SL-701 survived past the historical median of 9.6 months, including three children who have survived for periods in excess of 50% greater than the historical median survival. Additionally, the OS of adult patients with recurrent or refractory GBM and other HGGs who were treated with SL-701 was increased compared with historical results for similar patients treated with a wide range of therapies.

We plan to advance SL-701 into a pivotal Phase 2b clinical trial for the treatment of pediatric patients with newly diagnosed BSG. We also plan to initiate a randomized Phase 2b clinical trial in second-line GBM, with a development plan designed to culminate in registration. There are also clinical trials currently open for pediatric and adult patients with low-grade glioma, or LGG.

We hold an exclusive worldwide license with respect to SL-701.

We have developed a proprietary discovery platform, StemScreen®, for the identification of novel CSC-targeted compounds. StemScreen® contrasts with traditional drug discovery methods that have been designed to identify compounds that target tumor bulk, not CSCs. StemScreen® includes a cell-based assay that can track CSCs in their natural state during high throughput screening. We believe this approach represents a major technological advance because not only is it CSC-focused and high throughput, but it also does not require artificial manipulation to create CSC-like cells as other systems do. We have utilized StemScreen® to discover a number of our product candidates. We believe that this platform may be instrumental in the discovery of new compounds targeting a wide range of cancer types.

Our intellectual property portfolio includes 13 issued patents and more than 30 pending patent applications in the United States and abroad. This portfolio includes owned and exclusively in-licensed intellectual property that we believe is early and broad with respect to the use of CSC-directed therapeutics and diagnostics (including companion diagnostics), as well as drug discovery.

Management

We are led by a team with extensive experience in managing biopharmaceutical companies and in oncology drug development, including:

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Our Chairman, Chief Executive Officer and President, Ivan Bergstein, M.D., founded Stemline in 2003. He was previously Medical Director of Access Oncology Inc., a private clinical stage oncology-focused biotechnology company. Prior to that, Dr. Bergstein was a biopharmaceuticals analyst in the financial sector. He previously completed a residency and fellowship in internal medicine and hematology-oncology at the New York Presbyterian Hospital – Weill Medical College of Cornell University.

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Our Chief Medical Officer and Head of Research and Development, Eric K. Rowinsky, M.D., was previously the Chief Medical Officer for ImClone Systems, Inc. Dr. Rowinsky has more than 25 years of experience managing clinical trials and developing drugs in oncology, including leading the FDA approval of Erbitux® for head and neck and colorectal cancers. Dr. Rowinsky currently serves on the Board of Directors of Biogen Idec Inc., as well as several other public biopharmaceutical companies.

Strategy

Our goal is to maintain and fortify a leadership position in the discovery, acquisition and development of novel oncology therapies that target CSCs. The fundamental components of our business strategy to achieve this goal include the following:

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Be the first anti-CSC-focused company to commercialize a CSC-directed oncology drug. As the most clinically advanced anti-CSC-focused company, we aim to fortify our leadership position and be the first to commercialize a CSC-directed oncology drug.

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Develop and commercialize SL-401 in multiple hematological cancers. We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial with OS as the primary endpoint to treat adult AML patients as a third-line treatment, which is an unmet medical need, as well as pursue other potential indications in parallel. The SL-401 target, IL-3R, is expressed on a wide variety of hematologic cancers including other forms of leukemia, such as CML, MDS, and acute lymphoid leukemia, as well as lymphomas, such as Hodgkin's disease and multiple myeloma. Accordingly, we believe that SL-401 should be active in multiple hematologic cancers. These indications could represent significant market opportunities for SL-401.

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Develop and commercialize SL-701 in multiple brain cancers. We plan to advance SL-701 into a pivotal Phase 2b clinical trial for the treatment of pediatric patients with newly diagnosed BSG. If successful, we plan to submit a Biologics License Application, or BLA, to the FDA as a basis for marketing approval of SL-701. We also plan to initiate a randomized Phase 2b clinical trial in adult second-line GBM, with a development plan designed to culminate in registration.

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Leverage our proprietary drug discovery platform, StemScreen®, to identify new therapeutics. We intend to utilize our proprietary discovery platform to identify new CSC-targeted drug candidates. We may conduct some of these efforts internally and/or leverage our platform to forge strategic collaborations. We have utilized StemScreen® to identify a number of preclinical drug candidates and may initiate IND-enabling studies either alone or in collaboration with strategic partners.

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Develop commercialization capabilities in North America and Europe. We believe that the infrastructure required to commercialize our oncology products is relatively limited, which makes it cost-effective for us to internally develop a marketing effort and sales force. If SL-401 and SL-701 are approved by the FDA and other regulatory authorities for first use, we plan to commercialize them ourselves in North America and Europe through direct sales and distribution. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous.

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Continue to both leverage and fortify our CSC intellectual property portfolio. We believe we have a strong intellectual property position relating to the development and commercialization of CSC-targeted therapeutics, diagnostics, and drug discovery. We plan to continue to leverage this portfolio to create value. In addition to fortifying our existing intellectual property position, we intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

Clinical Pipeline

The following table summarizes key information about our two most advanced product candidates:

GRAPHIC

Abbreviations:

Acute myeloid leukemia (AML); Myelodysplastic syndrome (MDS); Chronic myeloid leukemia (CML); Tyrosine-kinase inhibitor (TKI); Complete Response (CR); High-grade glioma (HGG); Low-grade glioma (LGG); Brainstem glioma (BSG); Glioblastoma (GBM).

SL-401 – An IL-3R-Directed Compound Targeting CSCs and Tumor Bulk

Overview

SL-401 is a clinically active biologic-drug conjugate that targets the interleukin-3 receptor, or IL-3R, which is overexpressed on CSCs and more mature cancer cells derived from CSCs (i.e., tumor bulk) of multiple hematologic cancers. In AML, for example, IL-3R is overexpressed on both CSCs and tumor bulk of leukemia (i.e., blast cells). In a completed Phase 1/2 clinical trial in patients with advanced hematologic cancers, a single cycle of SL-401 alone demonstrated anti-tumor activity, including durable CRs, in relapsed or refractory patients. SL-401 also improved OS of the 34 most heavily pre-treated AML patients by more than two-fold compared with historical results achieved with traditional treatments in similar patients. Further, SL-401 was shown to be non-toxic to bone marrow, which is a key differentiating feature relative to many other hematologic cancer therapies and reflects the lack of IL-3R expression on normal bone marrow stem cells. Currently, there are limited effective treatment options for patients with relapsed or refractory hematologic cancers including AML. We believe that it is becoming increasingly accepted within the oncology field that a major reason for the failures of traditional treatments to provide long term benefit is that these treatments target tumor bulk rather than CSCs. Accordingly, by pursuing hematologic cancer indications with SL-401, a therapeutic that uniquely targets both CSCs and tumor bulk, we hope to provide benefit to patients who historically have been difficult to treat with traditional therapies.

We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial with OS as the primary endpoint to treat adult AML patients as a third-line treatment as our lead indication. We also plan to pursue Phase 1/2 trials of SL-401 in patients with earlier stages of AML as well as other hematologic cancer indications.

In February 2011, SL-401 received Orphan Drug designation from the FDA for the treatment of AML.

Acute Myeloid Leukemia

Acute myeloid leukemia, or AML, is a hematologic cancer characterized by dysregulated maturation of myeloid cells and failure of the bone marrow to properly function. AML is the most common type of acute leukemia in adults. Approximately 13,000 new AML cases occur annually in the United States, and approximately 16,000 to 18,000 new cases occur annually in Europe. The average age of an AML patient is 67 years. The National Cancer Institute estimated in 2007 that the one-year survival rate for adult patients with AML was approximately 34%. The one-year survival rate for AML after first relapse is approximately 20%, and after second relapse is approximately 8%. The median OS for AML patients after failing second-line treatment, based on two large series, is 1.5 months. Current first-line treatments for AML include chemotherapy drugs such cytarabine, daunorubicin and mitoxantrone. In certain circumstances, bone marrow transplantation is also used. In second-line AML, while there are currently no approved treatments, typical therapies include additional chemotherapy, often cytarabine again at various dosages and regimens. In third-line AML, there are currently no approved treatments, and these patients frequently have depressed bone marrow function and are often no longer optimal candidates for additional chemotherapy. As such, third-line AML constitutes an unmet medical need.

Myelodysplastic Syndrome

Myelodysplastic syndrome, or MDS, is a group of hematologic malignancies characterized by dysfunction of the blood and bone marrow, resulting in decreased peripheral blood counts and, at times, evolution into AML. Approximately 16,000 new cases of MDS are reported annually in the United States and approximately 15,000 to 25,000 new MDS cases are reported annually in Europe. MDS occurs most commonly in males 70 years or older. Five-year survival rates for MDS patients vary significantly depending on disease severity and prognosis and range from approximately 55% for low-risk patients, to 7% to 35% for intermediate-risk patients. Virtually all high-risk MDS patients die within five years. Treatment paradigms for MDS patients vary depending on disease classification and risk category. Current first-line treatments include azacitidine (Vidaza®), decitabine (Dacogen®), lenalidomide (Thalomid®), growth factors, chemotherapy, and allogeneic stem cell transplantation in certain cases. Almost all patients either do not respond or relapse following first-line treatment, and there are no approved therapies and limited effective treatment options in this high-risk setting.

Chronic Myeloid Leukemia

Chronic myeloid leukemia, or CML, is a hematopoietic stem cell disease resulting in impaired bone marrow function. Annually, approximately 5,000 new cases are reported in the United States each year and approximately 4,000 to 9,000 new cases are reported each year in Europe. The five-year OS rate for CML patients is 57%. When CML advances to an accelerated or blastic phase, the median OS is less than one year. In patients who have failed or are intolerant to tyrosine kinase inhibitors (or TKIs), a relapsed or refractory setting, the median OS is four to 11 months. Current first-line treatments for CML include three TKIs: imatinib (Gleevec®), nilotinib (Tasigna®) and dasatinib (Sprycel®). In cases of relapse, second- and third-line treatments include a TKI not previously used in that patient. In certain circumstances, interferon or bone marrow transplantation is also used.

Design of SL-401 and Mechanism of Action

SL-401 is a biologic-drug conjugate that targets the interleukin-3 receptor, or IL-3R. SL-401 consists of recombinant human interleukin-3, or IL-3, genetically coupled to a truncated diphtheria toxin payload. Mechanistically, the IL-3 domain of SL-401 directs the cytotoxic payload to IL-3R+ leukemia cells. SL-401 is then internalized by the cell, leading to inhibition of protein synthesis and cell death, or apoptosis. In addition to uniquely targeting CSCs, as well as tumor bulk, the mechanism by which SL-401 kills cells differs from that of available therapeutics commonly used to treat AML and other hematologic malignancies.

IL-3R is normally expressed on certain maturing hematopoietic cells of the myeloid, B cell, and dendritic cell lineages, but not normal hematopoietic stem cells, and is involved in cell maturation, differentiation, and survival. IL-3R is overexpressed on multiple hematological malignancies including AML, MDS, CML, B cell acute lymphoid leukemia, hairy cell leukemia, Hodgkin's disease, and certain aggressive Non-Hodgkin's lymphomas. In addition to expression on hematologic tumor bulk, IL-3R is also expressed on the CSCs of AML, CML, MDS, and T-cell acute lymphoid leukemia. Elevated IL-3R expression has been correlated with poor patient prognosis. For example, as described by Vergez in Haematologica in 2011, a higher percentage of IL-3R-expressing, or IL-3R+, CSCs within a patient's entire tumor correlates with poor outcome. In particular, AML patients with IL-3R+ CSCs that comprise greater than or equal to 1% of their entire leukemia were found to have a worse prognosis than patients with IL-3R+ CSCs that comprise less than 1% of their entire leukemia. These findings further validate that IL-3R is an important oncology target.

SL-401 Preclinical Activity and Safety

SL-401 has demonstrated preclinical in vitro and in vivo activity against both leukemia blasts (i.e., tumor bulk) and CSCs of a variety of human leukemia cell lines and primary leukemia cells from patients. In particular, SL-401 demonstrated potent cytotoxicity against leukemic cells in vitro in a dose-dependent fashion with IC50 (concentration that inhibits the growth of 50% of leukemia cells) values in the low picomolar range. Notably, normal bone marrow progenitor cells were relatively insensitive to SL-401. SL-401 also exhibited anti-CSC activity. In particular, SL-401 inhibited AML colony formation, an assay for stem cell activity, compared with normal human bone marrow. As further validation of an anti-CSC effect, SL-401 reduced engraftment and growth (i.e., tumorigenicity) of AML cells, relative to normal human bone marrow, when treated ex vivo and reimplanted into immunodeficient mice – indicating activity at the level of the CSC. In addition, SL-401 prolonged the survival of mice implanted with human leukemia xenografts compared with untreated mice, as described by Black in Leukemia in 2003.

To support first-in-man clinical studies, repeat-dose animal safety studies have been conducted in mice and monkeys. Toxicokinetic studies were performed to evaluate the relationships between toxicity and exposure to SL-401. Additionally, dose-limiting toxicity, or DLT, and maximal tolerated dose, or MTD, were determined from these studies to inform the subsequent Phase 1/2 human clinical trial.

Completed Phase 1/2 Clinical Trial – Advanced AML

Overview

SL-401 was evaluated in a completed multi-center Phase 1/2 clinical trial of patients with advanced hematologic cancers, which we refer to as the 401 AHC Study. As described below, SL-401 demonstrated single agent anti-tumor activity, including durable CRs, and was well-tolerated at clinically active doses. Although patients received only a single cycle of SL-401 treatment, the median OS of the most heavily pre-treated AML patients was almost two-fold greater than that achieved historically with traditional treatments in similar patients. Of note, we intend to administer multiple

cycles of SL-401 in our future trials, which we believe may increase the efficacy with respect to both clinical response and survival. Further, SL-401 was shown to be non-toxic to bone marrow, which is a key differentiating feature relative to other hematologic cancer therapies.

The 401 AHC Study was undertaken in 76 patients with advanced hematologic cancers, including relapsed or refractory adult AML patients (n=57), de novo elderly AML patients who were not candidates for chemotherapy (n=11), high risk MDS patients (n=7), or other patients (n=1), with "n" representing the number of patients. The median patient age was 66 years, with a range of seven to 84 years of age. Patients received a single cycle of SL-401, consisting of a 15-minute intravenous infusion on either an every-other-day schedule for up to six treatments, or daily for a five-day schedule.

The 401 AHC Study was conducted at MD Anderson Cancer Center (Houston, TX), the Scott and White Cancer Research Institute/Texas A&M (Temple, TX), Duke University (Durham, NC), and the British Columbia Cancer Agency (Vancouver, Canada). The 401 AHC Study results were presented at the American Society of Hematology (ASH) Annual Conference in December 2010.

Well-Tolerated at Clinically Active Doses

SL-401 was well-tolerated at clinically active doses. Mild to moderate adverse events, including fever and chills, were manageable and not dose-limiting. Moderate to severe adverse events included liver enzyme elevations in 25% of patients, which were mostly transient, and rapidly reversible manifestations of early capillary leak syndrome (e.g., reduced albumin, edema, and weight gain) in fewer than 10% of patients. Capillary leak syndrome was the principal dose-limiting toxicity, which was consistent with the principal dose-limiting toxicity of denileukin diftitox (Ontak®), a compound comprised of recombinant truncated diphtheria toxin that is registered for the treatment of persistent or recurrent cutaneous T-cell lymphoma.

Non-Toxic to Bone Marrow

SL-401 was not toxic to the bone marrow, which is a key distinguishing feature relative to other hematologic cancer chemotherapies, such as nucleoside inhibitors and anthracyclines. Prior to starting treatment with SL-401, the majority of patients in the 401 AHC Study had pre-existing bone marrow suppression, likely due to the extent of their disease and/or previous exposure to myelosuppressive therapies. During and after SL-401 treatment, these patients exhibited largely stable bone marrow function relative to their pre-treatment condition, as determined by mean absolute neutrophil, hemoglobin and platelet counts of evaluable patients. As a result, we expect that SL-401, in contrast to traditional chemotherapy, may not increase a patient's susceptibility to infection, anemia, or bleeding, or increase the frequency of red blood cell or platelet transfusions or growth factor infusions. Further, because SL-401 does not appear to have overlapping toxicity with traditional hematologic cancer therapies, SL-401 may be potentially combined with more traditional agents, without the need to reduce the doses of any of the agents, in future studies involving earlier-stage AML.

Anti-Tumor Activity

In the 401 AHC Study, one cycle of SL-401 administered alone demonstrated anti-tumor activity, including reductions in leukemia blast cells in the bone marrow (i.e., reductions in tumor bulk) or disease stabilization, in approximately half of all treated patients, the majority of whom were heavily pretreated, as summarized below. More specifically, reductions in leukemia blasts or disease stabilization were seen in 47% of patients with relapsed or refractory AML, 55% of de novo elderly AML who were not candidates for chemotherapy, and 43% of high-risk MDS patients. Durable CRs were induced in two patients with relapsed or refractory AML. There were also eight partial responses, or PRs, and ten minor responses, or MRs.

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SL-401 Clinical Anti-Tumor Activity in Patients with Advanced Hematologic Cancers

GRAPHIC

Of the two patients who sustained durable CRs, one chemo-refractory patient, who had decreased pretreatment blood counts and a bone marrow blast count of 30%, sustained a CR following SL-401 treatment of eight months duration, after failing standard AML induction chemotherapy prior to entry onto the 401 AHC Study. The other CR patient, who had decreased pretreatment blood counts and a bone marrow blast count of 52%, sustained a CR following SL-401 treatment that currently exceeds 25 months duration. This patient had failed three previous treatment regimens, including two previous stem cell transplantations prior to entry into the 401 AHC Study. It is notable that following only a single cycle of SL-401, both of these patients achieved durable CRs with normalization of blood counts and bone marrows.

Anti-CSC Effect

In addition to SL-401's clinical activity, SL-401 was also shown to have activity against leukemic CSCs collected from three patients enrolled in the 401 AHC Study. In this translational study that was coordinated with the 401 AHC Study, bone marrow samples collected from several patients both before and after SL-401 treatment were tested for CSC activity in a colony formation assay. As demonstrated by Konopleva in Blood in 2010, and as illustrated below, a substantial anti-CSC effect by SL-401 was observed, as demonstrated by considerable decreases in bone marrow CSC activity at 15 and 30 days after SL-401 treatment. At 30 days post-treatment, CSC activity decreased by an average of 79% of that measured at pretreatment. These studies also provided preliminary evidence that the beneficial clinical effects noted in some patients in the 401 AHC Study may have been due, in part, to the anti-CSC activity of SL-401. In particular, reductions in leukemic CSC activity 30 days post-treatment of 79% and 84% were observed in two patients, both of whom outlived the historical median OS of heavily pretreated AML

patients of 1.5 months by several fold, with survivals of equal to or greater than 5.5 months and 7.6 months, respectively. We intend to follow-up on these positive preliminary data in future clinical trials.

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SL-401 Demonstrates Clinical Anti-CSC Effect

(adapted from Konopleva et al. Blood 2010; 116:21: Abstract #3298)

GRAPHIC

Survival Benefit

In the 401 AHC Study, SL-401 demonstrated an improvement in OS of the 34 most heavily pretreated AML patients compared with historical survival results. In particular, in AML patients who had failed at least two previous therapies (i.e., third-line or greater), the median OS following a single cycle of SL-401 was 3.5 months, which is more than double the historical median OS of 1.5 months. The six-month and 12-month OS were also longer relative to comparable patients in a large contemporary series reported by Giles et al. in Cancer in 2005 and another large series reported by Keating et al., in the Journal of Clinical Oncology in 1989. These results are illustrated below (Kaplan-Meier survival curve bounded above and below by confidence intervals).

Kaplan-Meier Survival Curve of AML Patients Treated with SL-401

Who Had Previously Failed At Least Two Prior Treatment Regimens (i.e., Third-Line or Greater)

(+/- 95% Confidence Intervals)

(Stemline Therapeutics, Inc.; unpublished data)

GRAPHIC

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Overall Survival of AML Patients Treated with SL-401

Who Had Previously Failed At Least Two Prior Treatment Regimens (i.e., Third-Line or Greater)

versus Historical Data

GRAPHIC

(1) Giles et al., Cancer 2005; 104:547-554; (2) Keating et al., Journal of Clinical Oncology 1989; 7:1071-1080

Notably, these results are based on the 401 AHC Study dose regimen of only one cycle of SL-401. We believe that multiple-cycle administration of SL-401 will further increase the clinical benefit of SL-401. Accordingly, to maximize the potential benefits of SL-401, we plan to administer multiple cycles of SL-401 in our planned Phase 2b clinical trial, as well as in other clinical evaluations of SL-401.

Planned Phase 2b Clinical Trial for Third-Line AML

We plan to advance SL-401 into a 200 patient randomized Phase 2b clinical trial to treat adult relapsed or refractory AML patients who failed two previous treatments (i.e. third-line AML) with OS as the primary endpoint. In contrast to the prior Phase 1/2 study of SL-401 in which patients received only one cycle of treatment, in the planned Phase 2b trial multiple cycles of SL-401 will be administered to maximize its efficacy. We believe that multiple cycle administration of SL-401 may increase the duration of disease stabilization, response and ultimately survival, which is the primary endpoint of the study. In the proposed study, patients with refractory and relapsed AML in the third-line setting will be randomized to treatment with either SL-401 or "physician's choice" which consists of either an available, non-investigational (i.e., "standard") therapeutic agent or combination regimen. Based on existing clinical safety and efficacy data with SL-401, we believe that SL-401 will be able to be safely administered to patients that have received multiple prior lines of intensive cytotoxic chemotherapy for AML, and that patients enrolled in the proposed Phase 2b clinical study may benefit in terms of disease response and extended survival.

Phase 1/2 trials of SL-401 in advanced hematologic cancers are currently open for patients with MDS and CML. In addition, we plan to evaluate SL-401 as consolidation and/or maintenance therapy in patients with AML who are in CR following chemotherapy, but have a high likelihood of relapsing, as well as in first- and/or second-line AML in combination with chemotherapy and potentially patients with certain lymphoid and plasma cell cancers.

SL-701 – A Multi-Epitope Brain Cancer Vaccine

Overview

SL-701, a clinically active peptide vaccine comprised of synthetic peptides, is designed to direct the immune system to targets present on the CSCs and tumor bulk of brain cancer. High-grade gliomas, or HGGs, are the most aggressive brain cancers and have a poor prognosis. Treatment options are limited, particularly for pediatric patients with newly diagnosed HGG, including brainstem glioma, or BSG, and adult patients with recurrent or refractory HGG, including glioblastoma, or GBM. In completed Phase 1/2 clinical trials, SL-701 demonstrated uncommon single agent anti-tumor activity in these indications, inducing tumor shrinkage or disease stabilization in 84% (16/19) of HLA-A2+ (as defined below) pediatric glioma patients, and 59% (13/22) of HLA-A2+ adult patients with recurrent or

refractory HGG. To date, there have been seven major objective tumor responses (i.e., tumor regressions) in these two studies, consisting of two CRs and five partial responses, or PRs. These trial results were delivered via oral presentation at the American Society of Clinical Oncology (ASCO) Annual Conference in June 2011.

We plan to advance SL-701 into a pivotal Phase 2b clinical trial to treat HLA-A2+ pediatric patients with newly diagnosed BSG. We may seek grant funding to help support this trial. We also plan to initiate a randomized Phase 2b clinical trial in HLA-A2+ adult second-line GBM, with a development plan designed to culminate in registration.

Immune system cells utilize human leukocyte antigen, or HLA, molecules to bind and present antigenic peptides to T cells to initiate a specific immune response. The SL-701 peptides were designed to bind to HLA-A2, the most common Class I HLA molecule (approximately 45-50% of the North American population). Accordingly, in the completed Phase 1/2 trials, HLA-A2+ patients were specifically enrolled. Based on the clinical responses and survival signal seen in these studies, we plan to, directly or through investigator sponsors, continue to select HLA-A2+ patients for both the pivotal Phase 2b pediatric trial and the randomized Phase 2b adult second-line GBM trial. We also plan to test SL-701 peptide binding to other Class I HLA molecules to potentially expand the target population.

High-Grade Glioma (Including Adult Glioblastoma and Pediatric Brainstem Glioma)

Gliomas are histologically heterogeneous tumors that are derived from glial cells in the brain. Gliomas are graded from 1 to 4, based on World Health Organization, or WHO, classifications, with grade 4 glioma (i.e., glioblastoma, or GBM) and grade 3 glioma (i.e., anaplastic astrocytoma, or AG) as the most aggressive gliomas and referred to as high-grade gliomas, or HGGs. GBM makes up the majority of HGG cases, with an annual incidence of approximately 10,000 in the United States and 15,000 to 18,000 in Europe.

The standard of care for newly diagnosed adult GBM is resection, if operable, followed by a combination of radiation and temozolomide (i.e., the Stupp regimen). Although this combination treatment has improved patient outcomes, 85% to 90% of patients ultimately relapse, with a median OS from diagnosis of 15 months. Avastin® is approved as a second-line therapy for adult GBM based on partial response duration. However, most recurrent patients receiving Avastin® ultimately relapse, and the median OS for these second-line patients is approximately eight to nine months. Currently, no therapies have been approved for third-line treatment of GBM, which carries a median OS of three to four months.

Pediatric HGG, which includes brainstem glioma, or BSG, and non-brainstem HGG, is a highly malignant disease with very poor outcomes. The annual incidence of pediatric HGG is approximately 1,600 to 2,000 in the United States and approximately 3,400 in Europe. No therapy has been shown to have a favorable outcome in this population and almost all patients relapse after receiving first-line treatment. Pediatric patients with newly diagnosed BSG are typically treated with radiation alone and have an expected median OS from diagnosis of approximately 9.6 months.

Design of SL-701 and Mechanism of Action

SL-701 is comprised of short synthetic peptides that correspond to epitopes of the brain cancer targets IL-13Ra2 and EphA2. The IL-13Ra2 synthetic peptide is a mutant specifically designed to be highly immunogenic to amplify the vaccine's anti-tumor immune response.

Both the IL-13Ra2 and EphA2 targets are overexpressed on brain cancer cells. We determined that EphA2 was overexpressed, not only on brain tumor bulk, but also on brain CSCs (i.e., the CD133-expressing, or CD133+, subset of GBM cells, which is the CSC population), as shown below.

EphA2 Over-Expression on CSCs of GBM By Flow Cytometry

(Stemline Therapeutics, Inc.; unpublished data)

GRAPHIC

GRAPHIC

SL-701, like other cancer vaccines, is combined with additional elements designed to promote an immune response, including a helper peptide and an adjuvant. A helper peptide helps activate cytotoxic T-cells, and is mixed with SL-701 prior to administration. An adjuvant similarly helps stimulate the immune system, and is injected into the patient concurrently with SL-701 administration.

Immune response analyses, including enzyme-linked immunosorbent spot, or ELISPOT, and tetramer assays, were used to assess peripheral blood immune responses of patients to SL-701 administration. We believe that immune responses generated by SL-701 administration lead to tumor killing at the level of the tumor bulk and CSCs.

Completed Phase 1/2 Clinical Trial – Pediatric Glioma

In a completed Phase 1/2 trial, SL-701 was evaluated for safety and efficacy in pediatric patients with glioma. We refer to this trial as the 701 Ped-G Study. The 701 Ped-G Study was undertaken in 20 HLA-A2+ pediatric patients with glioma. Ten of these patients had newly diagnosed brainstem glioma, or BSG, five had newly diagnosed non-brainstem HGG, three had recurrent HGG and two had recurrent low-grade glioma, or LGG. Patients received a direct subcutaneous injection of SL-701 in the right or left upper arms associated with intact draining auxiliary lymph nodes once every three weeks for up to 24 weeks with a separate concurrent injection of an adjuvant.

Well-Tolerated at Clinically Active Doses

SL-701 was well-tolerated at clinically active doses. Adverse effects included local injection site reactions and low grade fevers in almost all patients, which were generally mild and controlled with analgesics.

Clinical Activity

In the 701 Ped-G Study, SL-701 demonstrated single agent clinical activity. 84% (16/19) of evaluable patients sustained durable tumor reductions or disease stabilizations, including two patients who experienced durable PRs with greater than 50% tumor shrinkage. One of these PR patients is a child with newly diagnosed BSG whose PR exceeds 15 months in duration. The second PR occurred in a child with newly diagnosed non-brainstem HGG. This PR exceeds eight months in duration. Notably, the majority of pediatric patients (7/10) with newly diagnosed BSG survived past the historical median OS of 9.6 months, including three patients who survived for periods in excess of 50% greater than the historical median survival. In addition, a patient with newly diagnosed non-brainstem HGG has survived for 16 months following SL-701 treatment.

In several cases, tumor pseudoprogression was seen. Tumor pseudoprogression is believed to represent a positive sign, or surrogate marker, of anti-tumor activity. Tumor pseudoprogression is manifested by edema and contrast enhancement on MRI and can transiently mimic tumor progression prior to

regression and thus must be carefully monitored. Pseudoprogression has been noted with the introduction of effective treatments for brain tumors, such as stereotactic radiotherapy, which have led to tumor responses. Notably, the PR patient whose response exceeds fifteen months is believed to have experienced tumor pseudoprogression prior to the PR.

Positive immunological assays (both ELISPOT and tetramer assays) were demonstrated in all five evaluable children, including the newly diagnosed BSG pediatric patient who sustained a durable PR that exceeds 15 months. We believe that these data indicate that SL-701 treatment stimulated the immune system in a highly specific fashion.

Completed Phase 1/2 Clinical Trial – Adult, Recurrent, High-Grade Glioma

In a completed Phase 1/2 clinical trial, SL-701 was evaluated in adult patients with recurrent or refractory HGG. We refer to this study as the 701 Adult-RHGG Study. The 701 Adult-RHGG Study enrolled 22 HLA-A2+ adult patients with recurrent or refractory HGG, 13 of which had refractory or recurrent GBM, and nine of which had anaplastic glioma, or AG. 50% of patients were second relapse or greater and two of the refractory or recurrent GBM patients had received prior treatment with Avastin®. SL-701 was loaded ex vivo onto patient-harvested dendritic cells, which were then re-injected intra/peri-nodally back into the patient with a separate concurrent injection of an adjuvant. This delivery method contrasts with that used in the 701 Ped-G Study, in which SL-701 was administered to patients and demonstrated robust antitumor activity as a direct subcutaneous injection.

Well-Tolerated at Clinically Active Doses

SL-701 was well-tolerated at clinically active doses. Injection site reactions were the most common adverse events and generally resolved within 24 hours. These side effects do not overlap with those of radiation, chemotherapy agents, and anti-angiogenic agents like Avastin®, which are mainstay therapies used to treat adult HGG. This implies that the development of SL-701-based combination regimens will likely be feasible.

Clinical Activity

In the 701 Adult-RHGG Study, SL-701 demonstrated single agent clinical activity. 46% (6/13) of refractory or recurrent GBM and 67% (6/9) of recurrent AG patients sustained an anti-tumor response or disease stabilization. This included two durable CRs, one of which occurred in a 62-year-old male GBM patient who was refractory to prior surgical resection, radiation therapy and temozolomide. Following SL-701 treatment, this patient's gadolinium enhanced tumor mass disappeared, and the patient was determined to have sustained a durable CR that exceeds 23 months. Notably, in this patient there was also a significant increase in target-specific T-cells by week 29 as determined by a tetramer assay, consistent with a positive immune response to SL-701. A recurrent AG patient with anaplastic oligoastrocytoma also sustained a CR that exceeds nine months. In addition to the two durable CRs, there were also three PRs. One PR was sustained by a patient with recurrent GBM (second salvage, i.e., third-line) and lasted seven months. Notably, a post-SL-701 brain biopsy from this PR patient demonstrated intratumoral infiltration of macrophages and CD8+ T lymphocytes. We believe this indicates that SL-701 induced the immune system, and cytotoxic T-cells in particular, to migrate to the area of the brain tumor and induce tumor shrinkage by targeting specific antigen-bearing CSCs and tumor bulk, and that this patient experienced a tumor pseudoprogression prior to the PR. This activity is consistent with the proposed mechanism of action of SL-701. A second PR was sustained by a patient with recurrent GBM whose PR exceeds 11 months in duration. The third PR was seen in a recurrent AG patient.

81% (13/16) of evaluable patients had at least one positive immunological assay. We believe this indicates that SL-701 treatment stimulated the immune system in a highly specific fashion.

Survival Benefit

SL-701 improved the median, six-month, and 12-month OS of adult patients with refractory or recurrent GBM as well as recurrent AG, compared with historical data. In refractory or recurrent GBM patients treated with SL-701, median OS was 13 months, six-month OS was 80%, and 12-month OS was 55%, as illustrated in the figure below. These rates represent improvements over the historical median OS of five to seven months, the historical six-month OS of 38% to 55%, and the historical 12-month OS of 14% to 25%. Recurrent AG patients treated with SL-701 also experienced an improvement in OS compared with historical results.

Kaplan-Meier Survival Curve

of Recurrent or Refractory Adult HGG Patients Treated with SL-701

(Okada et al., Journal of Clinical Oncology 2011; 29:330-336)

GRAPHIC

Low-Grade Glioma Trials in Pediatric and Adult Patients

There are currently two studies of SL-701 open in pediatric and adult patients with low-grade glioma, or LGG.

Planned Pivotal Phase 2b Clinical Trial and Regulatory Strategy

We plan to meet with the FDA in the second half of 2012 to present our design for a pivotal Phase 2b clinical trial in pediatric patients with newly diagnosed BSG. Patients will receive a direct subcutaneous injection of SL-701. We plan to seek grant funding to help support this trial. If we are able to proceed with the Phase 2b trial and the trial results are positive, we expect to file a BLA with the FDA as a basis for marketing approval of SL-701. We also plan to initiate a randomized Phase 2b clinical trial in adult second-line GBM directly or indirectly through investigator sponsors, with a development plan designed to culminate in registration.

The Cancer Stem Cell Opportunity

Limitations of Current Cancer Therapies

According to the National Cancer Institute, cancer is the second leading cause of death in the United States and is responsible for nearly one quarter of all deaths in the United States. The National Institutes of Health estimated that the total cost of treating cancer in 2010 was $125 billion. Current cancer treatments, which often include chemotherapy and radiation as well as newer targeted therapies, have shown a limited overall survival benefit when used in advanced stages of the most common cancers. Moreover, the impact of current treatments on many other cancers, including AML, brain malignancies and multiple other cancer types has also been quite small, if any. We believe that it is becoming increasingly accepted within the oncology field, based on a progressively increasing body of supportive data, that a major reason for such failures is that available therapeutics fail to effectively eliminate CSCs, which continue to repopulate the cancer despite these standard

treatments.

Cancer Stem Cell Overview

The field of CSCs is a rapidly emerging new area of cancer biology that we believe may fundamentally alter the approach to oncology drug development. CSCs comprise a highly malignant, self-renewing subpopulation of cancer cells within a tumor, often slow-growing, that is both highly tumorigenic, or tumor-producing, as well as resistant to traditional anti-cancer therapies relative to the rest of the largely fast-growing tumor bulk to which it gives rise.

CSCs have been identified in virtually all of the major tumor types including most of the common solid and hematologic cancer types. As shown in several examples below, researchers have identified numerous tumor types that harbor CSCs, including leukemia and cancers of the brain, breast, colon, prostate, pancreas, and others.

Examples of Tumor Types with CSCs

GRAPHIC

CSCs are Tumorigenic

CSCs are a small subpopulation of highly malignant cells within a tumor that many within the oncology field believe are responsible for the tumorigenicity, meaning the source of growth, of the entire cancer. CSCs typically comprise approximately 1% to 5% of the entire cancer and give rise to, or "seed", the tumor bulk that comprises the remaining ³95% of the tumor. In particular, isolated CSCs, not tumor bulk, have been shown capable of reconstituting the entire tumor anew when transplanted into immunocompromised mice and, importantly, are able to do so upon repeated serial retransplantation.

CSCs are Relatively Resistant to Traditional Therapies

In addition to being highly tumorigenic, CSCs are also resistant, relative to tumor bulk, to conventional anti-cancer therapies. This may be due to the many challenging characteristics of CSCs, including slow growth, presence of multi-drug resistance proteins, anti-cell death mechanisms, and upregulated DNA repair machinery. As shown in several examples below, researchers have shown that CSCs are resistant to chemotherapy, radiation, or targeted therapy relative to tumor bulk.

Examples of CSC Resistance to Traditional Therapies

GRAPHIC

Not only have CSCs been shown to resist traditional therapies, but in some cases CSCs have also been shown to increase, as a percentage of total tumor cells, as a result of exposure to a traditional therapy. For example, as described by Bao et al. in Nature in 2006, CSCs of brain tumors increase as a percentage of the entire cancer following radiation treatment. Similarly, as shown by Hermann et al. in Cell Stem Cell in 2007, pancreatic CSCs increase following gemcitabine treatment in in vivo xenograft models.

CSCs Correlate with Prognosis

Consistent with their pivotal role in the development of tumors and relapse, higher amounts of CSCs in patient tumors as a percentage of their entire cancer have been shown to correlate with poor prognosis. For example, CSC fractions greater than 3.5% and 1% of the entire cancer correlate with poor survival outcomes in patients with AML and brain cancer, respectively, as shown by van Rhenen et al. in Clinical Cancer Research in 2005 (for AML) and Zeppernick et al. in Clinical Cancer Research in 2008 (for brain cancer).

Stemline's Anti-CSC Drug Development Opportunity

While standard therapies may initially shrink tumors by targeting the tumor bulk, we believe it is increasingly accepted within the oncology field that the failure of these therapies to eradicate CSCs is a major contributor to treatment failure, tumor relapse and poor survival. Accordingly, we believe that targeting CSCs, in addition to tumor bulk, may represent a major advance in the fight against cancer. This premise has formed the basis of our drug development strategy, as illustrated below.

GRAPHIC

Since our inception in 2003, we have leveraged our knowledge of CSCs to anticipate and establish a leadership position in this new field of oncology. During this time, we have developed or strategically in-licensed key intellectual property, built and validated a drug discovery platform, and developed clinically active drug candidates. We believe that our early and comprehensive effort to develop the next generation of oncology therapeutics that target CSCs, as well as the tumor bulk, provides us with a significant competitive advantage.

Our Platform Technologies

We have developed an innovative platform technology, called StemScreen®, currently consisting of StemScreen®-1 and StemScreen®-2, for the identification of novel CSC-directed compounds. This platform contrasts with traditional drug discovery methods in oncology that have been designed to identify compounds that target tumor bulk, not CSCs. StemScreen®-1 is a technology developed to discover CSC-targeted compounds and involves the isolation of CSCs, the discovery of potential CSC targets through CSC gene expression analysis, and the identification and validation of compounds that impact candidate CSC targets. StemScreen®-2 utilizes a cell-based assay developed to track and follow CSCs in their natural state during high throughput screening. We believe that this approach represents a major technological advance in oncology drug discovery. We have utilized StemScreen® to discover several of our product candidates. We believe that this robust platform will be instrumental in the discovery of additional new therapies targeting a wide range of cancer types.

StemScreen®-1

StemScreen®-1 is a validated, proprietary drug discovery platform designed to identify CSC-targeted compounds based on the isolation of CSCs and evaluation of CSC gene expression profiles. CSCs are isolated from primary tumor tissue or cell lines, and then subjected to gene expression analysis using a variety of technologies, including microarray. A control tissue, such as normal bone marrow is analyzed as a comparator against the gene expression profile of the isolated CSCs. These data are then interfaced with an information base of compounds and their mechanisms of action (i.e. which gene products and pathways they impact). Compound classes are then identified as likely to impact

CSC-specific pathways discovered by the gene expression analyses. Select compounds within these classes are then tested in our anti-CSC functional in vitro and in vivo assays. Compounds that demonstrate anti-CSC activity are then considered for further development, which may include lead optimization. We have utilized StemScreen®-1 to discover a number of our preclinical drug candidates. These include SL-201, SL-301, and SL-601. In addition, SL-401 demonstrated activity against CSCs as determined by both an in vitro colony formation and in vivo animal implantation assay, thereby validating certain StemScreen®-1 anti-CSC assays.

StemScreen®-2

StemScreen®-2 is a proprietary high throughput drug discovery platform we are developing to discover novel anti-CSC compounds. Traditional oncology drug discovery screens have largely relied upon readouts that measure activity against tumor bulk, and have not been specifically designed to identify compounds with activity against CSCs. StemScreen®-2 is based on a key discovery, covered by intellectual property controlled by Stemline, that immortal cancer cell lines harbor not only tumor bulk but also CSCs. This discovery enables compounds to be screened, in a high throughput manner, for activity against CSCs in their natural state.

StemScreen®-2 utilizes a cell-based assay that can track and follow CSCs in their natural state during high throughput screening. In particular, StemScreen®-2 utilizes a CSC-specific promoter linked to a reporter as a method for identifying and following CSCs in their native environment of surrounding tumor bulk, as illustrated below. In this way, StemScreen®-2 enables the identification of compound "hits," in a high throughput manner, with anti-CSC activity.

GRAPHIC

Notably, prior to the development of StemScreen®-2, screens for anti-CSC compounds had been limited due to 1) reliance on finite sources of primary tissue specimens rather than immortal cancer cell lines, and 2) purification of CSCs away from the rest of the tumor, each thereby limiting screens to small libraries in relatively low throughput systems. Moreover, other CSC-focused screens have recently been developed that require artificial manipulation to create the CSC phenotype from non-CSCs in the context of an immortal cell line. Thus, we believe that StemScreen®-2, unlike other CSC-focused screening systems, is distinct because it is both high throughput and accurately represents the CSC phenotype in its native, unaltered state.

StemScreen®-2 also allows for further optimization, miniaturization, and screening in a high throughput manner for drug candidates with anti-CSC activity from large libraries of chemical or biologic compounds.

An initial screen of a moderately sized chemical compound library led to the identification of several "hits," comprising 2.4% of the library, that demonstrated activity against CSCs with greater than 50% growth inhibition. Several of these compounds were then further validated using

secondary functional assays to confirm anti-CSC activity. We plan to further optimize StemScreen®-2 for larger scale screening as well as expand its applicability for use in a broad range of tumor types either alone and/or in collaboration with a strategic partner.

Preclinical Pipeline

The table below summarizes our preclinical pipeline:

GRAPHIC

Stemline has assembled a pipeline of small molecules and monoclonal antibody-based, or mAb-based, compounds directed to targets on CSCs and tumor bulk. This pipeline was built through a variety of methods, including discovery via our proprietary platforms as well as through in-licensing of certain key intellectual property.

SL-301 is a small molecule gamma-secretase inhibitor that inhibits Notch, a pathway expressed by CSCs and tumor bulk of multiple cancer types. SL-301 has demonstrated activity against brain and pancreatic CSCs and tumor bulk in vitro, and against glioblastoma and medulloblastoma CSCs in in vivo animal models. SL-101 is a mAb -based compound that targets CD123 and has shown in vitro activity against certain hematologic cancers. SL-201 is a small molecule active against certain hematologic and solid tumor types. SL-601 is a mAb-based compound that targets a cell surface marker on bladder CSCs, which is also expressed on a variety of other solid tumor types.

We have also in-licensed certain intellectual property directed to mAb-based therapeutics to validated oncology targets including Glypican-3, Tie-1, CD133, Frizzled, Smoothened and Patched. Some of these antibody targets are also being pursued by other biopharmaceutical companies. We may develop, or partner with third parties to develop, any or all of these mAbs.

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Patents and Proprietary Rights

We strive to protect our product candidates and exclusivity rights, as well as both maintain and fortify our position in the CSC field. We believe our intellectual property portfolio consists of early and broad filings in the area. We have focused on patents and patent applications covering, where possible, our products and methods of use of our products in disease treatment. We have also focused on patents and patent applications covering, wherever possible, broad facets of CSC-directed therapeutics, diagnostics, including companion diagnostics, and drug discovery. We have sought and continue to seek the strongest possible intellectual property protection available to us in order to prevent others from directly competing with us, as well as to exclude competition around our products, their methods of use in disease treatment, as well as, more generally, CSC-directed therapeutics, diagnostics including companion diagnostics, and drug discovery.

Our intellectual property portfolio contains 13 issued patents and more than 30 pending applications in the U.S. and worldwide of both in-licensed and Stemline-originated inventions. This portfolio includes patents and proprietary rights around (i) Stemline's drug candidates and (ii) CSC-focused intellectual property, which includes early and broad filings in the CSC field covering CSC therapeutics, diagnostics, including companion diagnostics, and drug discovery.

Patents and Proprietary Rights Covering Stemline's Drug Candidates

We have an exclusive worldwide license to SL-401. These patent rights consist of an issued U.S. patent (U.S. Patent 7,763,242) covering a method of treating MDS that expires in 2027 and pending U.S. and foreign applications directed to methods of using SL-401 to treat MDS, AML and other diseases that, if issued, would also expire in 2027. In addition, we have filed U.S. and foreign patent applications for the method of using SL-401 to treat MDS and AML, although there can be no assurances that such patents will be issued. In addition to patent protections, we also have the exclusivity afforded by the FDA designation of SL-401 as an Orphan Drug and by the provisions of the Biologics Price Competition and Innovation Act of 2009. See "Government Regulation—Orphan Drug Designation" and "—U.S. Patent Term Restoration and Marketing Exclusivity—Biologics Price Competition and Innovation Act of 2009".

We have an exclusive worldwide license to SL-701 component, IL-13Ra2, and a non-exclusive worldwide license to SL-701 component, EphA2. These patent rights consist of an issued U.S. composition of matter patent (U.S. Patent 7,612,162) directed to an immunogenic mutant IL-13Ra2 peptide expiring in 2025 and issued U.S. method of use patent (U.S. Patents 7,297,337 and 8,114,407) directed to the use of EphA2 peptides used in SL-701 expiring in 2025 and 2024, respectively. We also have pending patent applications directed to methods of using SL-701 to treat certain diseases, which if issued would provide additional protection in the United States and certain non-U.S. territories and would expire in 2025.

We also in-licensed, or own, exclusive patent rights in the U.S. and abroad to several preclinical programs. We in-licensed exclusive rights to a family of pending patent applications covering SL-301, which covers the use of SL-301 and certain other gamma secretase inhibitors for the treatment of cancer and neurodegenerative diseases. We in-licensed exclusive rights to SL-101, an antibody-based compound targeting CD123. We in-licensed exclusive rights to a family of pending patent applications covering SL-601, an antibody-based compound that targets bladder CSCs. Also, we have invented, and own exclusive rights to patent applications covering SL-201, a small molecule cancer therapy.

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Patents and Proprietary Rights Covering CSC-Focused Intellectual Property

We have exclusive worldwide rights to early and broad patents and patent applications in the CSC field covering CSC therapeutics, diagnostics, including companion diagnostics, and drug discovery:

- A therapeutic patent (U.S. Patent 8,038,998) that covers a method to treat cancer through use of monoclonal antibodies and other antibody-based compounds that target CSCs, and related pending applications that cover methods to treat cancer through use of small molecule or oligonucleotide-based compounds that target CSCs. Patent protection for these patent families extends from 2017 or 2019, as applicable;

- A diagnostic patent (U.S. Patent 6,004,528), and related pending applications, that covers the diagnosis of cancer through detection of CSCs. Patent protection extends from 2017 or 2019, as applicable;

- Four issued patents that cover methods to treat cancer through use of monoclonal antibodies and other antibody-based compounds directed to six specific key targets: Frizzled, Glypican-3, Tie-1, CD133, Smoothened, and Patched. These U.S. Patents are: 7,361,336; 7,427,400; 7,504,103; and 7,608,259. Patent protection extends from 2017 or 2019, as applicable;

- Two pending patent applications filed in 2006 directed to CSC-directed therapies and regimens, including CSC-directed therapies and regimens for use in combination with companion diagnostics. Patent protection, to the extent it issues, would be expected to extend to 2027;

- A pending patent application that covers oligonucleotide-based oncology therapies, including CSC-targeted therapeutics, which target microRNA. Patent protection, to the extent it issues, would be expected to extend to 2022;

- A family of intellectual property covering methods to treat cancer through use of antibody-based compounds directed to IL-3R, including U.S. Patent 7,651,678; U.S. Patent 6,733,743; and other pending applications. Patent protection, to the extent it issues, would be expected to extend to 2021; and

- Pending patent applications covering CSC-focused drug discovery, including a novel high throughput screen to discover compounds that target CSCs. Patent protection, to the extent it issues, would be expected to extend to 2025.

Intellectual Property Strategy

We continually re-assess and fine-tune our intellectual property strategy in order to fortify our position in our market space. To that end, we are prepared to file additional patent applications in any of the above families should our intellectual property strategy require such filings and/or where we seek to adapt to competition or seize business opportunities. Further, we are prepared to file patent applications relating to the other products in our pipeline soon after the experimental data necessary for a strong application become available and our cost-benefit analyses justify filing such applications.

In addition to filing and prosecuting patent applications in the United States, we typically file counterpart patent applications in Europe, Canada, Japan, Australia and in additional countries where we think such foreign filing is likely to be beneficial.

We do not know if patents will be issued for all of the patent applications in our portfolio. Furthermore, for patent claims now issued and for claims to be issued in the future, we do not know if such claims will provide significant proprietary protection to our drug candidates and proprietary technologies or if they will be challenged, circumvented, or invalidated. Our success will in part depend on our ability to obtain and maintain patents protecting our drug candidates, technologies and

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inventions, to operate without infringing the proprietary rights of third parties, and to enforce and defend our patents and ensure others do not infringe on our proprietary rights.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent.

The patent term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We anticipate that some of our issued patents may be eligible for patent term extensions. For more information regarding U.S. patent laws, see "Business – Government Regulation."

In addition to the patent term extension rights described above, any of our product candidates that receive FDA approval may also be eligible for market exclusivity protection under the Federal Food, Drug and Cosmetic Act or the Biologics Price Competition and Innovation Act of 2009. For more information regarding market exclusivity laws, see "Business – Government Regulation."

Many pharmaceutical companies, biotechnology companies and academic institutions are competing with us in the field of oncology and filing patent applications potentially relevant to our business. In order to contend with the inevitable possibility of third party intellectual property conflicts, from time to time, we review and assess the third-party intellectual property landscape for competitive and other developments that may inform or impact our intellectual property development and commercialization strategies.

From time to time, we find it necessary or prudent to obtain licenses from third party intellectual property holders. Where licenses are readily available at reasonable cost, such licenses are considered a normal cost of doing business. In other instances, however, where a third party holds relevant intellectual property and is a direct competitor, a license might not be available on commercially reasonable terms or available at all. Accordingly, we attempt to manage the risk that such third party intellectual property may pose by conducting, among other measures, freedom-to-operate studies to guide our early-stage research away from areas where we are likely to encounter obstacles in the form of third party intellectual property. As our programs advance, we continue to monitor the intellectual property landscape in an effort to assess the advisability of licensing third party intellectual property or taking other appropriate steps to address such freedom-to-operate or development issues in the manner we deem in the best interests of the Company.

With respect to third party intellectual property, it is impossible to establish with certainty that our product candidates or discovery platform will be free of claims by third party intellectual property holders or whether we will require licenses from such third parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third party patent is identified, we may conclude upon a thorough

analysis, that we do not infringe the patent or that the patent is invalid. If the third party patent owner disagrees with our conclusion and we continue with the business activity in question, we might have patent litigation thrust upon us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third party patent invalid or not infringed by our activity. In either scenario, patent litigation typically is costly and time-consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data. Ultimately, in the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our discovery platform as a result of patent infringement claims asserted against us. This could have a material adverse affect on our business.

To protect our competitive position, it may be necessary to enforce our patent rights through litigation against infringing third parties. Litigation to enforce our own patent rights is subject to the same uncertainties discussed above. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or our platform technology, and then compete directly with us, without payment to us.

License and Research Agreements

Scott and White Memorial Hospital

Research and License Agreement (SL-401)

In June 2006, we entered into a research and license agreement with Scott and White Memorial Hospital for SL-401, our biologic-drug conjugate candidate targeting IL-3R. Under the agreement, Scott and White has granted us an exclusive, royalty-bearing, worldwide license under certain patent rights, know-how and materials to research, develop, make, have made, formulate, use, sell, offer to sell and import SL-401, and any products containing or comprising such compound in finished dosage pharmaceutical form, for the diagnosis, prophylaxis and/or treatment of any disease or condition in humans or animals. The patent rights exclusively licensed to us under the agreement are described in more detail above under "Business – Patents and Proprietary Rights."

We must pay Scott and White royalties based on adjusted gross sales, by us or our sublicensees, of products containing the licensed compound for a period of ten years following the first commercial sale of each product in each country. The royalty rates for each product are in the single digits and tiered based on our annual sales. We have sublicensing rights under the agreement, subject to our paying to Scott and White a percentage of the up-front payments we receive from a sublicensee.

We must exercise commercially reasonable efforts to develop and commercialize a licensed product and to achieve certain regulatory milestones within certain periods, subject to extensions based on unforeseen technical, scientific, intellectual property or regulatory issues. If we fail to comply with our diligence obligations with respect to at least one licensed product, then Scott and White may convert our exclusive license to a non-exclusive license.

The agreement survives 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, after which our license becomes fully paid up, irrevocable, perpetual, non-exclusive and royalty-free. We may terminate the license in whole or on a country-by-country and product-by-product basis upon prior written notice to Scott and White. If either we or Scott and White breach a material obligation under the agreement, and such obligation is not cured within a specified period of time following written notice from the other party, then the non-breaching party may terminate the agreement upon an additional written notice.

In addition, we have engaged Scott and White to conduct a research program on SL-401, which has included support for the regulatory advancement of SL-401. In March 2010, the research program was amended to further the regulatory advancement of SL-401. Additionally, upon our request, Scott and White is required to either assign to us its IND for SL-401 or grant us the exclusive right to reference its IND in the event we file our own IND for SL-401. We may assign the agreement to an affiliate of ours, a purchaser of all or substantially all of our assets or in connection with a merger, change in control or similar transaction by us.

University of Pittsburgh

Exclusive License Agreement to IL-13Ra2 peptide (SL-701 component)

In September 2009, we entered into an exclusive license agreement with the University of Pittsburgh, or the University, for the composition of matter, and use with other components, of a proprietary immunogenic mutant analog peptide of IL-13Ra2, an active ingredient of SL-701, our brain cancer vaccine candidate. Under the agreement, the University grants us an exclusive worldwide license under certain patent rights to make, have made, use, sell and import brain cancer peptide antigen vaccines (including SL-701, which has been developed by the University under a separate vaccine name designated by the University). The patent rights exclusively licensed to us under the agreement are described in more detail above under "Business – Patents and Proprietary Rights." The University retains the right to practice the licensed patent rights for non-commercial education and research purposes. The license is also subject to certain retained rights of the United States government. Our right to grant sublicenses to third parties is subject to the prior written approval of the University, which the University may not unreasonably withhold or delay.

We paid the University an initial license fee and will pay the University annual license maintenance fees until the first commercial sale of a licensed product. We must also pay the University a single digit royalty as a percentage of net sales of licensed products by us or our sublicensees, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize the licensed products. We must also pay a minimum annual royalty following the first commercial sale of a licensed product, but only to the extent the minimum annual royalty amount is greater than the annual royalty otherwise due. We also must pay the University a percentage of non-royalty revenue we receive from our sublicensees, which decreases if we enter into the applicable sublicense agreement after a certain clinical milestone has been met. We also must make certain payments to the University of up to approximately $4.1 million upon the achievement of specific regulatory and commercial milestone events.

We must use our commercially reasonable best efforts to develop or commercialize a licensed product as soon as practicable, and to continue active, diligent marketing efforts throughout the term of the agreement. We also must adhere to certain specific regulatory milestones with respect to initiating clinical trials and submitting an application for regulatory approval of a licensed product. If we fail to meet any such milestone through no fault of our own, we may negotiate with the University a one-time extension of the applicable dates, subject to paying the University a fee. If we do not meet the extended milestone dates, then the University may terminate the agreement.

The agreement survives until the expiration of the last to expire licensed patent. The University may terminate the agreement if we default in the performance of any of our obligations and do not cure the default within a specified period of time after receiving notice from the University, or if we challenge the validity, enforceability or ownership of the license patent rights anywhere in the world. The University may also terminate the

agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the University and payment of all amounts due to the University through the date of termination. Any sublicense agreement entered into prior to termination will survive, subject to certain customary

conditions. We may assign the agreement to an affiliate of ours, a purchaser of all or substantially all of our assets or in connection with a merger, change in control or similar transaction by us.

Non-Exclusive License Agreement to EphA2 peptide (SL-701 component)

In March 2012, we entered into a non-exclusive license agreement with the University for the use of EphA2 epitopes, another active ingredient of SL-701. Under the agreement, the University grants us a non-exclusive worldwide license under certain patent rights to use the EphA2 peptide in or packaged with the IL-13Ra2 peptide, as well as other vaccines we may develop and own or exclusively control, for the diagnosis, treatment or prevention of diseases and tumors of the brain in human patients. The patent rights licensed to us under the agreement are described in more detail above under "Business – Patents and Proprietary Rights." The University retains the right to practice the licensed patent rights for non-commercial education and research purposes. The license grant is also subject to certain retained rights of the United States government. We may only grant sublicenses to third parties who are permitted sublicensees under the exclusive IL-13Ra2 peptide license agreement with the University.

We must pay the University an initial license fee, and will pay the University annual license maintenance fees until the net sales of a licensed product exceed a specified amount. We must also pay the University a customary single digit royalty for a non-exclusive license as a percentage of net sales of licensed products by us or our sublicensees, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize the licensed products. We must also pay a minimum annual royalty following the first commercial sale of a licensed product, but only to the extent the minimum annual royalty amount is greater than the annual royalty otherwise due.

We must use our commercially reasonable best efforts to develop or commercialize a licensed product as soon as practicable, and to continue active, diligent marketing efforts throughout the term of the agreement. We also must adhere to certain specific regulatory milestones with respect to initiating clinical trials and submitting an application for regulatory approval of a licensed product. If we fail to meet any such milestone by certain specified dates, then the University may terminate the agreement.

The agreement survives until the expiration of the last to expire licensed patent. The University may terminate the agreement if we default in the performance of any of our obligations and do not cure the default within a specified time period of receiving notice from the University. The University may also terminate the agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the University and payment of all amounts due to the University through the date of termination. Any sublicense agreement entered into prior to termination will survive, subject to certain customary conditions. We may assign the agreement to an affiliate of ours, a purchaser of all or substantially all of our assets or in connection with a merger, change in control or similar transaction by us.

Non-Exclusive License Agreement to use and reference certain data, information and regulatory filings (SL-701)

In March 2012, we entered into a non-exclusive license agreement with the University. Pursuant to the agreement, we acquired a non-exclusive, worldwide license to use certain know-how, information and data that is contained in the INDs covering the clinical trials of SL-701 that were conducted by the University for the development, manufacture, regulatory approval and commercialization of pharmaceutical products. We may grant sublicenses in conjunction with a sublicense to a permitted sublicensee under the exclusive IL-13Ra2 peptide license agreement with the University.

We must pay the University an initial license fee, as well as payments following a regulatory milestone. We also must pay the University a percentage of non-royalty revenue we receive from our sublicensees. We must use our commercially reasonable best efforts to develop or commercialize a product derived from the use of the licensed data or information as soon as practicable. We also must adhere to a

specific regulatory milestone with respect to submitting an application for regulatory approval that incorporates the licensed data or information, and if we fail to meet the milestone, the University may terminate the agreement unless we have pre-paid the milestone payment listed above.

The term of the license agreement is 20 years, and the University may terminate the agreement earlier (i) if we default in the performance of any of our obligations and do not cure the default within a specified time period, (ii) upon the termination of the exclusive IL-13Ra2 peptide license agreement with the University, or (iii) if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement at any time prior to incorporating or referencing the data or University INDs, after a specified number of days following written notice. We may assign the agreement to an affiliate of ours, a purchaser of all or substantially all of our assets or in connection with a merger, change in control

or similar transaction by us.

Cambridge University Technical Services Limited

Exclusive Patent and Non-Exclusive Know-How License Agreement (Platform Technology)

In September 2004, we entered into a license agreement with Cambridge University Technical Services Limited, or CUTS, relating to our StemScreen® platform technology. Under the agreement, we acquired an exclusive, royalty-bearing, worldwide license under patent rights owned by CUTS to develop, manufacture, have manufactured, use, sell, offer to sell, market, have marketed, import, have imported, export and have exported products covered by the patent rights, including a platform technology to discover and screen for compounds that target CSCs. The patent rights exclusively licensed to us under the agreement are described in more detail above under "Business – Patents and Proprietary Rights." The license is subject to certain rights retained by CUTS for academic research and teaching. We also acquired a non-exclusive, worldwide license to know-how related to the licensed patent rights. The agreement provides us with full sublicensing rights. Under the agreement, we paid an upfront license fee and are obligated to make milestone payments upon specified regulatory events, as well as pay royalties on sales of licensed products. CUTS may terminate the agreement, including our rights to the platform technology, for specified cause or upon certain events involving our bankruptcy or insolvency.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology, and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are several biopharmaceutical companies whose primary focus appears to be developing therapies against CSCs, including Boston Biomedical, Inc., Eclipse Therapeutics, Inc., OncoMed Pharmaceuticals, Inc. and Verastem, Inc. There are also several biopharmaceutical companies that do not appear to be primarily focused on CSCs, but may be developing at least one CSC-directed compound. These companies include Astellas Pharma US, Inc., Boehringer Ingelheim GmbH, Dainippon Sumitomo Pharma Co. Ltd., Geron Corp., GlaxoSmithKline plc, ImmunoCellular Therapeutics, Ltd, Macrogenics Inc., Micromet, Inc. (an Amgen, Inc. Company), Pfizer Inc., Roche Holding AG, Sanofi U.S. LLC, and others.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Small or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over any competitive generic products.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy. These therapies are numerous and varied in their design, therapeutic application and mechanism of action. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval. In addition to currently marketed oncology therapies, there are also a number of products in late stage clinical development to treat cancer. These products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval.

Competition for SL-401

There are a limited number of drugs approved for the treatment of adult AML, and these include the traditional chemotherapies cytarabine, daunorubicin, and other anthracyclines which have been marketed for many years and are both currently available in generic formulations. There are a number of companies working to develop new treatments for AML, including Cyclacel Pharmaceuticals, Inc., Sunesis Pharmaceuticals Inc., Genzyme Corporation (now a Sanofi company), Clavis Pharma ASA, Ambit Biosciences Corporation, Celgene Corporation, Eisai Co. Ltd. and Celator Pharmaceuticals, Inc., among others.

Unlike many of these drug candidates, SL-401 has been developed to target both tumor bulk and CSCs and, to date, has been shown to spare the bone marrow of toxicity. While SL-401 is currently being developed as a single agent, its favorable safety profile suggests the potential to safely combine it with other agents.

Competition for SL-701

There are a limited number of drugs used for the treatment of brain cancer, including Temodar® (Merck & Co., Inc.), nitrosureas including Gliadel® (Eisai Co., Inc.), and Avastin® (Roche Holding AG). There are a number of companies working to develop brain cancer therapeutics with programs in

clinical testing including Roche Holding AG, Novartis AG, Merck & Co., Inc., Celldex Therapeutics, Inc., ImmunoCellular Therapeutics, Ltd. and others.

Unlike many of these drug candidates, SL-701 has been developed to target both tumor bulk and CSCs. While SL-701 is currently being developed as a single agent, its favorable safety profile suggests the potential to safely combine it with other agents.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, or the PHSA, and related regulations, and other federal, state and local statutes and regulations. Biological products include, among other things, viruses, therapeutic serums, vaccines and most protein products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

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Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;

•

Submission to the FDA of an Investigational New Drug Application, or an IND, which must become effective before human clinical trials may begin;

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Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug or biologic for its intended use;

•

Submission to the FDA of a New Drug Application, or an NDA, for a new drug product, or a Biologics License Application, or a BLA, for a new biological product;

•

Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug or biologic is to be produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;

•

Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA or BLA; and

•

FDA review and approval of the NDA or BLA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

Before testing any compounds with potential therapeutic value in humans, the drug or biological candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug or biological candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug or biological candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot assure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug or biological candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined:

•

Phase 1. The drug or biologic is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients having the specific disease.

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Phase 2. The drug or biologic is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.

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Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials, which usually involve more subjects than earlier trials, are intended to establish the overall risk/

benefit ratio of the product and provide an adequate basis for product labeling. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA or BLA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA by the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug or biological candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final drug or biologic. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug or biologic, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. We believe that we will be required to submit a BLA for SL-401 and SL-701.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or a BLA or supplement to an NDA or a BLA must contain data to assess the safety and effectiveness of the drug or biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted. PREA will expire on September 30, 2012 if it is not reauthorized before that time.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA or BLA and respond to the applicant, and six months for a priority NDA or BLA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs and BLAs. The FDA and stakeholders are currently discussing the goals that will be proposed to Congress by the FDA when and if PDUFA is reauthorized for

another 5-year period effective October 1, 2012. While user fees are likely to increase, as they have in prior PDUFA reauthorizations, we cannot predict what if any changes will be proposed for FDA review goals.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. In addition to its own review, the FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug or biologic. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect

one or more clinical sites to assure compliance with cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA or BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA will issue a "complete response" letter if the agency decides not to approve the NDA or BLA. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

In February 2011, we received Orphan Drug Designation for SL-401 for the treatment of AML in the United States.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug and biological products that meet certain criteria. Specifically, new drug and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Any product submitted to the FDA for marketing approval, including those submitted to a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared with marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and

that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to establish safety and efficacy for the approved indication. Failure to conduct such studies, or conducting such studies that do not establish the required safety and efficacy may result in revocation of the original approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any drug or biological products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or as required more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs and biologics for uses or in patient populations that are not described in the drug's or biologic's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of comprehensive records and documentation. Drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are also required to register their establishments and list any products made there with the FDA and comply with related requirements in certain states, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, and possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

U.S. Patent Term Restoration and Marketing Exclusivity

Drug Price Competition and Patent Term Restoration Act of 1984

Depending upon the timing, duration and specifics of the FDA approval of the use of our drug and biologics candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during federal regulatory review preceding the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or a BLA plus the time between the submission date of an NDA or a BLA and the approval of that application. Only one patent applicable to an approved drug or biologic is eligible for the extension and the application for the extension must be submitted within 60 days of approval and prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Federal Food, Drug and Cosmetic Act

Market exclusivity provisions under the FDCA, which are independent of patent status and any patent related extensions, can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. If the new drug is a new chemical entity subject to an NDA, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted by the FDA, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be

granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. Biologic products that are subject to the PHSA are not eligible for pediatric exclusivity under the FDCA.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create a new licensure framework for biosimilar products, which could ultimately subject our biological product candidates to competition. Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a referenced, branded biologic product. Previously, there had been no licensure pathway for such biosimilar or interchangeable products. For purposes of the BPCIA, a reference product is defined as the single biological product licensed under a full BLA against which a biological product is evaluated in an application submitted under a follow-on BLA.

The BPCIA also created a 12-year period of reference product exclusivity, which can be extended to 12.5 years with pediatric exclusivity. The 12-year exclusivity period begins on the date of first licensure of the reference product under the PHSA and during which the licensure of a follow-on application for a biosimilar or interchangeable product cannot be made effective. During the first four years (or four and one-half years with pediatric exclusivity) of the 12-year period, an application for a biosimilar or interchangeable version of the reference product cannot be submitted to the FDA. Under a budget proposal President Obama submitted to Congress in 2011, the Administration requested that reference product exclusivity would decrease from 12 to seven years beginning in 2012. Congress has not yet enacted such a change in the BPCIA, but could move to enact such a decrease in the reference product exclusivity period.

The BPCIA includes limits on obtaining 12-year reference product exclusivity for certain changes or modifications to the reference product. A separate 12-year reference product exclusivity period does not apply to:

- a BLA supplement for the product that is the reference product;
- a subsequent BLA filed by the same reference product sponsor or manufacturer (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or
- a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

In February 2012, the FDA issued three draft guidance documents on biosimilar product development. The FDA is soliciting comments on the draft guidance documents which are described by the FDA as follows: (1) Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, which is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application, called a "351(k)" application, to the FDA. This draft guidance describes a risk-based

"totality-of-the-evidence" approach that the FDA intends to use to evaluate the data and information submitted in support of a determination of biosimilarity of the proposed product to the reference product; (2) Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, which provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application; and (3) Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of

2009, which provides answers to common questions from people interested in developing biosimilar products. We cannot predict when or whether these draft guidance documents will ever be finalized.

In addition to creating a 12-year period of reference product exclusivity, the BPCIA clarifies the interaction of that exclusivity with orphan drug exclusivity, such that the licensure of a biosimilar or interchangeable version of a reference product that was designated and approved as an orphan drug may only occur after the later of the expiration of any applicable seven-year orphan drug exclusivity or the 12-year reference product exclusivity (or seven and one-half years and 12.5 years with pediatric exclusivity).

Like pediatric exclusivity applicable to drug products approved under the FDCA, pediatric exclusivity applicable to biological reference products is subject to an exception. Pediatric exclusivity will not apply to either the 12-year reference product or the seven-year orphan drug exclusivity periods if the FDA has not determined that the study reports a BLA sponsor submitted in response to a written request for pediatric studies met the terms of that request before nine months prior to the expiration of such period .

Our biological product candidates, if approved, could be considered reference products entitled to 12-year exclusivity. Even if our products are considered to be reference products eligible for exclusivity, another company could market a competing version of any of our biological products if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

The BPCIA also sets forth a complex mechanism for resolving patent disputes that involves a step-wise exchange of information prior to the initiation of a patent infringement lawsuit against a biosimilar or interchangeable product sponsor. Unlike the Hatch-Waxman Act, the BPCIA provides no automatic stay on approval of a biosimilar product application, except an interchangeable product receives the lesser of one year of exclusivity after the date of first commercial marketing or 18 months of exclusivity after FDA approval vis-à-vis any other approved, interchangeable follow-on biological products. The BPCIA does not prevent a competitor from conducting its own clinical trials and submitting a full BLA on the same or similar product.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, state attorney generals and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies including United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to

require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public

disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Europe/Rest Of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application to the European Medicines Agency, or the EMA. The application used to file an NDA or a BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. For example, the EMA has already established a number of guidelines for approval of various biosimilars.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug or biological candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug or biological product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug or biological product. Third-party payors may limit coverage to specific drug or biological products on an approved list, or formulary, which might not include all of the FDA-approved drug or biological products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our drug or biological candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug or biological product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs and biologics may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs and biologics. Future legislation could limit payments for pharmaceuticals such as the drug or biological candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed

once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug or biological candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug or biological candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-

party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Manufacturing

We do not currently own or operate any manufacturing facilities for the clinical or commercial production of our drug candidates. To date, all drug substance and drug product for SL-401 and SL-701 have been manufactured by our academic collaborators. We plan to work with third-party contract manufacturers to produce sufficient quantities of SL-401 and SL-701 for our contemplated clinical trials and potential commercialization. Our manufacturing programs are being developed by our manufacturing team, which is comprised of full-time employees and consultants with experience manufacturing protein biologics and peptides and developing drug product formulations.

SL-401 Manufacturing and Supply

SL-401 is a recombinant protein generated from an antibiotic-resistance driven DNA-based plasmid vector and manufactured by bacterial fermentation in E. Coli. The initial supply of SL-401 that was used for the investigator-sponsored Phase 1/2 clinical trial was manufactured at Wake Forest University. We have optimized the plasmid vector and developed the fermentation and purification steps of our manufacturing process at third-party contract research organizations. We are currently preparing to transfer this technology to a third-party contract manufacturer with expertise in bacterial fermentation, where it will be process optimized and scaled-up for production. We expect that the cGMP manufactured batches will be sufficient in quality and quantity to enable their use in corporate-sponsored clinical trials and commercialization.

SL-701 Manufacturing and Supply

SL-701 is a peptide vaccine that is comprised of short synthetic peptides. SL-701 can be administered as a peptide emulsion by direct subcutaneous injection into the patient, or by ex vivo delivery onto autologous dendritic cells which are then reinfused into the patient. We plan to focus largely on developing the direct peptide injection delivery method of SL-701 for future clinical trials and commercialization. Each of the component peptides of SL-701 is manufactured individually by solid-phase synthesis using standard Fmoc chemistry. We plan to mix and formulate the individual peptides to generate the SL-701 drug product. SL-701 used in the investigator-sponsored Phase 1/2 trials was manufactured at a third-party contract manufacturer. We plan to select a third-party contract manufacturer to produce SL-701 supply for our clinical trials and commercialization.

Sales and Marketing

We believe that the infrastructure required to commercialize oncology products is relatively limited, which makes it cost-effective for us to internally develop a marketing and sales force. If SL-401 and SL-701 are approved by the FDA and other regulatory authorities, we plan to build the infrastructure to commercialize these products in North America and Europe ourselves. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous.

The commercial infrastructure of specialty oncology products typically consists of a targeted, specialty sales force that calls on a limited and focused group of physicians supported by sales management, internal sales support, an internal marketing group, and distribution support. Additional capabilities important to the oncology marketplace include the management of key accounts, such as managed care organizations, group-purchasing organizations, specialty pharmacies, oncology group networks, and

government accounts. As SL-401 and SL-701 are being developed for orphan indications with a relatively small number of treating physicians, we anticipate that a reduced infrastructure, including a small, targeted sales force, will be sufficient to support our sales and marketing objectives. In order to implement this infrastructure, we will have to allocate management resources and make significant financial investments including some prior to product approval.

We may elect in the future to utilize strategic partners, distributors, or contract sales forces to assist in the commercialization of our products.

Facilities

We lease office space in New York, New York. We do not own, lease, or operate any laboratory or manufacturing facilities. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Employees

As of March 9, 2012, we had seven full-time employees, four of whom hold Ph.D. or M.D. degrees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We believe that we have a good relationship with our employees.

Legal Proceedings

We are not currently a party to any material legal proceedings.

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Management

The following table sets forth certain information about our executive officers, key employees and directors:

Name Age Position

Ivan Bergstein, M.D.

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President, Chief Executive Officer and Chairman

Eric K. Rowinsky, M.D.

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Executive Vice President, Chief Medical Officer and Head of Research and Development

John T. Cavan

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Chief Accounting Officer

Kenneth Hoberman

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Vice President of Operations

Thomas P. Cirrito, Ph.D.

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Vice President of Research and Development and Director of Business Development

Ron Bentsur

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Director

J. Kevin Buchi

56

Director

Kenneth Zuerblis

53

Director

(1)

Member of the audit committee.

(2)

Member of the nominating and corporate governance committee.

(3)

Member of the compensation committee.

Directors

Ivan Bergstein, M.D. founded Stemline in August 2003 and has served as our President and Chief Executive Officer and the Chairman of our board of directors since our inception. Prior to founding Stemline, Dr. Bergstein was Medical Director of Access Oncology, Inc., a private clinical stage oncology-focused biotechnology company. Previously, he was a senior biopharmaceuticals analyst at Cancer Advisors, Inc., a Wall Street-based firm that advised investment funds on public oncology-focused companies. Dr. Bergstein received a B.A. in Mathematics from the University of Pennsylvania and an M.D. from the Mount Sinai Medical Center, where he completed a general surgery internship. Subsequently, he was named the Jerome A. Urban post-doctoral fellow at Cornell University Medical College. Dr. Bergstein then went on to complete a residency in internal medicine and a clinical fellowship in hematology-medical oncology at the New York Presbyterian Hospital-Weill Medical College of Cornell University, where he is currently a voluntary faculty member. We believe that Dr. Bergstein is qualified to serve on our board of directors due to his many years of service as one of our directors and our President and Chief Executive Officer and his extensive knowledge of our Company and industry.

Ron Bentsur has served as a member of our board of directors since 2009. Mr. Bentsur has served as Chief Executive Officer of Keryx Biopharmaceuticals, Inc. and as a member of its board of directors since 2009. Prior to joining Keryx Biopharmaceuticals, Inc., Mr. Bentsur served as Chief Executive Officer of XTL Biopharmaceuticals, Inc. from 2006 to 2009. From 2000 to 2006, Mr. Bentsur was employed by Keryx Biopharmaceuticals, Inc., where he served as Vice President Finance and Chief Financial Officer from 2003 until 2006. From 1998 to 2000, Mr. Bentsur served as Director of Technology Investment Banking at Leumi Underwriters, where he was responsible for all technology and biotechnology private placement and advisory transactions. From 1994 to 1998, Mr. Bentsur was a New York City-based investment banker, primarily at ING Barings Furman Selz. Mr. Bentsur holds a B.A. in Economics and Business Administration with distinction from the Hebrew University of Jerusalem, Israel and an M.B.A., magna cum laude, from New York University's Stern Graduate School of Business. We believe that Mr. Bentsur is qualified to serve on our board of directors due to his

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leadership and management experience, his service as an executive of a public biopharmaceutical company and his knowledge of our business and industry.

J. Kevin Buchi has served as a member of our board of directors since March 2012. Mr. Buchi served as Chief Executive Officer of Cephalon, Inc. from December 2010 through its $6.8 billion acquisition by Teva Pharmaceutical Industries in October 2011. Mr. Buchi currently serves as Corporate Vice President, Global Branded Products for Teva. Mr. Buchi joined Cephalon, Inc. in March 1991 and, since December 2010, he has served as Chief Executive Officer. From January 2010 through December 2010, Mr. Buchi was Chief Operating Officer. In this role, he managed the company's global sales and marketing functions, as well as product manufacturing, business development and investor relations. From February 2006 through January 2010, Mr. Buchi served as Chief Financial Officer. At various times in his career at Cephalon, Inc., Mr. Buchi had oversight of corporate finance, accounting, information systems, facilities, human resources and administration. Mr. Buchi graduated from Cornell University with a B.A. in chemistry. He was a synthetic organic chemist for the Eastman Kodak Company before going on to obtain a Masters of Management from the J.L. Kellogg Graduate School of Management at Northwestern University. He worked for a large public accounting firm before beginning his career in the pharmaceutical industry with E.I. du Pont de Nemours and Company in 1983 and is a certified public accountant. He has previously served on the boards of directors of a number of public and private companies. We believe Mr. Buchi is qualified to serve on our board of directors due to his executive leadership and management experience, knowledge of the industry, financial expertise and experience serving as a member of the board of directors of a public biopharmaceutical company.

Kenneth Zuerblis has served as a member of our board of directors since March 2012. Mr. Zuerblis is currently Executive Vice President and Chief Financial Officer of Savient Pharmaceuticals, Inc. Prior to joining Savient, Mr. Zuerblis served as Chief Financial Officer and Senior Vice President at ImClone Systems from 2008 through 2009. In that role, he was responsible for the strategic planning and leadership of finance and

related operations and helped lead all aspects of the sale of the company to Eli Lilly and Company. From 1994 through 2005, Mr. Zuerblis served as Chief Financial Officer of Enzon Pharmaceuticals Inc., and held the position of Corporate Controller from 1991 through 1994. Enzon developed the first three FDA approved products using PEGylation technology. Most notably during Mr. Zuerblis' 14 year tenure, Enzon transformed from an early stage biotechnology company into a fully integrated biopharmaceutical company with five marketed products. He began his career at KPMG, LLP in 1982 where he held management positions of increasing responsibility over a ten-year period. Mr. Zuerblis previously served on the board of directors of Immunomedics, Inc. Mr. Zuerblis brings nearly 30 years of proven leadership expertise in building fully integrated biopharmaceutical organizations and has an established track record of managing complex commercial and research organizations, raising capital, overseeing multifaceted merger and acquisition transactions, and directing all investor and shareholder relations. Mr. Zuerblis earned his B.S. in Accounting from Seton Hall University and is a certified public accountant in the State of New Jersey. We believe Mr. Zuerblis is qualified to serve on our board of directors due to his extensive accounting and financial experience and years of executive leadership in the biopharmaceutical industry.

Executive Officers

Eric K. Rowinsky, M.D. has served as our Executive Vice President, Chief Medical Officer and Head of Research and Development since November 2011. Prior to joining Stemline, Dr. Rowinsky was co-founder and Chief Executive Officer of Primrose Therapeutics, Inc., a start-up biotechnology company, from June 2010 until September 2011 when it was acquired. He also served as a drug development and regulatory strategy consultant to the ImClone-Lilly Oncology Business Unit and several other biopharmaceutical and life sciences companies from 2010 to 2011. From 2005 to 2009,

Dr. Rowinsky was Executive Vice President and Chief Medical Officer of ImClone Systems, Inc., where he led the FDA approval of Erbitux® for head and neck and colorectal cancers and advanced eight other monoclonal antibodies through clinical development. From 1996 to 2004, Dr. Rowinsky held several positions at the Cancer Therapy and Research Center, including Director of the Institute of Drug Development (IDD) and the SBC Endowed Chair for Early Drug Development at the IDD. From 1996 to 2006, he was a Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio. From 1988 to 1996, Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins University School of Medicine. He was a longstanding National Cancer Institute principal and co-principal investigator from 1990 to 2004, and was integrally involved in pivotal clinical and preclinical investigations that led to the development of numerous cancer therapeutics, including paclitaxel, docetaxel, topotecan, irinotecan, erlotinib, gefitinib, and temsirolimus among others. Dr. Rowinsky is currently an Adjunct Professor of Medicine at New York University School of Medicine and he sits on the board of directors of several publicly traded biopharmaceutical and life sciences companies, including Biogen Idec Inc., as well as several private biopharmaceutical companies. During the past five years, Dr. Rowinsky has also served as a director of ADVENTRX Pharmaceuticals, Inc. and Tapestry Pharmaceuticals, Inc., both life sciences companies. Dr. Rowinsky received his M.D. from Vanderbilt University School of Medicine. He completed his residency in internal medicine at the University of California, San Diego and completed his fellowship in medical oncology at Johns Hopkins Oncology Center. He holds a B.A. from New York University.

John T. Cavan has served as our Chief Accounting Officer since March 2012. Prior to joining Stemline, Mr. Cavan was Chief Accounting Officer and Vice President of Aegerion Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, from 2009 to February 2012 and was its Corporate Controller from 2006 to 2009. Mr. Cavan served as Controller of AlgoRx Pharmaceuticals, a biotechnology company, from 2004 to 2006. Prior to AlgoRx, Mr. Cavan served in a variety of financial and operational positions with large multinational public companies, including Sony Corporation, American Express, International Specialty Products (an Ashland company) and Nestlé Group. Mr. Cavan holds a B.B.A in Accountancy from Iona College and an M.B.A. in Finance from Seton Hall University.

Key Employees

Kenneth Hoberman has served as our Vice President of Operations since March 2012. From 2004 to 2012, Mr. Hoberman was Vice President of Corporate and Business Development of Keryx Biopharmaceuticals, Inc., where he was instrumental in securing multiple sources of capital including over $200 million in equity investments through public and private offerings. He also initiated and executed a $100 million strategic alliance and originated, negotiated and closed dozens of licensing and operational contracts, and helped grow the company to a $900 million market capitalization at its peak. Previously, he was Managing Director at Hawkins BioVentures, a healthcare advisory firm and has served as a consultant to various healthcare-related companies since 2001. Mr. Hoberman received a B.S.B.A. in Finance from Boston University and completed post-baccalaureate studies at Columbia University.

Thomas P. Cirrito, Ph.D. has served as our Vice President of Research and Development and Director of Business Development since March 2012. Previously, Dr. Cirrito served as our Director of Operations since 2005. Prior to joining Stemline, Dr. Cirrito was a biopharmaceuticals equities analyst at Piper Jaffray, where he covered large and small cap biotechnology companies. Previously, he was a life sciences consultant for A.G. Edwards Capital Partners, a venture capital group. Dr. Cirrito received a B.A. in Biological Sciences and a Ph.D. in Immunology from Washington University (St. Louis, Missouri). He currently serves on the Scientific and Business Advisory Board of the Alzheimer's Drug Discovery Foundation.

Scientific Advisory Board

We have established a scientific advisory board comprised of leading experts in their fields. We regularly seek advice and input from these experienced scientific leaders on matters related to our research and development programs. The members of our scientific advisory board consist of experts across a range of key disciplines relevant to our programs and science. We intend to continue to leverage the broad expertise of our advisors by seeking their counsel on important topics relating to our drug discovery and development programs. Some members of our scientific advisory board enter into consulting agreements with us covering their respective financial arrangements and confidentiality, non-disclosure and proprietary rights matters and own or have owned shares of our common stock or options to purchase shares of our common stock.

All of the scientific advisors are employed by or have consulting arrangements with other entities and devote only a small portion of their time to us. Our current advisors are:

Hagop Kantarjian M.D., Chairman, Department of Leukemia, MD Anderson Cancer Center

Dr. Hagop M. Kantarjian is a professor of medicine and the Chairman of the Department of Leukemia and the holder of the Kelcie Margaret Kana Research Chair at The University of Texas M. D. Anderson Cancer Center. Dr. Kantarjian has been integrally involved with the design, development and registration of a wide range of chemotherapy agents, targeted therapies, and biological therapies for the treatment of AML, MDS and CML. Dr. Kantarjian has taken an active role in the medical community, participating in numerous editorial boards and medical societies and holding administrative positions. He has authored or co-authored more than 750 medical publications and abstracts and serves on editorial boards for four scientific journals. In 1997, he received the first Emil J. Freireich Award for Outstanding Clinical Research at M. D. Anderson. Dr. Kantarjian was named a Scholar of the Leukemia Society of America from 1989 to 1994 and a Special Fellow of the Leukemia Society of America from 1982 to 1983. Dr. Kantarjian received his B.S. and M.D. from The American University of Beirut in 1975 and 1979, respectively. He completed his residency in internal medicine at The American University of Beirut and a fellowship in medical oncology at M. D. Anderson.

David Reardon, M.D., Clinical Director, Neuro-Oncology, Dana-Farber/Harvard Cancer Center; Associate Professor, Harvard Medical School

Dr. David Reardon is Clinical Director at Dana-Farber Cancer Institute's Center for Neuro-Oncology and associate professor at Harvard Medical School. His research interests include mechanisms of brain and spinal tumors, the development of novel therapeutics to treat brain malignancies, clinical evaluations in neuro-oncology, targeted therapies, anti-angiogenic treatments, immunotherapy, and convection-enhanced delivery. Prior to joining the Dana-Farber Cancer Institute, Dr. Reardon served as Associate Deputy Director of The Preston Robert Tisch Brain Tumor Center at Duke University Medical Center. In 2007, Dr. Reardon was the recipient of the R. Wayne Rundles Award for Excellence in Cancer Research, which is awarded annually to a Duke investigator whose research has made an important contribution to the detection, treatment, or prevention of cancer. Dr. Reardon has co-authored approximately 140 peer-reviewed manuscripts focused on neuro-oncology and 15 additional articles and book chapters. His board certifications include Neuro-Oncology and Pediatric Hematology/Oncology. Dr. Reardon received his M.D. from Tufts Medical School in 1986 and completed a pediatrics residency at Johns Hopkins Hospital. He also completed a fellowship in pediatric hematology/oncology at the University of Michigan Hospital, MOTT Children's Hospital in 1992.

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Patrick Wen, M.D., Director, Neuro-Oncology, Dana-Farber/Harvard Cancer Center; Professor, Harvard Medical School; Chair, Novel Agents Section of the Adult Brain Tumor Consortium

Dr. Wen is a professor of neurology at Harvard Medical School and director of Neuro-Oncology at the Dana-Farber/Brigham and Women's Cancer Center in Boston, Massachusetts. He is chair of the Dana-Farber/Harvard Cancer Center Neuro-Oncology Clinical Trials Committee and principal or co-investigator of many ongoing clinical protocols. Dr. Wen's clinical research focuses on targeted molecular therapies and anti-angiogenic therapies for gliomas, meningiomas, and brain metastases. He serves on numerous national and international committees, including the NCI Developmental Therapeutics and the Cancer Diagnostic and Treatment SBIR Study Sections and co-chairs the American Brain Tumor Consortium New Agents Committees. He is Associate Editor for the Journal of Neuro-Oncology and on the editorial board of Neuro-Oncology. He is Vice President of the Society of Neuro-Oncology. Dr. Wen has authored or coauthored numerous peer-reviewed manuscripts, book chapters, reviews, editorials, and abstracts and is actively involved in a number of professional societies. He has received numerous awards, including the Society of Neuro-Oncology Research Excellence Award and the George Cannellos Award for Excellence in Clinical Care and Research from the Dana-Farber Cancer Institute. Dr. Wen earned his M.D. from the Medical College of St. Bartholomew's Hospital at the University of London. He completed his residency at the Harvard Longwood Neurology Training Program, followed by a fellowship in neurology at Brigham and Women's Hospital in Boston, Massachusetts.

Owen O'Connor, M.D., Ph.D. Associate Professor of Medicine and Leader of the Lymphoid Development and Malignancy Program at Columbia University Medical Center

Dr. O'Connor is an associate professor of medicine and a leader of the Lymphoid Development and Malignancy program at Columbia University Medical Center. His research and clinical efforts have led to numerous innovations and patents on novel small molecules, and have produced one of the largest portfolios of new drugs for the treatment of lymphoma in the world. Over the past decade, his work has contributed to the FDA approval of distinct drugs for the treatment of relapsed and refractory mantle cell lymphoma, cutaneous T-cell lymphoma, and relapsed or refractory peripheral T-cell lymphoma. Dr. O'Connor co-invented and developed pralatrexate at Memorial Sloan-Kettering Cancer Center, which became the first drug ever approved by the FDA for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. He received his B.S. in Biology, magna cum laude, from Manhattan College in 1982, his Ph.D. from NYU School of Medicine, and his M.D. from the University of Medicine & Dentistry of New Jersey-Robert Wood Johnson Medical School in 1994. He then went on to complete a medical internship and residency at The New York Hospital Cornell University Medical Center. Following his medical residency, he completed a fellowship in medical oncology at the Memorial Sloan-Kettering Cancer Center, where he was also chief fellow, and a fellowship in clinical pharmacology at New York Hospital-Cornell University Medical School. Dr. O'Connor was previously Deputy Director of Clinical Research and Cancer Treatment at the NYU Cancer Institute, Chief of the Division of Hematologic Malignancies and Medical Oncology in the Department of Medicine, and a professor of medicine and pharmacology at the NYU Langone Medical Center.

Board Composition and Election of Directors

Our board of directors is currently authorized to have members. We expect that upon the closing of this offering, our board of directors will consist of directors. In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with

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members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

•

the class I directors will be , and their term will expire at the annual meeting of stockholders to be held in 2013;

•

the class II directors will be , and their term will expire at the annual meeting of stockholders to be held in 2014; and

•

the class III directors will be , and their term will expire at the annual meeting of stockholders to be held in 2015.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. Our directors may be removed only for cause by the affirmative vote of the holders of 75% or more of our outstanding common stock.

Our board of directors has determined that of our directors, , are independent directors, as defined by the applicable NASDAQ Marketplace Rules. In making such determination, the board of directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

There are no family relationships among any of our directors or executive officers.

Board Committees and Independence

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which will operate, upon the closing of this offering, under a charter that has been approved by our board. The composition of each committee will be effective upon the closing of this offering.

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee, other than , are independent as defined under the NASDAQ Marketplace Rules, including, in the case of all the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934.

Audit Committee

The members of our audit committee are . chairs the audit committee. Upon the closing of this offering, our audit committee's responsibilities will include:

•

appointing, approving the compensation of and assessing the independence of our registered public accounting firm;

•

overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;

•

reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;

•

monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;

•

overseeing our internal audit function;

•

overseeing our risk assessment and risk management policies;

•

establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;

•

meeting independently with our internal auditing staff, registered public accounting firm and management;

•

reviewing and approving or ratifying any related person transactions; and

•

preparing the audit committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that is an "audit committee financial expert" as defined in applicable SEC rules.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are . chairs the nominating and corporate governance committee. Upon the closing of this offering, our nominating and corporate governance committee's responsibilities will include:

•

identifying individuals qualified to become members of our board of directors;

•

recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;

•

reviewing and making recommendations to our board of directors with respect to our board leadership structure;

•

reviewing and making recommendations to our board of directors with respect to management succession planning;

•

developing and recommending to our board corporate governance principles; and

•

overseeing an annual self-evaluation by our board of directors.

Compensation Committee

The members of our compensation committee are . chairs the compensation committee. Upon the closing of this offering, our compensation committee's responsibilities will include:

•

annually reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer;

•

reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;

•

overseeing an evaluation of our senior executives;

•

overseeing and administering our cash and equity incentive plans;

•

reviewing and making recommendations to our board of directors with respect to director compensation;

•

reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure required by SEC rules; and

•

preparing the compensation committee report required by SEC rules.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following this offering, a current copy of the code will be posted on the Corporate Governance section of our website, www.stemline.com.

Executive Compensation

Compensation Discussion and Analysis

Overview

This section discusses the principles underlying our policies and decisions with respect to the compensation of our executive officers and what we believe are the most important factors relevant to an analysis of these policies and decisions. This section also describes the material elements of compensation awarded to, earned by or paid to each of our named executive officers for 2011. Our "named executive officers" for 2011 consist of our President and Chief Executive Officer, Ivan Bergstein, M.D., and our Executive Vice President, Chief Medical Officer and Head of Research and Development, Eric K. Rowinsky, M.D. In addition, this section provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers and is intended to provide context for the data presented in the tables and narrative that follow.

The compensation of each of our current executive officers is based on individual terms approved by our board of directors at the time of hire. Our board of directors is in the process of developing and implementing the executive compensation program that will be in place following this offering. This section highlights key aspects of this program that we expect to implement. Following this offering, our compensation committee will oversee these compensation policies and, together with our board of directors, will periodically evaluate the need for revisions to ensure our compensation program is competitive with the companies with which we compete for executive talent.

Background and Overview of Our Executive Compensation Objectives, Practices and Philosophy

The primary objectives of our executive compensation program are to:

•

attract, retain and motivate experienced and talented executives;

•

ensure executive compensation is aligned with our corporate strategies, research and development programs and business goals;

•

recognize the individual contributions of executives while fostering a shared commitment among executives by aligning their individual goals with our corporate goals;

•

promote the achievement of key strategic, development and operational performance measures by linking compensation to the achievement of measurable corporate and individual performance goals; and

•

align the interests of our executives with our stockholders by rewarding performance that leads to the creation of stockholder value.

Each of our named executive officers was hired by us before our board of directors established a formal executive compensation program. Historically, in determining compensation levels of our executive officers, our board of directors has considered these objectives, our financial status, the contributions that the management team had made to our business and trends in the industry in which we compete, and their experiences and business judgment. Other than for new hires, the board of directors has made these determinations as part of an annual process occurring in the beginning of the year, in which bonuses for the prior year and base salaries for the coming year are determined for each executive officer. In addition, our board of directors has often made equity grants under our Amended and Restated 2004 Employee, Director and Consultant Stock Plan, which we refer to as the "2004 Equity Plan." To the extent we have employment agreements in effect with any of our executive

officers, our board of directors has considered the applicable terms of such agreements in making these annual compensation decisions. Currently, the only employment agreements we have are with our two named executive officers. We entered into an employment agreement with Dr. Bergstein, our President and Chief Executive Officer, in October 2007 and with Dr. Rowinsky, our Executive Vice President, Chief Medical Officer and Head of Research and Development, in November 2011 as part of our hiring process.

Historically, our President and Chief Executive Officer, Dr. Bergstein, has been actively involved in the compensation decisions regarding our executive officers and other employees, including evaluating and communicating with such employees and serving as a member of our board of directors (which for the past several years has consisted of Dr. Bergstein and one other member).

We expect to continue an annual compensation process under our new compensation program and compensation committee. We expect our Chief Executive Officer will continue to evaluate each executive, other than himself, from his own perspective and based on input from others

within our Company. This process will lead to a recommendation by our Chief Executive Officer to the compensation committee with respect to each executive officer, other than himself, as to:

•

the level of contributions made to the general management and guidance of the Company;

•

the need for salary increases;

•

the amount of bonuses to be paid, including the achievement of stated corporate and individual performance goals with respect to the annual review for performance in future years; and

•

whether or not equity incentive awards should be made.

These recommendations will be reviewed by our compensation committee and taken into account by the committee when it makes a final determination on all such matters.

To achieve our compensation objectives in the future, we expect that our board of directors, generally and compensation committee, in particular, will evaluate our executive compensation program with the goal of setting and maintaining compensation at levels that are justifiable based on each executive's level of experience, performance and responsibility and that the board believes are competitive with those of other companies in our industry and our region that compete with us for executive talent. In addition, we expect that our executive compensation program will tie a substantial portion of each executive's overall compensation to key strategic, financial and operational goals. We have provided, and expect to continue to provide, a portion of our executive compensation in the form of stock-based compensation, including stock options, restricted stock and restricted stock units, which we believe helps to retain our executives and aligns their interests with those of our stockholders by allowing them to participate in the longer term success of our Company as reflected in stock price appreciation.

Use of Compensation Consultants and Market Benchmarking

For purposes of determining total compensation and the primary components of compensation for our executive officers in 2011, we did not retain the services of a compensation consultant or use survey information or compensation data to engage in benchmarking. We expect that our compensation committee will consider publicly available compensation data for national and regional companies in the biotechnology and pharmaceutical industry to help guide their executive compensation decisions at the time of hiring and for subsequent adjustments in compensation, and they may engage a compensation consultant to assist in that effort.

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Components of Our Executive Compensation Program

The primary elements of our executive compensation program are:

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base salary;

•

annual performance-based cash bonuses;

•

stock-based awards;

•

health and welfare benefits; and

•

severance and change in control benefits.

We do not, and do not expect in the future to, have a formal or informal policy for allocating between long-term and short-term compensation, between cash and non-cash compensation or among the different forms of non-cash compensation. Instead, our board of directors, after reviewing data it considers relevant, has determined subjectively what it believes to be the appropriate level and mix of the various compensation components. Ultimately, the objective in allocating between long-term and currently paid compensation is to ensure adequate base compensation to attract and retain personnel, while providing incentives to maximize long-term value for our Company and our stockholders. Therefore, we provide cash compensation in the form of base salary to meet competitive salary norms and in the form of bonus compensation to incentivize and reward superior performance on an annual basis. To further focus our executives on longer-term performance and the creation of stockholder value, we rely upon equity-based awards that vest over a meaningful period of time. In addition, we provide our executives with benefits that are generally available to all our employees. Finally, we typically offer our executives severance benefits to incentivize them to continue to achieve stockholder value in connection with change in control or other situations in which they could be terminated without cause.

Our employment agreements with Dr. Bergstein and Dr. Rowinsky contain provisions relating to base salaries, annual bonuses and severance and change in control arrangements for these executive officers. We are amending and restating our employment agreement with Dr. Bergstein effective upon the closing of this offering. Details of these employment agreements are provided below under the heading " – Employment Agreements."

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities of our employees, including our executive officers. Base salaries for our named executive officers were established through arm's-length negotiation at the time the executive was hired, taking into account the position for which the executive was considered and the executive's qualifications, prior experience and prior salary.

Dr. Bergstein's annual base salary has been $350,000 since 2008. In accordance with a practice in effect since 2008, the board of directors has approved annual 7% base salary increases for Dr. Bergstein and certain key employees conditioned upon the occurrence of specified financing or other strategic corporate events, including an initial public offering, and the employee's continued employment with us at such time. The board of directors conditioned the payment of these base salary increases on certain specified financings or other strategic corporate events for the purposes of maintaining its cash balances. As a result, an aggregate of $153,980 in base salary increases, representing a 7% compounding annual salary increase for the years from 2008 to 2011, will be earned and is expected to be payable to Dr. Bergstein upon the closing of this offering as a lump sum payment.

Dr. Rowinsky's 2011 annual base salary was $250,000 pursuant to the terms of his employment agreement.

In approving these base salaries, our board of directors considered the factors discussed above, including the qualifications, prior experience and prior salary of each of Dr. Bergstein and Dr. Rowinsky, and, in the case of Dr. Bergstein, various Company accomplishments under his leadership. Because the determination of Dr. Rowinsky's base salary was made as part of our negotiation of the terms of his employment with us, the board of directors considered the overall terms of Dr. Rowinsky's employment agreement and his anticipated role in the Company.

In addition to amending and restating our employment agreement with Dr. Bergstein, we expect our compensation committee to consider increases in the base salaries of our current executive officers and other key employees to recognize their increased responsibilities with respect to serving as executives of a publicly-traded company. We believe that the base salaries currently established for our named executive officers are, and will be upon the closing of this offering, aligned with our executive compensation objectives stated above and competitive with those of similarly-situated companies.

We expect that our compensation committee will annually review and evaluate, with input from our Chief Executive Officer, the need for adjustment of the base salaries of our executives based on changes and expected changes in the scope of an executive's responsibilities, including promotions, the individual contributions made by and performance of the executive during the prior year, the executive's performance over a period of years, overall labor market conditions, the relative ease or difficulty of replacing the executive with a well-qualified person, our overall growth and development as a company, general salary trends in our industry and among our peer group and where the executive's salary falls in the salary range presented by that data. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with other companies. Following this offering, we do not expect that our past practice of making the payment of annual base salary increases conditioned upon the occurrence of specified events will continue.

Annual Cash Bonus

Historically, our board of directors has determined the amount of annual cash bonuses for our current executive officers based on attainment of certain performance measures. For years 2008 through 2011, our board of directors has required that the payment of any awarded annual cash bonuses to our executive officers and other key employees be conditioned upon the occurrence of specified financing or other strategic corporate events, including an initial public offering, and the employee's continued employment with us at such time, and, in some cases, additional conditions. The board of directors conditioned the payment of these annual cash bonuses on these certain specified financings or other corporate events for purposes of maintaining adequate cash balances.

Additionally, for 2011, the board of directors approved certain conditional bonus payments that are payable to each of our employees (with the exception of Dr. Rowinsky, who was already entitled to a bonus payment contingent upon an initial public offering pursuant to his employment agreement) upon the occurrence of an initial public offering and other specified conditions (which vary by individual), provided in such cases that the employee is still employed by the Company at the time of the completion of the initial public offering.

In accordance with the terms of his employment agreement, Dr. Bergstein is eligible to receive an annual bonus award in an amount equal to 50% of his base salary, taking into account the conditional 7% annual increases to his base salary that are subject to certain conditions. For years 2008, 2009 and 2010 our board of directors has approved the award of annual cash bonuses to Dr. Bergstein equal to $175,000, $187,250 and $50,179, respectively, payable to Dr. Bergstein upon the closing of this offering,

with an additional $50,000 in respect of 2010 payable one year after the closing of this offering, provided Dr. Bergstein is employed by us on each such date.

For 2011, the board of directors awarded Dr. Bergstein a cash bonus of $57,192 payable upon the closing of this offering, with an additional $50,000 payable one year after the closing of this offering, provided Dr. Bergstein is employed by us on each such date. The board of directors considered a variety of factors in making this determination and structuring the timing of the awards, including presentation of scientific data at major conferences and key patent issuances or allowances, and efforts in 2011 towards positioning the Company for an initial public offering, as well as the increased likelihood of an initial public offering and a desire to provide an incentive for Dr. Bergstein to remain with the Company following such offering.

In addition, Dr. Bergstein was awarded a bonus of $96,472, which payment is contingent upon the completion of an initial public offering of more than $30,000,000 and Dr. Bergstein's continued employment with us at such time. The board of directors approved this bonus amount as an incentive to maximize the value of the Company's initial public offering and recognize Dr. Bergstein's efforts in efficiently building the clinical pipeline and infrastructure necessary to achieve such an offering.

Pursuant to his employment agreement, Dr. Rowinsky is entitled to receive specified cash bonus amounts upon the occurrence of certain events, including the completion of this offering during his employment. Following this offering, Dr. Rowinsky is eligible to earn discretionary annual cash bonuses equaling amounts ranging from 30% to 35% of his then-base salary depending on our market capitalization. Details of Dr. Rowinsky's employment agreement are provided below under the heading " – Employment Agreements."

We are in the process of designing an annual cash bonus program to reward our executive officers in the future. In addition to Dr. Bergstein's amended and restated employment agreement to be effective upon the closing of this offering, we expect that our compensation committee will provide for increases in the target bonus percentage for our current executive officers to recognize their increased responsibilities with respect to serving as executives of a publicly-traded company. We expect that our annual cash bonus program will be based upon the achievement of specified annual corporate and individual goals that will be established in advance by our compensation committee. We expect that our annual cash bonus program will emphasize pay-for-performance and will be intended to closely align executive compensation with achievement of specified operating results as the amount paid will be calculated on the basis of achievement of corporate and personal goals. The performance goals established by our compensation committee will be based on the business strategy of the Company and the objective of building stockholder value.

Following this offering, we expect that our process for determining if and the extent to which an annual cash bonus will be payable to a named executive officer will consist of three steps. First, at the beginning of the year, our compensation committee will determine the target annual cash incentive award for the named executive officer based on a percentage of the officer's annual base salary for that year. Second, the compensation committee will establish the specific performance goals, including both corporate and individual objectives, that must be met for the officer to receive the award. Third, shortly after the end of the year, the compensation committee will determine the extent to which these performance goals were met and the amount of the award. We expect that our compensation committee will work with our Chief Executive Officer to develop corporate and individual goals that they believe can be reasonably achieved with hard work over the course of the year. We do not expect that our past practice of making the payment of annual cash bonuses conditional upon the occurrence of specified events will continue.

Stock-Based Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executives. While we do not have any equity ownership guidelines for our executives, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, the vesting feature of our equity awards contributes to executive retention by providing an incentive for our executives to remain in our employ during the vesting period. Prior to this offering, our executives were eligible to participate in the 2004 Equity Plan, and all equity awards granted in 2011 were pursuant to the 2004

Equity Plan. Following the closing of this offering, our employees and executives will be eligible to receive stock-based awards pursuant to our 2012 incentive plan. Under our 2012 incentive plan, executives will be eligible to receive grants of stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights and other stock-based equity awards at the discretion of our board of directors.

Historically, our equity awards have been in the form of stock options. Because our executives profit from stock options only if our stock price increases relative to the stock option's exercise price, we believe stock options provide meaningful incentives for our executives to achieve increases in the value of our stock over time. While we currently expect to continue to use stock options as the primary form of equity awards that we grant, we may in the future use alternative forms of equity awards, such as restricted stock and restricted stock units.

We expect that our compensation committee will continue to use equity awards to compensate our executive officers in the form of initial grants in connection with the commencement of employment and may make greater use of equity awards on an annual basis to our executive officers. We may also make additional discretionary grants, typically in connection with the promotion of an employee, to reward an employee, for retention purposes or in other circumstances recommended by management.

The equity awards that we have granted to our executives are subject to time-based vesting or event-based vesting, or a combination of each. The awards subject to time-based vesting generally vest over a period of between three to four years following the grant date. The awards subject to event-based vesting generally vest upon the occurrence of a significant financing or strategic event. Vesting ceases upon termination of employment and exercise rights cease shortly after termination of employment, except that in the case of a termination for cause exercise rights cease immediately upon termination of employment. Prior to the exercise of a stock option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights or the right to receive dividends or dividend equivalents.

We have granted stock options with exercise prices that are set at no less than the fair market value of shares of our common stock on the date of grant as determined by our board of directors. The exercise price of all stock options granted after the closing of this offering will be equal to the fair market value of shares of our common stock on the date of grant, which generally will be determined by reference to the closing market price of our common stock on the date of grant.

In February 2012, pursuant to our employment agreement with Dr. Rowinsky and in recognition of his service to us, we granted Dr. Rowinsky options to purchase a total of 62,092 shares of our common stock at an exercise price of $5.97 per share, the fair market value of our common stock on the date of grant as determined by our board of directors. Of these options, the right to purchase 9,830 shares vests upon the closing of this offering, while of the remaining, 25% vest on the first anniversary of the grant date and the remaining 75% vest in approximately equal quarterly installments through the fourth anniversary of the grant date. A portion of the options are subject to partial or full accelerated vesting upon the termination of Dr. Rowinsky's employment without "cause" or for "good reason" or upon a "change in control" transaction.

In March 2012, we granted Dr. Bergstein an option to purchase 100,000 shares of our common stock at an exercise price of $5.97 per share, the fair market value of our common stock on the date of grant as determined by our board of directors. These options vest over a four year period, in which 25% vest upon the first anniversary of the vesting commencement date, and the remaining 75% vest in equal quarterly installments. With respect to the right to purchase 50,000 of the shares underlying this option, the vesting commencement date is January 1, 2012, and with respect to the remaining 50,000 shares underlying this option, the vesting commencement date is the closing of this offering.

In March 2011, we granted Dr. Bergstein an option to purchase 50,000 shares of our common stock. This option vests with respect to 25,000 shares in equal annual installments through the fourth anniversary of the grant date and with respect to the remaining 25,000 shares upon the closing of a capital-raising financing by us of at least $25,000,000. The exercise price of this option is $5.27 per share, the fair market value of our common stock on the date of grant as determined by our board of directors.

Following this offering, while we may grant equity awards that have time-based or event-based vesting, we expect that most of our equity awards will have time-based vesting, consisting mostly of vesting with respect to 25% of the shares on the first anniversary of the grant date and with respect to the remaining shares in approximately equal quarterly installments through the fourth anniversary of the grant date.

Benefits and Other Compensation

We believe that establishing competitive benefit packages for our employees is an important factor in attracting and retaining highly qualified personnel. We maintain a health benefits program that is provided to all employees. After the close of our initial public offering we plan to implement a broad based benefits program including health and dental insurance and life and disability insurance. All of our executives are eligible to participate in all of our employee benefit plans, in each case on the same basis as other employees. Consistent with our compensation philosophy, we intend to continue to maintain our current benefits for our named executive officers.

In certain circumstances, we may award cash signing bonuses or may reimburse relocation expenses when executives first join us as employees. Whether a signing bonus is paid or relocation expenses are reimbursed, and the amount of either such benefit, is determined by our board of directors on a case-by-case basis based on the specific hiring circumstances and the recommendation of our Chief Executive Officer.

Pursuant to his employment agreement, Dr. Rowinsky is entitled to an annual allowance of $15,000 for commuting expenses (which is pro-rated for periods of less than one year and accrues until the consummation of this offering when it is payable in a lump sum payment), as well as reimbursement of certain professional memberships and the cost of attendance at industry conferences.

Severance and Change in Control Benefits

Pursuant to employment agreements we have entered into with certain of our executives, these executives are entitled to specified benefits in the event of the termination of their employment under specified circumstances, including termination following a change in control of our Company. Please refer to " – Employment Agreements" for a more detailed discussion of these benefits. We have provided estimates of the value of the severance payments made and other benefits provided to executives under various termination circumstances, under the heading " – Potential Payments Upon Termination or Change in Control" below.

We believe providing these benefits helps us compete for executive talent. Based on the substantial business experience of the members of our board of directors, we believe that our severance and change in control benefits are generally in line with severance packages offered to executives by companies at comparable stages of development in our industry and related industries.

Risk Considerations in Our Compensation Program

Our board of directors is evaluating the philosophy and standards on which our compensation plans will be implemented across our Company. It is our belief that our compensation programs do not, and in the future will not, encourage inappropriate actions or risk-taking by our executive officers. We do not believe that any risks arising from our employee compensation policies and practices are reasonably likely to have a material adverse effect on our Company. In addition, we do not believe that the mix and design of the components of our executive compensation program will encourage management to assume excessive risks. We believe that our current business process and planning cycle fosters the behaviors and controls that would mitigate the potential for adverse risk caused by the action of our executives. We believe that the following aspects of our executive compensation program that we plan to implement will mitigate the potential for adverse risk caused by the action of our executives:

- annual establishment of corporate and individual objectives for our performance-based cash bonus programs for our executive officers, which we expect to be consistent with our annual operating and strategic plans, designed to achieve the proper risk/reward balance and not require excessive risk taking to achieve;

- the mix between fixed and variable, annual and long-term and cash and equity compensation, which we expect to be designed to encourage strategies and actions that balance the Company's short-term and long-term best interests; and

- equity incentive awards that vest over a period of time, which we believe will encourage executives to take a long-term view of our business.

Tax and Accounting Considerations

Section 162(m) of the Internal Revenue Code of 1986, as amended, which will become applicable to us upon the closing of this offering, generally disallows a tax deduction for compensation in excess of $1.0 million paid to our Chief Executive Officer and our three other most highly paid officers (other than the Chief Executive Officer and the Chief Financial Officer). Qualifying performance-based compensation is not subject to the deduction limitation if specified requirements are met. We will periodically review the potential consequences of Section 162(m) and we generally intend to structure the performance-based portion of our executive compensation, where feasible, to comply with exemptions in Section 162(m) so that the compensation will remain tax deductible to us. However, the board of directors may, in its judgment, authorize compensation payments that do not comply with the exemptions in Section 162(m) when it believes that such payments are appropriate to attract and retain executive talent and are in the best interests of our stockholders.

We account for equity compensation paid to our employees in accordance with Financial Accounting Standards Board, or FASB, Accounting Standard Codification Topic 718, Compensation-Stock Compensation, or ASC 718, which requires us to measure and recognize compensation expense in our financial statements for all share-based payments based on an estimate of their fair value over the service period of the award. We record cash compensation as an expense at the time the obligation is accrued.

2011 Summary Compensation Table

The following table sets forth the total compensation awarded to, earned by or paid to our named executive officers during 2011:

Name and Principal Position Year Salary ($) Bonus ($) Option

Awards

($)(1) All Other

Compensation ($) Total ($)

Ivan Bergstein, M.D.

2011 350,000 (3) – (4) 95,128 – 445,128

President and Chief Executive Officer(2)

Eric K. Rowinsky, M.D.(5)

2011

41,667

–

–

–

41,667

Executive Vice President, Chief Medical Officer

and Head of Research and Development

(1)

The amounts in the "Option Awards" column reflect the aggregate grant date fair value of stock options granted during the year computed in accordance with the provisions of ASC 718. For those stock option awards made in 2011 that are subject to performance conditions, the amounts shown reflect the value of the award at the grant date based upon the probable outcome of such condition, which amount is consistent with the estimate of aggregate compensation cost to be recognized over the service period determined as of the grant date under ASC 718, excluding the effect of estimated forfeitures (which in our case were none). Assuming all performance conditions were achieved, the value of Dr. Bergstein's stock option awards were $190,256 in 2011. The assumptions that we used to calculate these amounts are discussed in Note 9 to our financial statements appearing at the end of this prospectus.

(2)

During 2011 Dr. Bergstein also served as our principal financial officer.

(3)

Giving effect to annual base salary increases of 7% from 2008 through 2011 that were approved but conditioned upon the occurrence of specified financing or other strategic corporate events, including an initial public offering, and Dr. Bergstein's continued employment with us at such time, his 2011 base salary would have been $428,765.

(4)

For 2011 Dr. Bergstein was awarded an annual cash bonus of $57,192 payable upon the closing of this offering, with an additional $50,000 payable one year after the closing of this offering, which payments are conditioned upon the occurrence of a specified financing or other strategic corporate events, including an initial public offering, and Dr. Bergstein's continued employment with us at each such time. In addition, Dr. Bergstein was awarded a bonus of $96,472, which payment is contingent upon the completion of an initial public offering of more than $30,000,000 and Dr. Bergstein's continued employment with us at such time.

(5)

Dr. Rowinsky commenced his employment with the Company in November 2011.

Grants of Plan-Based Awards in 2011

The following table sets forth information regarding grants of plan-based awards to our named executive officers during 2011:

Name Grant Date Estimated

Future Payouts

Under Equity

Incentive Plan

Awards

Target (#) All Other

Option Awards:

Number of Securities

Underlying

options (#) Exercise or Base

Price of

Option Awards

($/Sh) Grant Date Fair

Value of Stock

and Option Awards

($)(2)(3)

Ivan Bergstein, M.D.

3/08/11 25,000 (1) 25,000 (1) 5.27 95,128

Eric K. Rowinsky, M.D.

– – – –

(1)

Represents an option to purchase 50,000 shares of our common stock granted to Dr. Bergstein on March 8, 2011. Of the 50,000 shares underlying the option award, the 25,000 listed under "All Other Option Awards" will vest 25% per year over four years beginning one year after the date of grant and the remaining 25,000 listed under "Estimated Future Payouts Under Equity Incentive Plan Awards" will vest upon the successful completion of a capital raise of at least $25 million. Assuming all performance conditions were achieved, the value of Dr. Bergstein's stock option awards were $190,256 in 2011. The assumptions that we used to calculate these amounts are discussed in Note 9 to our financial statements appearing at the end of this prospectus.

(2)

Option awards have been granted with exercise prices equal to the fair market value of our common stock on the date of grant. For a discussion of our methodology for determining the fair market value of our common stock, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Estimates."

(3)

The amounts in the "Grant Date Fair Value of Stock and Option Awards" column reflect the grant date fair value of stock and option awards granted in 2011 calculated in accordance with ASC 718. The value presented is based on the probable outcome of performance conditions.

Outstanding Equity Awards at December 31, 2011

Option Awards

Name Number of

securities

underlying

unexercised

options (#)

exercisable Number of securities

underlying

unexercised

options (#)

unexercisable Equity Incentive

Plan Awards:

Number of Securities

Underlying Unexercised

Unearned Options

(#) Option

exercise price

($) Option

Expiration

Date

Ivan Bergstein, M.D.

23,975 (1) – – 3.93 5/19/2013

– 150,000 (2) 150,000 4.00 3/22/2020

6,250 (3) 43,750 25,000 5.27 3/8/2021

Eric K. Rowinsky, M.D.

– – – – –

(1)

Represents an option to purchase up to 23,975 shares of our common stock granted to Dr. Bergstein on May 19, 2008. The shares underlying this option vested as follows: 5,994 shares on December 31, 2008, 1,499 shares per quarter commencing with March 31, 2009 and ending on September 30, 2011 and 1,492 shares on December 31, 2011.

(2)

Represents an option to purchase up to 150,000 shares of our common stock granted to Dr. Bergstein on March 22, 2010. The shares underlying this option vest upon a successful capital raise of at least $20 million, an initial public offering, a sale of the Company, termination of Dr. Bergstein's employment with the Company for any reason other than Cause (as defined in Dr. Bergstein's employment agreement with the Company dated October 9, 2007) or a diminution of job responsibilities, duty or authority.

(3)

Represents the exercisable portion of an option to purchase 50,000 shares of our common stock granted to Dr. Bergstein on March 8, 2011. Of the 50,000 shares underlying the option award, 25,000 will vest 25% per year over four years beginning one year after the date of grant and the remaining 25,000 will vest upon the successful completion of a capital raise of at least $25 million.

Options Exercised and Stock Vested in 2011

None of our named executive officers exercised any options during 2011, and we did not have any shares of restricted stock outstanding in 2011.

Employment Agreements

The only employment agreements we currently have are with our two named executive officers, Ivan Bergstein, M.D., our President and Chief Executive Officer, and Eric K. Rowinsky, M.D., our Executive Vice President, Chief Medical Officer and Head of Research and Development. The following is a summary of the material terms of each employment agreement. For complete terms, please see the respective employment agreements attached as exhibits to the registration statement of which this prospectus forms a part.

Each of these employment agreements provides that employment will continue for an indefinite period until either we or the employee provides written notice of termination in accordance with the terms of the agreement. In addition, each of these executive officers is bound by non-solicitation, non-competition, confidentiality and inventions assignment provisions that, among other things, prevent the executive from competing with us during the term of his employment and for a specified time thereafter.

Ivan Bergstein, M.D.

We entered into an employment agreement with Ivan Bergstein, M.D. in October 2007. The employment agreement provides for an initial annual base salary of $350,000, which is reviewed annually by the board of directors and may be increased (but not decreased) at its discretion. In

addition, Dr. Bergstein is eligible to receive an annual cash bonus of up to 50% of his then-base salary, as determined by the board of directors. Our existing employment agreement with Dr. Bergstein also contains severance and change in control provisions, as well as other provisions. We intend to amend and restate our existing employment agreement with Dr. Bergstein effective upon the closing of this offering on such terms satisfactory to Dr. Bergstein and the Compensation Committee.

Eric K. Rowinsky, M.D.

We entered into an employment agreement with Eric K. Rowinsky, M.D. in November 2011. The employment agreement provides for an initial annual base salary of $250,000, which is subject to increase up to a maximum of $425,000 as determined by our market capitalization during the thirty trading days immediately following the closing of this offering. In each year following this offering, Dr. Rowinsky's base salary will range between $350,000 and $425,000 according to our market capitalization, measured annually. Dr. Rowinsky will also be entitled to a cash bonus of at least $100,000 and up to $200,000 if he is still employed by us upon the closing of this offering. This bonus amount shall be increased to the extent that the completion of this initial public offering is delayed. Specifically, if the closing occurs on or after November 6, 2012, this bonus amount shall be increased by an additional $75,000 for each 12-month period following the effective date of the employment agreement during which the closing does not occur. Following this offering, Dr. Rowinsky will be eligible to receive an annual cash bonus at a target amount of between 30% and 35% of his then-base salary, as determined by our market capitalization measured annually and Dr. Rowinsky's performance. Dr. Rowinsky is entitled to an annual allowance of $15,000 for commuting expenses (which is prorated for periods of less than one year and accrues until the consummation of this offering when it is payable in a lump sum payment), as well as reimbursement of certain professional memberships and the cost of attendance at industry conferences.

Pursuant to the employment agreement, Dr. Rowinsky was granted an option, which we refer to as the New Hire Option, to purchase 38,807 shares of our common stock, as well an option, which we refer to as the Anti-Dilution Option, to purchase 10,349 shares of our common stock, each at an exercise price of $5.97 per share. In addition, Dr. Rowinsky was granted an option to purchase 12,936 shares of our common stock, at an exercise price of $5.97 per share. The Anti-Dilution Option will only become exercisable, to the extent vested, if upon the closing of this offering Dr. Rowinsky's aggregate holdings of our common stock and options to purchase shares of our common stock equal less than 1.25% of our issued and outstanding capital stock (giving effect to this offering) (such amount is the Minimum Equity Holdings Amount), and in such case the Anti-Dilution Option shall only be exercisable to the extent necessary so that Dr. Rowinsky's aggregate holdings equal the Minimum Equity Holdings Amount. To the extent the Anti-Dilution Option becomes exercisable and Dr. Rowinsky's aggregate holdings equal less than the Minimum Equity Holdings Amount, we are obligated to grant Dr. Rowinsky an additional option to purchase that number of shares of our common stock such that his aggregate holdings shall equal the Minimum Equity Holdings Amount.

If we terminate Dr. Rowinsky without "cause" or if he terminates employment with us for "good reason," (each as defined in his employment agreement) including if such termination occurs within 12 months following a change in control, we are obligated to pay Dr. Rowinsky his base salary for 12 months, and up to 24 months, following such termination (in the case of a termination following a change in control, the payment is made in a lump sum) and provide continuing coverage under our group medical benefits for between 12 months and 18 months following such

termination. The durations of these severance periods are based on when following the closing of this offering Dr. Rowinsky's employment is terminated, as well as our market capitalization at the time of such termination. Additionally, we are obligated to pay him a pro-rata portion of certain cash bonuses

earned and awarded under the employment agreement, as well as a pro-rata bonus for the portion of the year in which he was employed by us.

Potential Payments Upon Termination or Change in Control

The following tables set forth information regarding potential payments that each named executive officer who was serving as an executive officer as of December 31, 2011 would have received if the executive officer's employment had terminated as of December 31, 2011 under the circumstances set forth below, assuming in the case of Dr. Bergstein that his amended and restated employment agreement described above was in effect as of December 31, 2011:

Termination Without Cause or for Good

Reason Absent a Change in Control

Name Cash Payment Value of Stock

Options with

Accelerated Vesting Value of Benefits

Ivan Bergstein, M.D.

$ $ $

Eric K. Rowinsky, M.D.

$ – $ – $ –

Termination Without Cause or for Good Reason in

Connection With or Following a Change in Control

Name Cash Payment $ Value of Stock

Options with

Accelerated Vesting Value of Benefits $

Ivan Bergstein, M.D.

$ $ $

Eric K. Rowinsky, M.D.

$ 250,000 (1) $ – $ 250,000

(1)

Represents twelve months of base salary.

Pension Benefits

We do not maintain any defined benefit pension plans.

Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

Stock Option and Other Employee Benefit Plans

The two incentive plans described in this section are the 2004 Equity Plan and the 2012 incentive plan. Prior to this offering, we granted awards to eligible participants under the 2004 Equity Plan. Following the closing of this offering, we expect to grant awards to eligible participants under the 2012 incentive plan, which will become effective immediately prior to the closing of this offering.

2012 Incentive Plan

Our 2012 incentive plan was adopted by our board of directors in 2012 and approved by our stockholders in 2012. The 2012 incentive plan will become effective immediately prior to the closing of this offering. The 2012 incentive plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based or cash awards. Upon effectiveness of the plan, the number of shares of our common stock that will be reserved for issuance under the 2012 incentive plan will be the sum of (i)

shares plus (ii) the number of shares (up to shares) equal to the sum of the number of shares of our common stock then available for issuance under the 2004 Equity Plan and the number of shares of our common stock subject to outstanding awards under the 2004 Equity Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2012 incentive plan. However, incentive stock options may only be granted to our employees. The maximum number of shares of our common stock with respect to awards which may be granted to any participant under the 2012 incentive plan is per calendar year. For purposes of this limit on the maximum number of shares that may be awarded to any participant, the combination of an option in tandem with a stock appreciation right will be treated as a single award. The maximum amount of cash awards which may be granted to any participant under the 2012 incentive plan is $ per calendar year.

Pursuant to the terms of the 2012 incentive plan, our board of directors administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

•

the number of shares of our common stock covered by options and the dates upon which the options become exercisable;

•

the type of options to be granted;

•

the duration of options, which may not be in excess of ten years;

•

the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and

•

the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

Our board of directors has delegated authority to our Chief Executive Officer to grant awards under our 2012 incentive plan. The Chief Executive Officer has the power to make awards to all of our employees, except himself, subject to parameters established by our board of directors from time to time.

Upon a merger or other reorganization event, our board of directors may, in its sole discretion, take any one or more of the following actions pursuant to the 2012 incentive plan as to some or all outstanding awards other than restricted stock:

•

provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);

•

upon written notice to a participant, provide that all of the participant's unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant;

•

provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;

•

in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or

•

provide for a cash payment to the participants with respect to each award held by a participant equal to (1) the number of shares of common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and

•

provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds.

Our board of directors does not need to take the same action with respect to all awards and may take different actions with respect to portions of the same award.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock awards will continue for the benefit of the successor company and will, unless the board of directors may otherwise determine, apply to the cash, securities or other property into which shares of our common stock are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2012 incentive plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

No award may be granted under the 2012 incentive plan on or after , 2022. Our board of directors may amend, suspend or terminate the 2012 incentive plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

2004 Equity Plan

The 2004 Equity Plan was most recently amended and restated by our board of directors and approved by our stockholders in March 2011. Upon the closing of this offering and the approval of the 2012 incentive plan, we do not expect to grant any additional awards under the 2004 Equity Plan.

The 2004 Equity Plan provides for the grant of stock options and stock grants. The number of shares of our common stock that are reserved for issuance under the 2004 Equity Plan is 1,232,267.

Our employees, directors, consultants and advisors are eligible to receive awards under the 2004 Equity Plan. However, incentive stock options may only be granted to our employees.

In the event of a change of control, our board of directors may provide for (i) the substitution by the surviving corporation or its parent of options or restricted stock units with substantially the same terms for such outstanding options or restricted stock units, as applicable, (ii) the acceleration of the vesting of such options or restricted stock units immediately prior to or as of the date of the transaction, and the expiration of such outstanding options to the extent not timely exercised by the date of the transaction or (iii) the cancellation of all or any portion of such outstanding options or restricted stock by a cash payment of the excess, if any, of the fair market value of the shares subject to such outstanding options or restricted stock or portions thereof being canceled over the option price thereof or restricted stock grants then being fully vested.

Our board of directors does not need to take the same action with respect to all awards and may take different actions with respect to portions of the same award.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2004 Equity Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

Immediately upon termination of employment of an employee for a reason other than for cause, the unvested portion of any stock option will terminate and the balance, to the extent exercisable, will remain exercisable for the lesser of (i) a period of three months or (ii) the period ending on the latest date on which such stock option could have been exercised pursuant to such employee's option agreement. The 2004 Equity Plan provides exceptions for the vesting of options upon an individual's death, disability or termination for cause.

As of December 31, 2011, there were options to purchase an aggregate of 682,380 shares of common stock outstanding under the 2004 Equity Plan at a weighted-average exercise price of $4.53 per share and no shares of common stock issued upon the exercise of options granted under the 2004 equity incentive plan. If the 2012 incentive plan is approved by our stockholders, we will grant no further stock options or other awards under the 2004 equity incentive plan. However, any shares of common stock reserved for issuance under the 2004 Equity Plan that remain available for issuance and any shares of common stock subject to awards under the 2004 Equity Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at the original issuance price pursuant to a contractual repurchase right will be available for issuance under the 2012 incentive plan up to a specified number of shares.

Limitation of Liability and Indemnification

Our certificate of incorporation, which will become effective upon the closing of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

•

for any breach of the director's duty of loyalty to us or our stockholders;

•

for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

•

for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or

•

for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our certificate of incorporation, which will become effective upon the closing of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with our directors. These indemnification agreements may require us, among other things, to indemnify each such director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his service as one of our directors.

Certain of our non-employee directors may, through their relationships with their employers, be insured and/or indemnified against certain liabilities incurred in their capacity as members of our board of directors.

Rule 10b5-1 Sales Plans

Following the closing of this offering, our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

During 2011 we did not pay any cash compensation to our directors.

In March 2011, we granted Ron Bentsur an option to purchase 5,000 shares of our common stock. The option vests with respect to 625 shares in equal annual installments through the fourth anniversary of the grant date and with respect to the remaining 2,500 shares upon the closing of a capital-raising financing by us of at least $25.0 million. The exercise price of the option is $5.27 per share, the fair market value of our common stock on the date of grant as determined by our board of directors.

Effective upon the closing of this offering, our directors will be compensated for service on our board of directors as follows:

•

an annual retainer for our non-employee directors for service on our board of directors of $

•

for members of the audit committee, an annual fee of $ ($ for the chair);

•

for non-employee members of the nominating and corporate governance committee, an annual fee of $ ($ for the chair);

•

for members of the compensation committee, an annual fee of $ ($ for the chair);

•

for any non-employee chairman of our board of directors, an additional annual fee of $;

•

for any lead director of our board of directors, an additional annual fee of $;

•

for any newly elected director, an initial stock option grant of shares of our common stock; and

•

for continuing service on our board of directors, an annual stock option grant of shares of our common stock.

Subject to the director's continued service a director, the initial and annual stock option grants will vest in approximately equal monthly installments through the first anniversary of the grant date.

In addition, we will continue to reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending board of director meetings.

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Transactions with Related Persons

Since January 1, 2009, we have engaged in the following reportable transactions with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediately family members of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Redemption of Series A Preferred Stock

On March 16, 2010, we entered into a note purchase agreement pursuant to which we redeemed from funds affiliated with Pequot Capital Management, Inc., or the Pequot Funds, all of the shares of our Series A Preferred Stock held by them, which represented all of our issued and outstanding shares of Series A Preferred Stock, in exchange for (i) an aggregate cash payment of $750,000, (ii) 227,759 shares of our common stock and (iii) 2.45% senior unsecured convertible notes in the aggregate principal amount of $1,250,000. Pursuant to the note purchase agreement, the Pequot Funds immediately transferred such shares of common stock and the notes to Neuberger Berman Athyrium LLC, a fund affiliated with Neuberger Berman Group LLC, which presently holds such shares and notes.

Before the redemption of the Series A Preferred Stock, we, the Pequot Funds and certain holders of our common stock were party to an investors' rights agreement that provided the Pequot Funds with demand registration rights, piggyback registration rights, information rights and rights of first offer in respect of certain future issuances of our securities. This agreement also required the approval of the directors designated by the Pequot Funds and certain holders of our common stock for certain actions proposed to taken by us. The parties to the investors' rights agreement terminated the agreement in connection with the redemption of the Series A Preferred Stock.

Agreements with Our Stockholders

We have entered into a third amended and restated stockholders' agreement with certain holders of our common stock that contains agreements with respect to the election of our board of directors, restrictions on transfer of shares and drag-along rights in the event of a Company sale. Certain of our current directors were elected pursuant to the terms of this stockholders' agreement or an antecedent version thereof, and one of our stockholders has a board nomination right pursuant to the stockholders' agreement, which it has waived indefinitely. This stockholders' agreement will terminate upon the closing of this offering.

We have entered into an amended and restated right of first refusal and co-sale agreement with certain holders of our common stock. This agreement provides us with a right of purchase in respect of sales of securities by certain holders of our common stock, and also contains restrictions on transfer of shares. This right of first refusal and co-sale agreement will terminate immediately before the closing of this offering.

Assignment Agreement and License Agreement with Our Chief Executive Officer

Effective upon the closing of this offering, Dr. Bergstein will transfer to us certain patent rights currently owned by him and licensed to us, and the existing license arrangement between Dr. Bergstein and us, as described below, will be terminated. These patent rights include several therapeutic and diagnostic patents (including U.S. Patents 6,004,528, 7,361,336, 7,427,400, 7,504,103, 7,608,259 and 8,038,998) and related pending applications (including USSN 12/187,198 and 12/187,177) covering methods to treat and diagnose cancer, and pending patent application (USSN 10/849,037) covering

oligonucleotide-based oncology therapies. These patent rights do not relate to our product candidates SL-401 and SL-701.

We are currently party to a license agreement with Dr. Bergstein, dated December 1, 2003, pursuant to which Dr. Bergstein licensed to us his interest in the oncology-related patent rights described above, and all technology and know-how related to such patent rights, as well as improvements thereto. We are required to pay Dr. Bergstein $2.0 million in cash or our common stock the first time we obtain regulatory approval of each licensed product in the United States for certain major cancer indications, as well as a royalty in the low single digits as a percentage of net sales. We granted Dr. Bergstein certain piggyback registration rights with respect to any common stock we issue him in connection with a milestone payment. As mentioned above, this agreement will be terminated concurrent with the closing of this offering.

Indemnification Agreements

Our certificate of incorporation in effect upon the closing of this offering provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with our directors. See "Executive Compensation – Limitation of Liability and Indemnification" for additional information regarding these agreements.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which we are a participant, the amount involved exceeds $120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our Chief Executive Officer. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the committee to review and, if deemed appropriate,

approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the committee will review and consider:

•

the related person's interest in the related person transaction;

•

the approximate dollar value of the amount involved in the related person transaction;

•

the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;

•

whether the transaction was undertaken in the ordinary course of our business;

•

whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;

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•

the purpose of, and the potential benefits to us of, the transaction; and

•

any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

•

interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity) that is a participant in the transaction, where (i) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (ii) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and (iii) the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

•

a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it was our policy for our board of directors to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.

Principal Stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 9, 2012 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled "Percentage of Shares Beneficially Owned – Before Offering" is based on a total of 1,904,774 shares of our common stock outstanding as of March 9, 2012, and it excludes (i) the optional conversion of all principal and accrued and unpaid interest on our senior convertible note due 2015 upon the closing of this offering into shares of our common stock, and (ii) the automatic conversion of all principal and accrued and unpaid interest on our convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering into shares of our common stock.

The column entitled "Percentage of Shares Beneficially Owned – After Offering" is based on shares of our common stock to be outstanding after this offering, including (i) the shares of our common stock that we are selling in this offering, (ii) the optional conversion of all principal and accrued and unpaid interest on our senior convertible note due 2015 upon the closing of this offering into an aggregate of shares of our common stock, and (iii) the automatic conversion of all principal and accrued and unpaid interest on our convertible notes due 2017, at 87.5% of the initial public offering price, upon the closing of this offering into an aggregate of shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of March 9, 2012 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise indicated in the footnotes below, we believe the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the footnotes below, the address of the beneficial

owner is c/o Stemline Therapeutics, Inc., 750 Lexington Avenue, Sixth Floor, New York, New York 10022.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned After Offering
Directors and Executive Officers		
%	%	
Ivan Bergstein, M.D.		
1,034,726 (1)	53.47	

Ron Bentsur

17,536 (2) *

J. Kevin Buchi

– –

Kenneth Zuerblis

– –

John T. Cavan

– –

Eric K. Rowinsky, M.D.

– (3) –

All directors and executive officers as a group (6 persons)

1,052,262 (4) 53.94

5% Stockholders

Ivan Bergstein, M.D.

1,034,726 (1) 53.47

Madoff Family LLC

285,108 (5) 14.97

Neuberger Berman Athyrium LLC

227,759 (6) 11.96

*

Represents beneficial ownership of less than one percent of our outstanding common stock.

(1)

Consists of (i) 1,004,501 shares of common stock and (ii) 30,225 shares of common stock underlying options that are exercisable as of March 9, 2012 or will become exercisable within 60 days after such date. Excludes (i) 150,000 shares of common stock underlying options that will vest upon the earlier of (A) the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $20,000,000, (B) a sale of the Company, (C) the completion of this offering, (D) the termination of Dr. Bergstein's employment with the Company for any reason other than Cause (as defined in the Employment Agreement between the Company and Dr. Bergstein dated October 9, 2007) or (E) a material diminution in Dr. Bergstein's authority, duties and responsibilities with the Company, and (ii) 25,000 shares of common stock underlying options that will vest upon the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $25,000,000.

(2)

Consists of (i) 1,800 shares of common stock and (ii) 15,736 shares of common stock underlying options that are exercisable as of March 9, 2012 or will become exercisable within 60 days after such date. Excludes 2,500 shares of common stock underlying options that will vest upon the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $25,000,000.

(3)

Excludes 9,830 shares of common stock underlying options that will vest upon the closing of this offering.

(4)

Consists of (i) 1,006,301 shares of common stock and (ii) 45,961 shares of common stock underlying options that are exercisable as of March 9, 2012 or will become exercisable within 60 days after such date. Excludes (i) 150,000 shares of common stock underlying options that will vest upon the earlier of (A) the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $20,000,000, (B) a sale of the Company, (C) the completion of this offering, (D) the termination of Dr. Bergstein's employment with the Company for any reason other than Cause (as defined in the Employment Agreement between the Company and Dr. Bergstein dated October 9, 2007) or (E) a material diminution in Dr. Bergstein's authority, duties and responsibilities with the Company, (ii) 25,000 shares of common stock underlying options that will vest upon the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $25,000,000, (iii) 2,500 shares of common stock underlying options that will vest upon the closing of a financing for capital raising purposes in which the aggregate proceeds to the Company from the sale of the Company's securities equal or exceed $25,000,000, and (iv) 9,830 shares of common stock underlying options that will vest upon the closing of this offering.

(5)

Consists of 285,108 shares of common stock. The address of the beneficial owner is c/o 34 Pheasant Run, Old Westbury, NY 11568. The manager of the Madoff Family LLC, Peter Barnett Madoff, has sole voting and investment power with respect to the shares. All the shares of common stock were acquired in 2004. Ongoing proceedings, of which the Company is not a party, may result in a transfer of these shares for the benefit of the claimants in such proceedings.

(6)

The shares are held by NB Athyrium LLC. Consists of 227,759 shares of common stock acquired in 2010. Excludes the conversion of all principal and accrued and unpaid interest on the senior convertible note due 2015 upon the closing of this offering into shares of our common stock, conversion of which is at the election of NB Athyrium LLC, which holds the notes. The address of the beneficial owner is 605 Third Avenue, 22nd Floor, New York, NY 10158. NB SOF Holdings (D) LP is the managing member of NB Athyrium LLC, and has sole voting and investment power with respect to the shares.

Description of Capital Stock

General

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We have filed copies of these documents with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of shares of our common stock, par value $0.0001 per share, and shares of our preferred stock, par value $0.0001 per share, of which all preferred stock will be undesignated.

As of December 31, 2011, we had issued and outstanding 1,904,774 shares of our common stock held by 33 stockholders of record.

As of December 31, 2011, we also had outstanding options to purchase 682,380 shares of our common stock at a weighted-average exercise price of $4.53 per share.

Upon the closing of this offering, (i) all principal and accrued and unpaid interest on our senior convertible note due 2015 may, at the option of the noteholder, convert into shares of our common stock and (ii) all principal and accrued and unpaid interest on our convertible notes due 2017 will automatically convert, at 87.5% of the initial public offering price, into shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may

designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. There are no shares of preferred stock presently outstanding, there will be no shares of preferred stock outstanding upon the closing of this offering, and we have no present plans to issue any shares of preferred stock.

Stock Options

As of December 31, 2011, options to purchase 682,380 shares of our common stock at a weighted average exercise price of $4.53 per share were outstanding under our Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

Anti-Takeover Provisions

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Staggered Board; Removal of Directors

Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, a director may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company.

Super-Majority Voting

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes which all our stockholders would be entitled to cast in an election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described in the prior two paragraphs.

Stockholder Action; Special Meeting of Stockholders

Our certificate of incorporation provides that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such stockholders and may not be effected by any consent in writing by such stockholders. Our certificate of incorporation and our amended and restated bylaws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors.

Authorized But Unissued Shares

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of the NASDAQ Global Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be .

NASDAQ Global Market

We are applying to list our common stock on the NASDAQ Global Market under the symbol "STML."

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Shares Eligible for Future Sale

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity or equity-related securities.

As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we have applied to list our common stock on the NASDAQ Global Market, we cannot assure you that there will be an active market for our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of shares of our common stock, assuming (i) the underwriters do not exercise their over-allotment option, (ii) no options outstanding as of , 20 are exercised, (iii) the conversion of all principal and accrued and unpaid interest on our senior convertible note due 2015 into shares of our common stock and (iv) the automatic conversion of all principal and accrued and unpaid interest on our convertible notes due 2017, at 87.5% of the initial public offering price, into shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2012 (the expected closing date of this offering).

Of the shares to be outstanding immediately after the closing of this offering, we expect that the shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock outstanding after this offering will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

In general, subject to the lock-up restrictions described below, beginning 90 days after the effective date of the registration statement, of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

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Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the NASDAQ Global Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, subject to the lock-up restrictions described above, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us.

If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Upon expiration of the 180-day lock-up period described below, approximately shares of our common stock will be eligible for sale under Rule 144, including shares eligible for resale immediately upon the closing of this offering as described above. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the 180-day lock-up period described below.

Subject to the 180-day lock-up period described below, approximately shares of our common stock will be eligible for sale in accordance with Rule 701.

Lock-Up Agreements

We, each of our directors and executive officers and holders of substantially all of our outstanding shares of common stock have agreed that, without the prior written consent of on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, subject to extension in specified circumstances:

•

sell, offer to sell, contract or agree to sell, hypothecate, pledge, grant any option to purchase or otherwise dispose of or agree to dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock, or publicly announce an intention to do the same;

•

establish or increase a put equivalent position or liquidate or decrease a call equivalent position with respect to any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock, or publicly announce an intention to do the same;

•

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock, whether such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise, or publicly announce an intention to do the same; or

•

make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock.

The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under "Underwriting."

Stock Options

As of December 31, 2011, we had outstanding options to purchase 682,380 shares of our common stock, of which options to purchase 280,634 shares were vested. Following this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and options and other awards issued or issuable pursuant to our 2012 incentive plan and shares of common stock subject to outstanding options issued pursuant to our 2004 Equity Plan. See "Executive Compensation – Stock Option and Other Employee Benefit Plans" for additional information regarding this plan. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

Underwriting

Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of shares of common stock listed next to its name in the following table.

Underwriters

Number of

Shares

Oppenheimer & Co. Inc.

$

JMP Securities LLC

Total

$

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of nondefaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters' over-allotment option described below. The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the representatives.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

Per Share Without Option With Option

Public offering price

$ $ $

Underwriting discounts and commissions

Proceeds, before expenses, to us

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately $ and are payable by us.

Over-Allotment Option

We have granted the underwriters an option to purchase up to additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 30 days from the date of this prospectus solely to cover sales of shares of common stock by the underwriters in excess of the total number of shares set forth in the table above. If any shares are purchased pursuant to this over-allotment option, the underwriters will purchase the

additional shares in approximately the same proportion as shown in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

Determination of Offering Price

Prior to this offering, there has been no public market for our common stock. The initial public offering price was negotiated between us and the representatives. Among the factors considered in these negotiations were:

•

the prospects for our Company and the industry in which we operate;

•

our past and present financial and operating performance;

•

financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;

•

the prevailing conditions of U.S. securities markets at the time of this offering; and

•

other factors deemed relevant.

Lock-Up Agreements

We, our officers and directors and holders of substantially all of our outstanding stock and options have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock or securities convertible into, or exchangeable or exercisable for, common stock, during a period ending 180 days after the date of this prospectus, without first obtaining the written consent of representatives of the underwriters.

Specifically, we and these other individuals have agreed not to:

•

offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or

•

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or other securities, in cash or otherwise.

The restrictions described above do not apply to:

•

the sale of shares of common stock to the underwriters pursuant to the underwriting agreement;

•

the issuance by us of shares of common stock upon the exercise of an option or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing or that is described in this prospectus;

•

the grant by us of stock options or other stock-based awards, or the issuance of shares of common stock upon exercise thereof, to eligible participants pursuant to employee benefit or equity incentive plans described in this prospectus, provided that, prior to the grant of any such stock options or other stock-based awards that vest within the restricted period, each recipient of such grant shall sign and deliver a lock-up agreement agreeing to be subject to the restrictions on transfer described above;

•

transactions by security holders relating to any shares of common stock acquired from the underwriters in connection with this offering;

•

transactions by security holders relating to any shares of common stock or other securities acquired in open market transactions after the closing of this offering;

•

transfers of shares of common stock by security holders in connection with a merger, reorganization or consolidation of us with or into another entity, including through the purchase of our outstanding capital stock, pursuant to which our stockholders immediately prior to such transaction will own less than 50% of the surviving entity's voting power after such transaction;

•

the establishment of a 10b-5 trading plan under the Exchange Act by a security holder for the sale of shares of common stock, provided that such plan does not provide for the transfer of common stock during the restricted period;

•

transfers by security holders of shares of common stock or other securities as a bona fide gift or by will or intestacy;

•

transfers by distribution by security holders of shares of common stock or other securities to partners, members, or shareholders of the security holder; or

•

transfers by security holders of shares of common stock or other securities to any trust for the direct or indirect benefit of the security holder or the immediate family of the security holder;

provided that in the case of each of the preceding three types of transactions, the transfer does not involve a disposition for value and each transferee or distributee signs and delivers a lock-up agreement agreeing to be subject to the restrictions on transfer described above.

The 180-day restricted period is subject to extension if (1) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (2) prior to the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the restricted period, in which case the restrictions imposed in the lock-up agreements will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

NASDAQ Listing

We are applying to list our common stock on the NASDAQ Global Market under the symbol "STML."

Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering. "Covered" short sales

are sales made in an amount not greater than the underwriters' option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. "Naked" short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, each of which we refer to as a relevant member state, with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state, or the relevant implementation date, an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

•

to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

•

to any legal entity that has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than €43,000,000 and (iii) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of representatives for any such offer; or

- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares of common stock in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the same may be varied in that member state by any measure implementing the Prospectus Directive in that member state and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

Other Relationships

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

Legal Matters

The validity of the shares of common stock offered hereby is being passed upon for us by Edwards Wildman Palmer LLP. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. is acting as counsel for the underwriters in connection with this offering.

Edwards Wildman Palmer LLP beneficially holds an aggregate of 2,938 restricted shares of our common stock, which represents less than 0.15% of our outstanding common stock. The shares of restricted stock vest as to 75% of the award in equal annual installments, with the remaining 25% vesting upon the closing of this offering.

Experts

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2011 and 2010, and for each of the three years in the period ended December 31, 2011, as set forth in their report included in this prospectus. We have included our financial statements in this prospectus and elsewhere in this registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Where You Can Find More Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains a website, which is located at www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's website.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC. All documents filed with the SEC are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at www.stemline.com. You may access our reports, proxy statements and other information free of charge at this website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information on such website is not incorporated by reference and is not a part of this prospectus.

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STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Financial Statements

For the Period From August 8, 2003 (Inception) to December 31, 2011

and the Years Ended December 31, 2009, 2010 and 2011

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Stemline Therapeutics, Inc.

We have audited the accompanying balance sheets of Stemline Therapeutics, Inc. (a development stage company) as of December 31, 2010 and 2011, and the related statements of operations, preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011 and the period from August 8, 2003 (Inception) to December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Stemline Therapeutics, Inc. at December 31, 2010 and 2011 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011 and the period from August 8, 2003 (Inception) to December 31, 2011, in conformity with U.S. generally accepted

accounting principles.

As discussed in Note 1 to the financial statements, the Company's recurring losses from operations raise substantial doubt about its ability to continue as a going concern (management's plans as to these matters are also described in Note 1). The financial statements as of and for the year ended December 31, 2011 do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

MetroPark, New Jersey

April 2, 2012

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STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Balance Sheets

December 31,

2010 2011

Assets

Current assets:

Cash and cash equivalents

$ 7,226,366 $ 5,829,886

Prepaid expenses and other current assets

276,546 223,210

Total current assets

7,502,912 6,053,096

Deferred financing fees

– 400,000

Total assets

$ 7,502,912 $ 6,453,096

Liabilities and stockholders' equity (deficit)

Current liabilities:

Accrued liabilities

$ 634,318 $ 1,582,410

Total current liabilities

634,318 1,582,410

Convertible notes

927,473 1,566,116

Put option liability

89,560 99,230

Total liabilities

1,651,351 3,247,756

Stockholders' equity:

Preferred stock $0.0001 par value, 100,000 shares authorized, none issued and outstanding at December 31, 2010 and 2011

– –

Common stock $0.0001 par value, 3,000,000 shares authorized at December 31, 2010 and 2011, 1,904,774 shares issued and outstanding at December 31, 2010 and 2011

191 191

Additional paid-in capital

3,991,217 4,099,622

Retained earnings/(deficit) accumulated during the development stage

1,860,153 (894,473)

Total stockholders' equity

5,851,561 3,205,340

Total liabilities and stockholders' equity

$ 7,502,912 $ 6,453,096

See accompanying notes.

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STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statements of Operations

Period From

August 8, 2003

(Inception) to

December 31,

2011

Year Ended December 31,

2009 2010 2011

Operating expenses:

Research and development

$ 1,520,225 $ 1,800,507 $ 2,045,253 $ 11,076,403

General and administrative

560,896 459,333 671,801 3,386,488

Total operating expenses

2,081,121 2,259,840 2,717,054 14,462,891

Loss from operations

(2,081,121) (2,259,840) (2,717,054) (14,462,891)

Other income

102,257 484,905 46,673 633,834

Other expense

– – (9,670) (9,670)

Interest expense

– (69,493) (98,643) (178,185)

Interest income

201,088 43,045 24,068 950,676

Net loss from operations

(1,777,776) (1,801,383) (2,754,626) (13,066,236)

Less accretion of preferred stock dividends

(1,100,107) (239,720) – (2,591,165)

Add discount on redemption of preferred stock

– 12,171,765 – 12,171,765

Net (loss) income attributable to common stockholders

$ (2,877,883) $ 10,130,662 $ (2,754,626) $ (3,485,636)

Net (loss) income attributable to common stockholders per common share:

Basic

$ (1.84) $ 5.55 $ (1.45)

Diluted

$ (1.84) $ 5.08 $ (1.45)

Weighted-average shares outstanding:

Basic

1,563,135 1,825,526 1,904,774

Diluted

1,563,135 1,996,101 1,904,774

See accompanying notes.

(A Development Stage Company)

Statements of Preferred Stock and Stockholders' Equity (Deficit)

Period From August 8, 2003 (Inception) to December 31, 2011

Preferred Stock Common Stock

Subscription

Receivable Additional

Paid-in

Capital Earnings (Deficit)

Accumulated During

the Development Stage Total

Stockholders'

Equity (Deficit)

Shares Capital Shares Capital

Balance, August 8, 2003 (Inception)

Issuance of common stock to founder

— $ — $ 1,000,000 $ 100 $ — $ 11,837 $ — $ 11,937

Nonemployee stock based compensation

— — — — — 16,670 — 16,670

Issuance of common stock

— — 250,000 25 — 499,975 — 500,000

Subscription receivable

— — — — (25,000) — — (25,000)

Net loss

— — — — — — (166,538) (166,538)

Balance, December 31, 2003 —

— — 1,250,000 125 (25,000) 528,482 (166,538) 337,069

Issuance of common stock

— — 270,800 27 — 1,999,973 — 2,000,000

Nonemployee stock based compensation

— — — — — 551,826 — 551,826

Payment of subscription receivable

— — — — 25,000 — — 25,000

Net loss

— — — — — — (950,448) (950,448)

Balance, December 31, 2004 —

— — 1,520,800 152 — 3,080,281 (1,116,986) 1,963,447

Nonemployee stock based compensation

— — — — — 286,931 — 286,931

Net loss

— — — — — — (807,622) (807,622)

Balance, December 31, 2005 —

— — 1,520,800 152 — 3,367,212 (1,924,608) 1,442,756

Issuance of common stock

— — 41,768 4 — 739,707 — 739,711

Stock-based compensation

— — — — — 403,132 — 403,132

Net loss

— — — — — — (1,415,982) (1,415,982)

Balance, December 31, 2006 —

— — 1,562,568 156 — 4,510,051 (3,340,590) 1,169,617

Issuance of preferred stock

455,518 12,500,000 — — — — — —

Issuance of common stock

— — 567 — — 10,043 — 10,043

Stock-based compensation

— — — — — (35,706) — (35,706)

Accretion of preferred stock dividend

— 230,137 — — — (230,137) — (230,137)

Net loss

— — — — — — (1,571,755) (1,571,755)

Balance, December 31, 2007—

455,518 $ 12,730,137 1,563,135 156 — $ 4,254,251 $ (4,912,345) $ (657,938)

Stock-based compensation

— — — — — 143,738 — 143,738

Accretion of preferred stock dividend

— 1,021,201 — — — (1,021,201) — (1,021,201)

Net loss

— — — — — — (1,820,108) (1,820,108)

Balance, December 31, 2008—

455,518 13,751,338 1,563,135 156 — 3,376,788 (6,732,453) (3,355,509)

Stock-based compensation

— — — — — 71,177 — 71,177

Accretion of preferred stock dividend

— 1,100,107 — — — (1,100,107) — (1,100,107)

Net loss

— — — — — — (1,777,776) (1,777,776)

Balance, December 31, 2009—

455,518 14,851,445 1,563,135 156 — 2,347,858 (8,510,229) (6,162,215)

Issuance of common stock

— — 341,639 35 — 1,802,544 — 1,802,579

Stock-based compensation

— — — — — 80,535 — 80,535

Accretion of preferred stock dividend

— 239,720 — — — (239,720) — (239,720)

Redemption of preferred stock

(455,518) (15,091,165) — — — — 12,171,765 12,171,765

Net loss

— — — — — — (1,801,383) (1,801,383)

Balance, December 31, 2010

— — 1,904,774 191 — 3,991,217 1,860,153 5,851,561

Stock-based compensation

— — — — — 108,405 — 108,405

Net loss

— — — — — — (2,754,626) (2,754,626)

Balance, December 31, 2011

— $ — 1,904,774 $ 191 $ — $ 4,099,622 $ (894,473) $ 3,205,340

See accompanying notes.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

Statements of Cash Flows

Period From

August 8, 2003

(Inception) to

December 31,

2011

Year Ended December 31,

2009 2010 2011

Cash flows from operating activities

Net loss

$ (1,777,776) $ (1,801,383) $ (2,754,626) $ (13,066,236)

Adjustments to reconcile net loss to net cash used in operating activities:

Stock-based compensation expense

71,177 80,535 108,405 1,638,645

Non-cash interest expense

– 69,493 98,643 178,185

Mark to market of put option liability

– (21,860) 9,670 (12,190)

Changes in operating assets and liabilities:

Prepaid expenses and other current assets

(33,582) (183,600) 53,336 (223,210)

Other assets

– – (400,000) (400,000)

Accrued liabilities

179,464 (5,785) 948,092 1,582,410

Net cash used in operating activities

(1,560,717) (1,862,600) (1,936,480) (10,302,396)

Cash flows from investing activities

Purchase of marketable securities

– – – (20,545,087)

Redemption of marketable securities

8,600,231 – – 20,545,087

Net cash provided by investing activities

8,600,231 – – –

Cash flows from financing activities

Proceeds from issuance of preferred stock, net

– – – 12,500,000

Redemption of preferred stock

– (750,000) – (750,000)

Proceeds from issuance of common stock

– 602,571 – 3,842,282

Proceeds from issuance of convertible notes

– – 540,000 540,000

Net cash (used in) provided by financing activities

– (147,429) 540,000 16,132,282

Net increase (decrease) increase in cash and cash equivalents

7,039,514 (2,010,029) (1,396,480) 5,829,886

Cash and cash equivalents at beginning of period

2,196,881 9,236,395 7,226,366 –

Cash and cash equivalents at end of period

$ 9,236,395 $ 7,226,366 $ 5,829,886 $ 5,829,886

Supplemental disclosure of non-cash transactions

Discount on redemption of preferred stock

$ – $ 12,921,765 $ – $ 12,921,765

Issuance of common stock on redemption of preferred stock

$ – $ 1,200,000 $ – $ 1,200,000

Accretion of preferred stock dividend

$ 1,100,107 $ 239,720 $ – $ 1,339,827

See accompanying notes.

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STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

December 31, 2011

1. Organization and Basis of Presentation

Organization

Stemline Therapeutics, Inc., (the "Company"), is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target both cancer stem cells, ("CSCs"), and tumor bulk. The Company's activities to date have primarily consisted of advancing its two clinical stage programs, expanding and strengthening its intellectual property portfolio, developing its proprietary drug discovery platform, identifying and acquiring additional product and technology rights and raising capital. Accordingly, the

Company is considered to be in the development stage as defined in Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 915, Development Stage Entities. The Company was incorporated in Delaware on August 8, 2003 (Inception) and has its principal office in New York, New York.

Liquidity

The Company has incurred losses from operations since inception of $13.1 million. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. The Company's success depends primarily on the successful development and regulatory approval of its product candidates. At December 31, 2011, the Company's current assets totaled approximately $6.1 million compared to current liabilities of $1.6 million, resulting in working capital of approximately $4.5 million. Management estimates that cash and cash equivalents of $5.8 million as of December 31, 2011, will be insufficient to fund research and development activities for the next twelve months. Accordingly, additional financing will be needed by the Company to fund its operations and the commercialization of its products. There is no assurance that such financing will be available when needed or on acceptable terms.

The Company expects its research and development expenses to increase significantly in connection with its planned randomized Phase 2b clinical trial of SL-401 for the treatment of patients with acute myeloid leukemia ("AML") and its planned Phase 2b clinical trials of SL-701 for the treatment of patients with brain cancer. Furthermore, upon the closing of the initial public offering (the "IPO"), the Company expects to incur additional costs associated with operating as a public company. As a result, the Company expects to continue to incur significant and increasing operating losses for the foreseeable future.

The Company may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations and strategic and licensing arrangements. If adequate funds are not available to the Company on a timely basis, or at all, the Company may be required to terminate or delay clinical trials or other development activities for SL-401 or SL-701, or for one or more indications for which it is developing SL-401 and SL-701, or delay its establishment of sales and marketing capabilities or other activities that may be necessary to commercialize SL-401 or SL-701, if the Company obtains marketing approval.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital, to fund its research and development and commercial programs and meet its obligations on a timely basis. If the Company is unable to successfully raise sufficient additional capital, through future debt and equity financings and/or strategic and collaborative ventures

1. Organization and Basis of Presentation (Continued)

with potential partners, the Company will likely not have sufficient cash flows and liquidity to fund its business operations, which could significantly limit its ability to continue as a going concern. In that event, the Company may be forced to limit many, if not all, of its programs and consider other means of creating value for its stockholders, such as licensing to others the development and commercialization of products that it considers valuable and would otherwise likely develop itself. If the Company is unable to raise the necessary capital, it may be forced to curtail all of its activities and, ultimately, potentially cease operations. Even if the Company is able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

The Company utilizes estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors, with input from management.

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

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid instruments purchased with an original maturity of three months or less. At December 31, 2011, cash equivalents consist of deposits in financial institutions. The Company maintains its cash deposits and cash equivalents with well-known and stable financial institutions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents. The Company invests its excess cash in major U.S. banks and financial institutions, and its deposits, at times, exceed federally insured limits. The Company has not experienced any losses from credit risks.

Deferred Financing Fees

Deferred financing fees include legal fees directly attributable to the Company's offering of its equity securities. These fees are deferred and capitalized on the balance sheet. Costs attributable to equity offerings are charged against proceeds of the offering once the offering is completed.

2. Summary of Significant Accounting Policies (Continued)

Research and Development Costs

Research and development costs are comprised primarily of costs for personnel, including salaries and benefits; clinical studies performed by third parties; materials and supplies to support the Company's clinical programs; contracted research; manufacturing; related consulting arrangements; costs related to upfront and milestone payments under license agreements; and other expenses incurred to sustain the Company's overall research and development programs. Internal research and development costs are expensed as incurred. Third-party research and development costs are expensed as the contracted work is performed.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The asset and liability method requires that deferred tax assets and liabilities be recorded without consideration as to their reliability. The deferred tax asset primarily includes net operating loss and tax credit carryforwards, accrued expenses not currently deductible and the cumulative temporary differences related to certain research and patent costs, which have been charged to expense in the accompanying statements of operations but have been recorded as assets for income tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance. A valuation allowance has been established against all of the deferred tax assets (see Note 9), as it is more likely than not that these assets will not be realized given the history of operating losses.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position.

Stock-Based Compensation

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

For stock options granted as consideration for services rendered by non-employees, the Company recognizes expense in accordance with the requirements of ASC Topic 505-50, Equity Based Payments to Non-Employees. Non-employee option grants that do not vest immediately upon grant are recorded as

an expense over the vesting period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the stock options are fully vested.

The board of directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of its common stock. In connection with the Company's proposed IPO, the Company performed a retrospective determination of the fair value of its common stock for the years ended December 31, 2010 and 2011.

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

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

Year Ended December 31,			
	2009	2010	2011
Research and development	$ 47,673	$ 50,311	$ 79,955
General and administrative	23,504	30,224	28,450
Total	$ 71,177	$ 80,535	$ 108,405

No tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The weighted average fair value of the options granted during 2009, 2010 and 2011 was estimated at $2.72, $2.67 and $3.52, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

Year Ended December 31,

2009 2010 2011

Risk-free interest rate

2.45 % 2.78 % 2.66 %

Expected volatility

76.00 % 74.48 % 72.86 %

Dividend yield

– – –

Expected life

6.20 years 6.02 years 6.26 years

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

2. Summary of Significant Accounting Policies (Continued)

Segment information

The Company reports segment information in accordance with applicable guidance on segment disclosures. The Company has one reportable segment.

Recent Accounting Pronouncements

Effective January 1, 2010, the Company adopted ASU No. 2009-17, Consolidations (Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17. The amendments in this update replace the quantitative-based risks and rewards calculation for determining which reporting entity, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which reporting entity has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. An approach that is expected to be primarily qualitative will be more effective for identifying which reporting entity has a controlling financial interest in a variable interest entity. The amendments in this update also require additional disclosures about a reporting entity's involvement in variable interest entities, which will enhance the information provided to users of financial statements. The Company evaluated its business relationships to identify potential variable interest entities and has concluded that no such entities exist. On a quarterly basis, the Company reassesses its involvement with variable interest entities.

In May 2011, the Financial Accounting Standards Board issued guidance that changed the requirement for presenting "Comprehensive Income" in the financial statements. The update requires an entity to present the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The currently available option to disclose the components of other comprehensive income within the statement of stockholders' equity will no longer be available. The update is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and should be applied retrospectively. The adoption of the standard will have no impact on the Company's financial position or results of operations.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

3. Net (Loss) Income Per Common Share

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

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

Year Ended December 31,

2009 2010 2011

Basic net (loss) income per common share calculation:

Net loss

$ (1,777,776) $ (1,801,383) $ (2,754,626)

Less: Preferred dividends

(1,100,107) (239,720) –

Plus: Redemption of preferred stock at a discount to carrying value

– 12,171,765 –

Net (loss) income attributable to common shareholders – basic

(2,877,883) 10,130,662 (2,754,626)

Basic weighted-average common shares

1,563,135 1,825,526 1,904,774

Basic net income (loss) per share

$ (1.84) $ 5.55 $ (1.45)

Diluted net (loss) income per common share calculation:

Net (loss) income attributable to common shareholders – basic

$ (2,877,883) $ 10,130,662 $ (2,754,626)

Plus: Preferred dividends

– 239,720 –

Net (loss) income attributable to common shareholders – diluted

(2,877,883) 10,370,382 (2,754,626)

Basic weighted-average common shares

1,563,135

1,825,526

1,904,774

Effect of dilutive securities:

Redeemable preferred stock

– 93,600 –

Employee stock options

– 76,975 –

Weighted-average shares used to compute diluted net income (loss) per share

1,563,135 1,996,101 1,904,774

Diluted net (loss) income per share

$ (1.84) $ 5.08 $ (1.45)

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STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

3. Net (Loss) Income Per Common Share (Continued)

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

Year Ended December 31

2009 2010 2011

Redeemable convertible preferred stock

455,518 – –

Options outstanding

307,880 558,380 682,380

Total

763,398 558,380 682,380

4. Fair Value Measurements

The Company's financial instruments consist of cash and cash equivalents, accrued liabilities and a Put Option (as defined in Note 6) for the 2.45% Convertible Note. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 – Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

Level 3 – Inputs that are unobservable for the asset or liability.

STEMLINE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

4. Fair Value Measurements (Continued)

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liability measured at fair value on a recurring basis as of December 31, 2010 and 2011:

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At December 31, 2011				
Cash	$ 5,829,886	$ –	$ –	$ 5,829,886
Put Option	$ –	$ –	$ (99,230)	$ (99,230)
At December 31, 2010				
Cash	$ 7,226,366	$ –	$ –	$ 7,226,366
Put Option	$ –	$ –	$ (89,560)	$ (89,560)

The changes in fair value of the Company's Level 3 financial instruments included in other income and other expense during the years ended December 31, 2010 and 2011 were $21,860 and $(9,670), respectively. The Put Option fair value is derived through discounted cash flows, a Level 3 input. The Company's discounted cash flow analysis considered, among other things, the difference in the implied and actual interest rates on the 2.45% Convertible Note, estimated time to exercise and probability of exercise.

5. Other Accrued Liabilities

Other accrued liabilities consist of the following:

December 31,	

	2010	2011
Accrued research and development costs	$ 524,591	$ 807,120
Accrued compensation	50,729	129,009
Accrued legal	17,419	504,445
Other accrued liabilities	41,579	141,836
Total	$ 634,318	$ 1,582,410

6. Convertible Notes

On March 16, 2010, in connection with the redemption of the Series A preferred stock, the Company issued a Senior Convertible Note ("the 2.45% Convertible Note") in the amount of $1.25 million. The 2.45% Convertible Note was initially recorded at fair value of $0.90 million (See Note 4). The 2.45% Convertible Note and the related interest expense are due on March 16, 2015. Interest is being charged at a rate of 2.45% per annum.

6. Convertible Notes (Continued)

The carrying value of the 2.45% Convertible Note consists of $1.3 million of principal and accrued interest less $0.3 million of unamortized debt discount as of December 31, 2011 and $1.3 million of principal and accrued interest less $0.3 million of unamortized debt discount as of December 31, 2010.

Upon the occurrence of a qualified financing event as defined in the agreement, the 2.45% Convertible Note and any accrued interest are mandatorily convertible into shares of the same securities issued in the qualified financing at the same price per share used in the qualified financing. In addition, upon the occurrence of a non-qualified financing event, as defined in the agreement, the 2.45% Convertible Note and any accrued interest are convertible at the option of the holder into cash or shares (the "Put Option") of the same securities issued in the non-qualified financing event at the same price per share used in the non-qualified financing event, or the holder may elect to continue to retain the note. The Put Option was recorded at approximately $111,000, its fair value on the date of issuance and is marked to fair value at each reporting period. During the years ended December 31, 2009, 2010 and 2011, changes in the fair value of the Put Option of approximately $0, $(22,000) and $10,000, respectively, were recorded in Other Income and Other Expense in the Statement of Operations.

In January 2012, the Company issued $0.9 million in convertible notes (the "1.27% Convertible Notes") at face value for cash. Of this amount, approximately $0.5 million was received on or before December 31, 2011 and before the note agreements were signed. These amounts were classified as long term liabilities on the balance sheet consistent with the terms of the notes that were signed in January 2012. For additional disclosures refer to Note 12.

During the years ended December 31, 2009, 2010 and 2011, the Company recorded interest expense of approximately $0, $69,000 and $99,000, respectively, related to the amortization of the debt discount.

7. Capital Structure

Common Stock

As of December 31, 2011, the Company was authorized to issue 3,000,000 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. Certain of the Company's stockholders have the right to appoint two directors, provided certain minimum ownership levels are maintained. These appointment rights terminate upon the closing of an IPO. The Company will, at all times, reserve and keep available, out of its authorized but unissued shares of common stock, sufficient shares to effect the conversion of the shares of the convertible notes and stock options. As of December 31, 2010 and 2011, the Company reserved 578,809 and 703,809 shares of common stock, respectively, for future issuance related to the exercise of the Company's outstanding stock options, and reserved an adequate number of shares of common stock for future issuance related to the conversion of the Company's Convertible Notes.

7. Capital Structure (Continued)

Preferred Stock

In October 2007, the Company sold 455,518 shares of 8% Series A Redeemable Convertible Preferred Stock at a purchase price of $27.44 per share, resulting in net proceeds of $12.5 million.

At any time on or after the fourth anniversary date of the issuance of the Series A Preferred Stock, the holders of the Series A Preferred Stock could require the Company to redeem the shares for a price per share equal to the original issuance price plus any accumulated but unpaid dividends. As a result, the carrying value of the Series A Preferred Stock was accreted to their redemption value by a charge to additional paid-in capital. For the years ended December 31, 2009, 2010 and 2011 and for the period from inception (August 8, 2003) to December 31, 2011, the Company recorded dividends amounting to $1,100,107, $239,720, $0 and $2,591,165, respectively, related to the accretion of the Series A Preferred Stock to their redemption value.

Redemption of Series A Preferred Stock

On March 16, 2010, the Company entered into a Note Purchase Agreement with several investment funds (the "Pequot Funds") that held the Company's Series A preferred stock (the "Preferred Shares") and NB Athyrium LLC. In exchange for 455,518 outstanding shares of the Preferred Shares, with a carrying value of $15.1 million, including $2.6 million for the accretion of dividends through the date of redemption, the Company paid $0.75 million of cash, issued 227,759 shares of its common stock valued at $1.2 million and issued a $1.25 million senior unsecured convertible note, represented by the 2.45% Convertible Note. This transaction was accounted for as an extinguishment of the Preferred Shares, as it resulted in the surrender and cancellation of the Preferred Shares. The 2.45% Convertible Note and common stock issuances were recorded at their issuance date fair value of $0.90 million and $1.0 million, respectively (See Note 4). The consideration given for the redemption of the Preferred Shares was immediately transferred from the Pequot Funds to NB Athyrium LLC. The transaction resulted in a $12.2 million discount from the redemption of the Preferred Shares, including the cash payment over the carrying value of the Preferred Shares, and was accounted for in accordance with ASC Topic 260-10, Earnings per share. The discount on the redemption of the Preferred Shares has been reflected as a reduction of the Accumulated Deficits in the Company's Statement of Preferred Stock and Stockholders Equity (Deficit) and also as an offset to the net operating losses in the Company's Statement of Operations to arrive at $10.1 million of net income available to common stockholders for the year ended December 31, 2010.

Before the redemption of the Series A Preferred Stock, the Company, the Pequot Funds and certain holders of the Company's common stock were party to an investors' rights agreement that provided the Pequot Funds with demand registration rights, piggyback registration rights, information rights and rights of first offer with respect to certain future issuances of the Company's securities. This agreement also required the approval of the directors designated by the Pequot Funds and certain holders of the Company's common stock for certain actions proposed to be taken. The parties to the investors' rights agreement terminated the agreement in connection with the redemption of the Series A Preferred Stock.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

8. Stock-Based Compensation

The Company's 2004 Stock Option and Grant Plan (the "2004 Plan") was adopted by the board of directors in September 2003 and approved by the stockholders in September 2003. The 2004 Plan authorizes the Company to grant up to 703,809 shares of common stock to eligible employees, directors, consultants and advisors to the Company in the form of options to purchase common stock in the Company at a price not less than the estimated fair value at the date of grant, or 110% of the estimated fair value at the date of grant if the optionee is a 10% owner of the Company. Under the provisions of the 2004 Plan, no option will have a term in excess of 10 years.

The 2004 Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business. The board of directors is responsible for determining the individuals to receive option grants, the number of options each individual will receive, the option price per share and the exercise period of each option. Options granted pursuant to the 2004 Plan generally vest over four years and have been granted at the estimated fair value of the Company's common stock, as determined by the board of directors, as of each grant date. In establishing its estimates of fair value of the Company's common stock, the Company considered the guidance set forth in the AICPA Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, and performed a retrospective determination of the fair value of its common stock for the years ended December 31, 2010 and 2011.

In December 2004, the FASB issued SFAS 123(R), which requires compensation costs related to share-based transactions, including employee share options, to be recognized in the financial statements based on fair value. SFAS 123(R) revises SFAS No. 123, as amended, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB No. 25").

The Company performed a retrospective determination of the fair value of the Company's common stock for the years ended December 31, 2010 and 2011 and granted stock options with exercise prices as follows:

Grant Date

Number of Options

Granted Exercise

Price Retrospective

Determination

of Fair Value Intrinsic

Value

March 22, 2010

250,500 $ 4.00 $ 5.34 $ 1.34

March 8, 2011

124,000 $ 5.27 $ 5.61 $ 0.34

As of December 31, 2011, there were 21,429 shares of common stock available for future grants under the 2004 Plan.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

8. Stock-Based Compensation (Continued)

The following is a summary of stock option activity under the Plan through December 31, 2011:

Options Weighted-

Average

Exercise Price Weighted-

Average

Remaining

Contractual Life Aggregate

Intrinsic

Value

Outstanding at January 1, 2009

301,886 $ 4.69

Options granted

10,994 4.00

Options exercised

– –

Options forfeited

(5,000) 17.71

Outstanding at December 31, 2009

307,880 $ 4.67

Options granted

250,500 4.00

Options exercised

– –

Options forfeited

– –

Outstanding at December 31, 2010

558,380 $ 4.37

Options granted

124,000 5.27

Options exercised

– –

Options forfeited

– –

Outstanding at December 31, 2011

682,380 $ 4.53 6.30 $ 1,165,750

Options exercisable at December 31, 2011

280,634 $ 4.34 3.71 $ 596,307

Intrinsic value in the above table was calculated as the difference between the Company's estimated stock price on December 31, 2011 and the exercise price, multiplied by the number of options. For any of the Company's outstanding stock options with an exercise price equal to or greater than the Company's estimated stock price on December 31, 2011, the intrinsic value was considered to be zero.

As of December 31, 2011, there was $1.1 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.4 years. There were no exercises of stock options during the years ended December 31, 2009, 2010 and 2011.

The Company periodically remeasures fair value of stock-based awards issued to non-employees and records expense over the requisite service period. The Company granted 254,322 options to non-employees and has recorded compensation expense of $24,062, $29,397 and $23,883 for the years ended December 31, 2009, 2010 and 2011, respectively.

Performance Share Awards

The following information relates to awards of performance shares and performance share, units, included in the preceding table, that have been granted to employees under the 2004 Plan.

In March 2010, the Company issued 228,000 options, with a weighted average exercise price of $4.00 per share, to consultants and key employees that fully vest upon the occurrence of an IPO or a qualified financing. Also, in March 2011, the Company issued 62,000 options with a weighted average

8. Stock-Based Compensation (Continued)

grant price of $5.27 per share that fully vest upon the occurrence of an IPO or a qualified financing to directors, consultants, and key employees.

For awards with performance conditions, such as capital raises, an IPO, a change in control or a sale of the company, no expense will be recognized, and no measurement date can occur, until the occurrence of the event is probable. As of December 31, 2011, it was not probable that one of these performance conditions would be met, and as such, there is no accounting for these shares at this time.

9. Income Taxes

The benefit for income taxes consists of the following for the years ended December 31:

12/31/2009 12/31/2010 12/31/2011

Deferred:

Federal

$ (442,103) $ (582,411) $ (786,282)

State and local

$ (264,479) $ (348,416) $ (470,377)

$ (706,582) $ (930,827) $ (1,256,659)

Increase in valuation allowance

$ 706,582 $ 930,827 $ 1,256,659

Total tax expense

$ — $ – $ —

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

Year Ended December 31,

2009 2010 2011

Percent of pre-tax income:

U.S. federal statutory income tax rate

(34.0)% (34.0)% (34.0)%

State taxes, net of federal benefit

(11.3) (13.8) (12.2)

Permanent items

5.5 (3.9) 0.6

Change in valuation allowance

39.8 51.7 45.6

Effective income tax rate

– % – % – %

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

December 31,

2010 2011

Net operating loss carryforwards

$ 3,776,529 $ 4,913,971

Research credits

314,176 378,359

Convertible debt interest expense

15,504 44,167

Nonqualified stock compensation

574,003 600,374

Valuation allowance

4,680,212 5,936,871

Total noncurrent deferred tax assets

(4,680,212) (5,936,871)

$ – $ –

9. Income Taxes (Continued)

In assessing the reliability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2009, 2010 and 2011.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2011:

	Amount	Expiration
Federal net operating losses	$ 10,884,000	2023 – 2031
Research and development credits	$ 378,000	2023 – 2031

The Internal Revenue Code of 1986, as amended (the "Code") provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the Code) that could limit the Company's ability to utilize these carryforwards. At this time, the Company has not completed a study to assess whether an ownership change under section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation, due to the costs and complexities associated with such a study. The Company may have experienced various ownership changes, as defined by the Code, as a result of past financing transactions. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

The Company did not have unrecognized tax benefits as of December 31, 2011 and does not expect this to change significantly over the next twelve months. As of December 31, 2011, the Company has not accrued interest or penalties related to uncertain tax positions. The Company's tax returns for the years ended December 31, 2008 through December 31, 2011 are still subject to examination by major tax jurisdictions.

10. Commitments and Contingencies

License Agreements

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

10. Commitments and Contingencies (Continued)

Under the Company's license agreements, the Company could be required to pay up to a total of $28.7 million upon achieving certain milestones, such as the products initiation of clinical trials or the granting of patents. From inception through December 31, 2011, the Company

has paid or accrued $1.7 million in payments resulting from the execution of certain agreements, patent approvals, the initiation of sponsor research agreements, and compound development agreements. Milestone payments will also be due upon the issuance of certain patents, the initiation of certain clinical trials, the submission of regulatory applications and certain regulatory approvals, in addition to sales milestones and royalties payable on commercial sales if any occur.

Scott and White

In June 2006, the Company entered into a research and license agreement, as amended in December 2008, March 2010 and July 2011 (collectively the "S&W Agreement"), with Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation, and its affiliate Scott and White Clinic (collectively "S&W") to fund the activities of S&W to conduct research involving SL-401, a clinical-stage compound that the Company has exclusively licensed. This compound is being developed to treat patients with AML and other hematologic cancers. The Company is required to pay customary single digit royalties on sales, if any, of new products approved utilizing the licensed compounds, and a percentage of up-front payments the Company receives from a sublicensee. The S&W Agreement will expire in its entirety upon the later of (i) the 10th anniversary of the first commercial sale of a product, or (ii) the expiration of the last issued patent claiming or covering a product. The Company may terminate the S&W Agreement at its sole discretion at any time after a specified number of days following written notice and either party may terminate for a material breach of the agreement that is not cured within a specified number of days.

University of Pittsburgh

In September 2009, the Company entered into an exclusive license agreement with the University of Pittsburgh ("UP") that covers patent rights claiming an analog peptide of IL-13Ra2, an active ingredient of SL-701, a vaccine that is being developed to treat patients with advanced brain cancer (the "UP Agreement"). The Company paid UP an upfront license fee that was expensed to research and development cost for the year ended December 31, 2009. In addition to the upfront payment, the Company will be required to pay annual fees, milestones (which are contingent upon achievement of pre-defined clinical, regulatory and commercial events) single-digit royalties on net sales, if any, of new products approved utilizing the licensed compounds, and a percentage of non-royalty revenue from sublicensees, which decreases if the applicable sublicense agreement is entered into after a certain clinical milestone has been met. The UP Agreement will expire in its entirety upon the expiration of the last issued patent claiming or covering the product. The Company may terminate the UP Agreement at its sole discretion at any time after a specified number of days following written notice and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days.

10. Commitments and Contingencies (Continued)

In March 2012, the Company entered into a non-exclusive license agreement with UP that covers patent rights claiming a peptide of EphA2, another active ingredient of SL-701, which the Company may use in or packaged with proprietary vaccines, including SL-701, for the diagnosis, treatment or prevention of diseases and tumors of the brain. The Company paid UP an initial license fee, part of which is deferred until September 2012, and will be required to pay UP annual license maintenance fees until the first commercial sale of a licensed product, a customary single digit royalty on sales, and a minimum annual royalty following the first commercial sale of a licensed product. The UP Agreement will expire in its entirety upon the expiration of the last issued patent claiming or covering the product. The Company may terminate the UP Agreement at its sole discretion at any time after a specified number of days following written notice and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days.

In March 2012, the Company also entered into a non-exclusive license agreement with UP for the right to use certain information and data contained in the INDs for the clinical trials of SL-701 that were conducted by UP. The Company may use the information and data for the development, manufacture, regulatory approval and commercialization of pharmaceutical products, and UP has granted the Company a right of reference to such INDs for its planned SL-701 clinical trial of pediatric patients with glioma. The Company paid UP an initial license fee, part of which is deferred until March 2013, and will be required to make a payment following a specified regulatory milestone, and a percentage of non-royalty revenue received from any sublicensees. The UP Agreement will expire in its entirety in March 2032 unless earlier terminated by a party. The Company may terminate the UP Agreement at its sole discretion at any time prior to incorporating or referencing the data or UP INDs, after a specified number of days following written notice, and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days or if the IL-13Ra2 license agreement is terminated.

Other

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

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

10. Commitments and Contingencies (Continued)

Compensation Arrangements

Certain bonuses and salary increases in the amount of $998,948 are contingent and payable upon approval of the board of directors, continued employment, and the occurrence of a specified financing, with an additional $495,552 subject to the same contingencies and payable one year after the occurrence of a specified financing. No amounts have been recorded in respect of either the bonuses or salary increases at December 31, 2011 as payment is not considered probable.

In June 2008, the Company entered into an office sharing agreement relating to its corporate headquarters in New York, New York. Expense incurred under the office sharing agreement was $60,000 for each of the years ended December 31, 2009, 2010, and 2011. The Company subsequently terminated the office sharing agreement as of December 2011.

11. Related Party Transactions

Since January 1, 2009, the Company has engaged in the following transactions with its directors, executive officers, holders of more than 5% of voting securities, and affiliates or immediate family members of the directors, executive officers and holders of more than 5% of voting securities. The Company believes that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

License Agreement and Assignment Agreement with the Company's Chief Executive Officer

The Company is party to a license agreement with Dr. Bergstein, dated December 1, 2003, pursuant to which Dr. Bergstein licensed to the Company his interest in the oncology-related patent rights, and all technology and know-how related to such patent rights, as well as improvements thereto. These patent rights do not relate to the Company's product candidates SL-401 and SL-701. The Company is required to pay Dr. Bergstein $2.0 million in cash or common stock the first time the Company obtains regulatory approval of each licensed product in the United States for certain major cancer indications, as well as a royalty in the low single digits as a percentage of net sales. As part of this license agreement, the Company granted Dr. Bergstein certain piggyback registration rights with respect to any common stock the Company issues him in connection with a milestone payment. Effective upon the closing of an IPO, the Company expects Dr. Bergstein will transfer the patent rights to the Company and the existing license agreement will terminate. Currently, there is no formal contract in place that documents this arrangement, but it is the Company's expectation to get this documented and signed by all relevant parties.

12. Subsequent Events

The Company evaluated events that occurred subsequent to December 31, 2011 through April 2, 2012, the date the financial statements were available to be issued.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011

12. Subsequent Events (Continued)

2012 Private Placement of 1.27% Convertible Notes

In January 2012, the Company issued $0.9 million of convertible notes (the "1.27% Convertible Notes") at face value for cash. Of this amount, approximately $0.5 million was received on or before December 31, 2011 and before the note agreements were signed. These amounts were classified as long term liabilities on the balance sheet, consistent with the terms of the notes that were signed in January 2012.

The 1.27% Convertible Notes and the related interest expense are due in 5 years if the notes are not converted prior to that date. Interest is being charged at a rate of 1.27% per annum. The 1.27% Convertible Notes and related accrued interest are convertible into common stock at a conversion price equal to 87.5% of the IPO price per share upon the occurrence of an IPO, as defined in the 1.27% Convertible Notes agreement. Additionally, the 1.27% Convertible Notes are convertible upon the occurrence of a qualified or non-qualified financing, as defined in the 1.27% Convertible Notes agreement, at a price equal to 85% of the price per share used in the each financing.

The 1.27% Convertible Notes also contain a beneficial conversion option such that immediately upon the occurrence of one of the financings discussed above, the 1.27% Convertible Notes shall convert into shares of newly issued common stock in the case of an IPO or the same securities issued in the case of a qualified or non-qualified financing. The 1.27% Convertible Notes holders shall be entitled to receive a number of shares determined by dividing the applicable 1.27% Convertible Note balance as of the conversion date by an amount equal to the share price as determined above. Upon a triggering event that forces conversion where both the price and quantity of the shares are known, a beneficial conversion charge will be determined representing the difference between the conversion price and the fair value of the new shares multiplied by the number of shares and a beneficial conversion charge will be recorded to earnings with a corresponding credit to additional paid-in capital.

New Lease Arrangement for Corporate Headquarters

In February 2012, the Company entered into a leasing agreement with respect to its current corporate offices at 750 Lexington Avenue, New York, New York, for a monthly rent of $2,041. The term of this lease agreement is six months. The Company is currently considering its alternatives with respect to the leasing of suitable office space on a longer-term basis.

2012 Stock Option Grants

In March 2012, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock from 3,000,000 shares to 3,515,000 shares. In addition, the Company amended its Amended and Restated 2004 Employee, Director and Consultant Stock Plan to increase the number of shares reserved for issuance under the plan from 703,809 shares to 1,232,267 shares.

During the first quarter of 2012, the Company granted various employees, consultants and service providers options to purchase an aggregate of 344,118 shares of common stock. The options were granted at an exercise price of $5.97 per share, the fair market value of the Company's common stock on the date of grant as determined by the Company's board of directors. The options are subject to various vesting conditions.

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Shares

GRAPHIC

Common Stock

PROSPECTUS

, 2012

Oppenheimer & Co. JMP Securities

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

Until , 2012 (25 days after the commencement of this offering) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II – INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc. filing fee.

Securities and Exchange Commission registration fee	5,730
Financial Industry Regulatory Authority, Inc. filing fee	5,500
NASDAQ listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue sky fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	$ *

To be filed by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action,

suit or proceeding to which he or she is party or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our certificate of incorporation also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we don't assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with our directors. In general, these agreements provide that we will indemnify the director to the fullest extent permitted by law for claims arising in his or her capacity as a director of our Company or in connection with his or her service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director makes a claim for indemnification and establish certain presumptions that are favorable to the director.

We maintain a general liability insurance policy which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.

Set forth below is information regarding shares of common stock and convertible promissory notes issued, and options granted, by us within the past three years that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Also included is the consideration, if any,

received by us for such shares, notes and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuances of Common Stock and Convertible Notes

In March 2010, we entered into a note purchase agreement pursuant to which we redeemed from the Pequot Funds all of the shares of our Series A Preferred Stock held by them, which represented all of our issued and outstanding shares of Series A Preferred Stock, in exchange for (i) an aggregate cash payment of $750,000, (ii) 227,759 shares of our common stock and (iii) 2.45% senior unsecured convertible notes in the

aggregate principal amount of $1,250,000. Pursuant to the note purchase agreement, the Pequot Funds immediately transferred such shares of common stock and the notes to a fund affiliated with Neuberger Berman Group LLC, which presently holds such shares and notes.

In April 2010, we issued and sold an aggregate of 113,880 shares of our common stock to certain existing investors at a purchase price per share of $5.2687 for an aggregate purchase price of $599,999.55.

In January 2012, we sold an aggregate of $0.9 million of convertible promissory notes in a private placement to certain existing and other investors. The notes accrue interest at a rate of 1.27% per annum and have a maturity date of January 2, 2017, unless converted prior thereto. The principal amount of the notes and accrued and unpaid interest thereon will automatically convert into shares of our common stock upon the closing of this offering, at a conversion price equal to 87.5% of the initial public offering price.

In March 2012, we issued a total of 13,221 shares of restricted common stock to our directors and service providers. These shares of restricted stock vest as to 25% of the award upon the closing of this offering, with the remaining 75% vesting in equal annual installments, as long as the respective party continues as a director or service provider, as applicable, through the third anniversary of the date of grant.

No underwriters were involved in the foregoing sales of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, including in some cases, Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our common stock and convertible notes described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares and convertible notes for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Stock Option Grants

Since January 1, 2009, we have issued to certain employees, directors and consultants options to purchase an aggregate of 380,494 shares of common stock as of December 31, 2011, of which, as of December 31, 2011, none had been exercised or forfeited, and options to purchase 682,380 shares of common stock remained outstanding at a weighted-average exercise price of $4.53 per share.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our

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employees, directors and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of common stock and the convertible notes described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

The exhibits to the Registration Statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

ITEM 17. UNDERTAKINGS.

(a)

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b)

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in

the Act and will be governed by the final adjudication of such issue.

(c)

The undersigned registrant hereby undertakes that:

(1)

For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2)

For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on this 2nd day of April, 2012.

STEMLINE THERAPEUTICS, INC.

By:

/s/ IVAN BERGSTEIN, M.D.

Ivan Bergstein, M.D.

Chairman, President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Stemline Therapeutics, Inc., hereby severally constitute and appoint Ivan Bergstein, M.D. our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution in him for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any other registration statement for the same offering pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature

Title

Date

/s/ IVAN BERGSTEIN, M.D.

Ivan Bergstein, M.D. Chairman, President, Chief Executive

Officer and Director

(Principal Executive Officer) April 2, 2012

/s/ JOHN T. CAVAN

John T. Cavan

Chief Accounting Officer

(Principal Financial and Accounting Officer)

April 2, 2012

/s/ J. KEVIN BUCHI

J. Kevin Buchi

Director

April 2, 2012

/s/ KENNETH ZUERBLIS

Kenneth Zuerblis

Director

April 2, 2012

/s/ RON BENTSUR

Ron Bentsur

Director

April 2, 2012

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EXHIBIT INDEX

Exhibit No. Description

1.1* Underwriting Agreement.

3.1

Second Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on March 16, 2010.

3.2

Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on March 15, 2012.

3.3

Bylaws of the Registrant.

3.4*

Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.

3.5*

Bylaws of the Registrant to be effective upon the closing of this offering.

4.1*

Specimen certificate evidencing shares of common stock.

5.1*

Opinion of Edwards Wildman Palmer LLP.

10.1†

Research and License Agreement by and among the Company, Scott and White Memorial Hospital, Scott, Sherwood and Brindley Foundation and Arthur E. Frankel, M.D., dated June 15, 2006; as amended by that certain First Amendment to Research and License Agreement dated December 9, 2008, that certain Second Amendment to Research and License Agreement dated March 17, 2010 and that certain Third Amendment to Research and License Agreement dated July 12, 2011.

10.2†

Exclusive License Agreement between the Company and the University of Pittsburgh, dated September 30, 2009.

10.3†

Exclusive Patent and Non-Exclusive Know-How Licence Agreement between the Company and Cambridge University Technical Services Limited, dated September 16, 2004.

10.4†

Non-Exclusive License Agreement between the Company and the University of Pittsburgh, dated March 30, 2012.

10.5†

Non-Exclusive License Agreement between the Company and the University of Pittsburgh, dated March 21, 2012.

10.6 ¨

Employment Agreement, dated November 6, 2011, between the Registrant and Eric K. Rowinsky, M.D.

10.7 ¨*

Offer letter between the Company and John T. Cavan dated March 1, 2012.

10.8 ¨*

Employment Agreement dated , 2012, between the Registrant and Ivan Bergstein, M.D.

10.9*

Form of Indemnification Agreement between the Registrant and each director.

10.10

Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

10.11

Form of Incentive Stock Option Agreement under Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

10.12

Form of Non-qualified Stock Option Agreement under Amended and Restated 2004 Employee, Director and Consultant Stock Plan.

10.13*

2012 Incentive Plan.

10.14*

Form of Incentive Stock Option Agreement under 2012 Incentive Plan.

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Exhibit No. Description

10.15* Form of Non-qualified Stock Option Agreement under 2012 Incentive Plan.

10.16 ¨

2011 Employee Cash Bonus Plan.

10.17

Senior Unsecured Convertible Note issued by the Company in favor of NB Athyrium LLC, dated March 16, 2010.

23.1

Consent of Ernst & Young LLP, Independent Registered Accounting Firm.

23.2*

Consent of Edwards Wildman Palmer LLP (to be included in Exhibit 5.1).

24.1

Power of Attorney (included on signature page)

*

To be filed by amendment.

†

Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

¨

Denotes management contracts and compensatory arrangements.