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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

OR

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

For the transition period from to .

Commission File Number: 001-35619

STEMLINE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0522567**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

750 Lexington Avenue
Eleventh Floor
New York, New York 10022
(Address of principal executive offices) (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value $0.0001 per share	**NASDAQ Capital Market**
(Title of Class)	(Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐ Yes ☒ No

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

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

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

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was $ 162,410,910 as of June 30, 2014, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 17,819,923 shares of the registrant's common stock outstanding as of March 12, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2015 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K ("Form 10-K") includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K 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 product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

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

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

- the success and timing of our preclinical studies and clinical trials, including patient accrual;
- our ability to obtain and maintain regulatory approval of our product candidates for trial initiation or marketing, and the labeling under any approval we may obtain;
- our plans to develop and commercialize our product candidates;
- the loss of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- our ability to successfully compete in the potential markets for our product candidates, if commercialized;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- market conditions in the pharmaceutical and biotechnology sectors;
- our available cash;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to maintain the license agreements for SL-401, SL-701 and our other in-licensed product candidates;
- the ability of our product candidates to successfully perform in clinical trials;
- the successful development of our sales and marketing capabilities;
- our ability to manufacture and the performance of third-party manufacturers, clinical research organizations, or CROs, clinical trial sponsors and clinical trial investigators; and
- our ability to successfully implement our strategy.

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

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

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

Part I

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

Item 1. Business

Overview

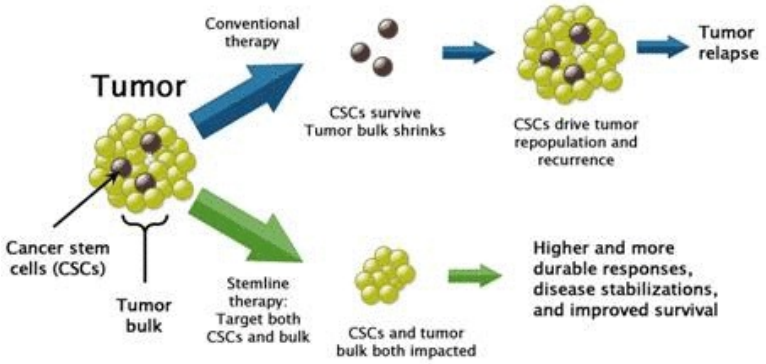
We are a clinical stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target cancer stem cells, or CSCs, and tumor bulk. We are currently developing two clinical stage product candidates, SL-401 and SL-701, as well as a pipeline of preclinical candidates that include SL-801.

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R, present on CSCs and tumor bulk of a variety of hematologic cancers. In July 2014, we opened a corporate sponsored investigational new drug, or IND, with the FDA. Three multicenter clinical trials with SL-401 are currently open in the following indications: 1) blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed/refractory acute myeloid leukemia (AML), the BPDCN portion of which we have designed to serve as a potential registration trial; 2) AML patients in first complete remission (CR) with minimal residual disease (MRD); and 3) four types of advanced high-risk myeloproliferative neoplasms (MPN), including systemic mastocytosis, advanced symptomatic hypereosinophilic disorder, myelofibrosis, and chronic myelomonocytic leukemia. Additional SL-401 studies are currently planned in other indications including myeloma and certain other lymphomas and leukemias.

SL-701 is an enhanced immunotherapy designed to activate the immune system to attack tumors. SL-701 is currently being developed as a single agent in adult patients with second-line glioblastoma multiforme, or GBM. In April 2014, we opened a corporate sponsored IND with the FDA. A multicenter, open-label clinical trial with SL-701 is currently accruing patients with the expectation to enroll approximately 80-100 patients. Previously, an earlier version of the therapy demonstrated clinical activity, including tumor shrinkages, disease stabilizations, and an overall survival signal compared to historical data, in investigator sponsored Phase 1/2 trials in advanced adult and pediatric brain cancers.

We plan to advance our preclinical pipeline of product candidates, which includes SL-801. SL-801 is a novel oral small molecule reversible inhibitor of nuclear transport, targeting Exportin-1, or XPO1. We intend to submit an IND for SL-801 and advance this compound into Phase 1 disease-directed proof-of-concept studies in both solid and hematologic cancers.

The field of CSCs is an emerging area of cancer biology that we believe is fundamentally altering 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. Moreover, many of the characteristics of CSCs, such as their slow growth, presence of multi-drug resistance proteins, anti-cell death mechanisms, and increased activity of cellular mechanisms that repair damaged DNA, may enable CSCs to resist therapeutic agents traditionally used to treat cancer. Further, we believe there is now a significant body of evidence indicating that while standard therapies may initially shrink tumors by targeting the tumor bulk, their failure to effectively eradicate CSCs contributes to treatment failure, tumor relapse and poor survival. Accordingly, we believe that targeting both CSCs and 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.



Our Company

We were incorporated under the laws of the State of Delaware in August 2003. Our principal executive offices are located at 750 Lexington Avenue, Eleventh Floor, New York, New York 10022 and our telephone number is (646) 502-2311.

Our website address is www.stemline.com. The information set forth on our website is not a part of this report. We will make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is **http://www.sec.gov/.**

Management

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

- Ivan Bergstein, M.D. — Ivan Bergstein, M.D. — Chairman, Chief Executive Officer and President. Dr. Bergstein is Chief Executive Officer and Founder of Stemline Therapeutics. He led Stemline through multiple private financings and ultimately its successful IPO and subsequent follow-on offerings, raising over $165 million as a public company. Dr. Bergstein's early and broad intellectual property founded and positioned Stemline with a deep domain expertise competitive edge and in the rapidly emerging cancer stem cell (CSC) field of oncology. He then went on to manage the company's evolution from early-stage research and development to current late clinical stage. Prior to founding Stemline, Dr. Bergstein was Medical Director of Access Oncology, Inc., a clinical stage oncology-focused biotechnology company where he was a key member of a small team responsible for the acquisition and development of the company's clinical stage assets and ultimately the sale of the company to Keryx Biopharmaceuticals (Nasdaq: KERX). Previously, he was a senior biopharmaceuticals analyst at a Wall Street-based firm that advised funds on investment opportunities in public companies with late clinical stage assets. He received a BA in mathematics from the University of Pennsylvania and was elected to the Pi Mu Epsilon National Mathematics Honor Society, an MD from the Mount Sinai School of Medicine where he was elected to the Alpha Omega Alpha Honor Medical Society, received the Merck Award for Clinical Excellence, and subsequently completed an internship in general surgery. He then became the Jerome A. Urban Post-Doctoral Research Fellow at the Cornell University Medical College where he studied and published work relating to Wnt genes in human breast cancer. He then went on to complete an internal medicine residency and hematology-oncology fellowship at the New York Presbyterian Hospital—Weill Medical College of Cornell University where he studied and published work on gene therapy manipulations of the sonic hedgehog pathway. He currently holds a voluntary faculty position at the New York Presbyterian Hospital — Weill Medical College of Cornell University.

- Eric K. Rowinsky, M.D. — Executive Vice President, Chief Medical Officer and Head of Research and Development. Dr. Rowinsky 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 Food and Drug Administration, or FDA, approval of Erbitux® for head and neck and colorectal cancers and advancing eight other biological therapeutics through clinical development while at ImClone. He has also played integral roles in the development and registration of a wide range of cancer therapeutics, including paclitaxel, docetaxel, irinotecan, topotecan, erlotinib, gefitinib, panitumumab, lapatinib, and temsirolimus, among others. Dr. Rowinsky currently serves on the Board of Directors of Biogen Idec Inc., as well as several other public biopharmaceutical companies, and is an Adjunct Professor at New York University School of Medicine. He completed a medical oncology fellowship at The Johns Hopkins Hospital. Dr. Rowinsky was an Associate Professor of Oncology at Johns Hopkins and then Head of Clinical Research and Director of the Institute for Drug Development of the Cancer Therapy and Research Center in San Antonio, Texas.

- Kenneth Hoberman — Chief Operating Officer. Mr. Hoberman has extensive financial, accounting, investor relations, corporate governance and business development experience including M&A, strategic alliances and partnerships both domestic and international. His operational expertise includes regulatory oversight, human resources, manufacturing and clinical development. He was previously Vice President of Corporate and Business Development of Keryx Biopharmaceuticals, Inc., where he was instrumental in the success of the company. He also helped secure 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, helping to grow the company's market capitalization to over $1 billion. He also led the team that

originated, in-licensed, and developed Auryxia™ which recently gained FDA approval. He is on the Board of Directors of TG Therapeutics (Nasdaq: TGTX). He received a B.S.B.A. in Finance from Boston University and completed post-baccalaureate studies at Columbia University.

- David Gionco —Vice President of Finance and Chief Accounting Officer. Mr. Gionco was previously Vice President, Chief Financial Officer and Chief Accounting Officer of Savient Pharmaceuticals, Inc. where he oversaw the finance function for the organization and was instrumental in helping to grow the company, raising over $350 million. Prior to this, Mr. Gionco held audit, corporate accounting, financial planning, finance and controller roles at companies including Merck & Co., Inc. ("Merck") and, previously, Medco Health Solutions, Inc., which was acquired by Merck during his tenure. At Merck, Mr. Gionco held various financial and accounting positions of increasing responsibility. Mr. Gionco also held senior financial positions at Progenics Pharmaceuticals, Inc. and Odyssey Pharmaceuticals, Inc. (a subsidiary of Pliva, Inc., now Teva Pharmaceutical Industries Ltd.). Mr. Gionco previously had 7 years of financial auditing experience with a major public accounting firm. Mr. Gionco holds a B.S. in Accounting from Fairleigh Dickinson University and an MBA in Finance from Rutgers University. Mr. Gionco is a Certified Public Accountant in the State of New York.

Strategy

Our goal is to maintain and fortify a leadership position in the discovery, acquisition and development of novel oncology therapies that target CSCs and to build a fully integrated pharmaceutical company with commercial infrastructure to support the marketing of our CSC-targeted oncology drugs, if approved. The fundamental components of our business strategy to achieve this goal include the following:

- *Develop and commercialize SL-401 in multiple hematological cancers.* We have advanced SL-401 into corporate sponsored trials for multiple hematologic cancer indications including blastic plasmacytoid dendritic cell neoplasm, or BPDCN, where we are pursuing a registration-directed path. We have also opened a clinical trial in patients with acute myeloid leukemia, or AML, who are in first complete remission, or CR, with evidence of minimum residual disease, or MRD. In addition, we have opened trials in additional rare IL-3R+ malignancies including certain myeloproliferative neoplasms that include mastocytosis, hypereosinophilic syndrome, myelofibrosis, and chronic myelomonocytic leukemia. We also intend to pursue additional indications including multiple myeloma and certain other lymphomas and leukemias.

- *Develop and commercialize SL-701 in brain cancer.* We have advanced SL-701 into a corporate sponsored trial in adult patients with recurrent glioblastoma multiforme, or GBM, following initial treatment with surgery, radiation, and chemotherapy. We also plan to pursue a trial of SL-701 in pediatric patients with brainstem and non-brainstem high-grade glioma.

- *Develop and commercialize SL-801 in solid and hematologic cancers.* We plan to advance SL-801 toward investigational new drug, or IND, filing and initiate Phase 1 disease-directed proof-of-concept studies in both solid and hematologic cancers.

- *Continue to advance and build out our pipeline.* We also plan to advance and build out our pipeline of product candidates. In addition to advancing SL-401, SL-701 and SL-801, we plan to advance SL-501, our next generation IL-3R-targeted compound with potential applications in both malignant and non-malignant (autoimmune) indications, into IND-enabling studies.

- *Develop commercialization capabilities in North America and Europe.* We believe that the infrastructure required to commercialize our oncology product candidates may make it cost-effective for us to internally develop a marketing effort and sales force. If SL-401, SL-701, SL-801 or any of our other product candidates is approved by the FDA or other regulatory authorities, we intend to commercialize our product candidates in North America and potentially in Europe through direct sales and distribution. However, we will remain opportunistic in seeking strategic partnerships in these and other markets when advantageous to us.

- *Continue to both leverage and fortify our intellectual property portfolio.* We believe that we have a very strong intellectual property position relating to the development and commercialization of our product candidates and technology and CSC-targeting in general. 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, and we may in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

SL-401

Overview

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R. IL-3R is overexpressed on CSCs and/or more mature cancer cells derived from CSCs (i.e., tumor bulk) of multiple hematologic cancers including acute myeloid leukemia, or AML, chronic myeloid leukemia, or CML, myelodysplastic syndrome, or MDS, certain lymphomas including Hodgkin's disease, multiple myeloma, or MM, and multiple rare hematologic malignancies such as blastic plasmacytoid dendritic cell neoplasm, or BPDCN, and others. In a completed investigator sponsored Phase 1/2 clinical trial in patients with advanced hematologic cancers, single agent SL-401 administered in a single cycle regimen demonstrated anti-tumor activity, including durable CRs, in relapsed or refractory patients. Specifically, a single cycle of single-agent SL-401 induced seven CRs: five CRs in BPDCN and two CRs in relapsed or refractory AML. Notably, SL-401 also improved the median overall survival, or OS, relative to historical data, of the 16 most heavily pretreated AML patients who had failed at least two previous therapies (i.e., third-line or greater) and who received therapeutically relevant doses of SL-401, with only a single cycle. Further, SL-401 has not demonstrated the protracted myelosuppression typically seen with traditional chemotherapy, which is a key differentiating feature relative to many other hematologic cancer therapies and which we believe is due to the lack of IL-3R expression on normal hematopoietic stem cells. Currently, there are limited effective treatment options for patients with relapsed or refractory hematologic cancers including BPDCN and AML. We believe that a major reason for the failures of traditional treatments to provide long-term benefit is that these traditional treatments target tumor bulk rather than both tumor bulk and CSCs, and are often toxic to the bone marrow. Accordingly, by pursuing hematologic cancer indications with SL-401, a therapeutic that uniquely targets both CSCs and tumor bulk and does not induce the protracted myelosuppression associated with standard therapy, we intend to provide benefit to patients who historically have been difficult to treat with traditional therapies.

In July 2014, we opened a corporate sponsored investigational new drug, or IND, with the U.S. Food and Drug Administration, or FDA. Three multicenter clinical trials with SL-401 are currently open in the following indications: 1) blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed/refractory acute myeloid leukemia (AML), the BPDCN portion of which we have designed to serve as a potential registration trial; 2) AML patients in first complete remission (CR) with minimal residual disease (MRD); and 3) four types of advanced high-risk myeloproliferative neoplasms (MPN), including systemic mastocytosis, advanced symptomatic hypereosinophilic disorder, myelofibrosis, and chronic myelomonocytic leukemia. Additional SL-401 studies are currently planned in other indications including myeloma and certain other lymphomas and leukemias.

In June 2013, SL-401 was awarded Orphan Drug designation from the FDA for the treatment of BPDCN. Previously, in February 2011, SL-401 was awarded Orphan Drug designation from the FDA for the treatment of AML.

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

BPDCN is a rare and aggressive hematologic cancer that carries a poor prognosis. BPDCN had been previously classified as blastic NK cell lymphoma, agranular CD4+/CD56+ hematodermic neoplasm, and plasmacytoid dendritic cell cancer. In 2008, this disease was renamed BPDCN by the World Health Organization, or WHO, due to its derivation from plasmacytoid dendritic cells, which are specialized immune cells. BPDCN most commonly affects middle-aged and older patients and is approximately three times more common in men than women. This malignancy has features of both lymphomas, including cutaneous lymphomas, as well as leukemias, and typically presents with skin lesions, as well as extracutaneous disease that may include the bone marrow, blood, lymph nodes, and spleen. BPDCN growth in the bone marrow results in decreased blood cell counts, which can lead to serious infections, fatigue, bleeding, and death. Although BPDCN can be controlled for brief periods with various combination chemotherapy regimens, including high dose chemotherapy with allogeneic stem cell transplantation, overall prognosis remains poor. There are currently no approved therapies for BPDCN, and an optimal therapeutic regimen for BPDCN has not yet been established.

Other rare IL-3R cancers

A number of other rare hematologic diseases, each qualifying as an unmet medical need, express IL-3R including certain myeloproliferative syndromes such as mastocytosis, clonal eosinophilic disorders, myelofibrosis, and chronic myelomonocytic leukemia, as well as other malignancies such as hairy cell leukemia. For a majority of patients with these conditions, there is no effective, disease modifying therapy.

Mastocytosis. Systemic mastocytosis is a proliferative disorder characterized by an overabundance of mast cells in various organs and tissues. Mastocytosis can be systemic or localized to one or a few organs. The WHO classifies mastocytosis into the following categories: cutaneous, indolent, systemic (with associated hematologic non-mast cell lineage disease), aggressive systemic, mast cell leukemia, mast cell sarcoma, and extracutaneous astrocytoma. There are approximately 3,000 cases of mastocytosis diagnosed annually in the United States. Patients with indolent disease typically have a favorable prognosis, whereas aggressive cases of

mastocytosis carry an overall survival of under 3.5 years. There are no currently approved drugs and no cure for mastocytosis. Treatment for aggressive variants includes various chemotherapy agents, imatinib (Gleevec® Novartis AG), corticosteroids, and antihistamines.

Eosinophilic disorders. Primary (clonal) eosinophilic disorders include chronic eosinophilic leukemia, or CEL, idiopathic hypereosinophilic syndrome, or HES, lymphocyte-variant HES, and primary eosinophilia associated with an 8p11 chromosomal translocation. These rare disorders are characterized by a persistently elevated eosinophil count that may result in various symptoms depending on which organs are involved. Damage to the heart, lungs, peripheral nervous system, and other organs can occur. An acquired (non-familial) form of HES is particularly aggressive and debilitating. Acquired forms of HES are subclassified as secondary (reactive), idiopathic, and clonal HES, the latter often transitioning into CEL, which can result in myocardial fibrosis and congestive heart failure. Eosinophils are known to ubiquitously express the IL-3R. Current treatments for CEL include corticosteroids, mepolizumab, alemtuzumab (Campath® Genzyme Corporation), and imatinib (Gleevec®), the latter of which is approved by the FDA for approximately 10% of HES patients who express the FIP1L1-PDGFRA fusion protein. However, some of these agents can cause severe toxicity and may not induce durable responses. Therefore, newer and more effective therapies are needed for certain patients, including those with symptomatic disease and/or extra-cutaneous organ involvement.

Myelofibrosis. Primary myelofibrosis, or PMF, is characterized by the proliferation of an abnormal clone of hematopoietic progenitor cells in the bone marrow and other sites, which results in fibrosis, or the replacement of the bone marrow with collagenous connective tissue fibers that, in turn, causes decreased blood cell counts. The yearly calculated incidence of PMF in the U.S. ranges from approximately 1,260 to 4,410 individuals per year. Median age at diagnosis is 65 years. About 20% of affected patients are less than 55 years of age. Manifestations include decreased blood cell counts, splenomegaly that is commonly painful, and increased immature white blood cells and basophils in the peripheral blood. The one known treatment of potential long-term benefit is high-dose chemotherapy followed by allogeneic stem cell transplantation. Other treatment options are largely supportive, and do not alter the course of the disorder. These options may include administration of folic acid, allopurinol, and/or blood cell transfusions. Corticosteroids, alpha-interferon and/or hydroxyurea are also used. Splenectomy is sometimes considered as a treatment option for patients with PMF in whom massive splenomegaly is contributing to anemia because of hypersplenism, particularly if there is a heavy requirement for blood transfusions. Ruxolitinib (Jakafi® Incyte Inc.), which has recently received regulatory approval in the United States and elsewhere for the treatment for PMFs, has been associated with symptomatic improvement and increased overall survival, but its overall benefits can be short lived. Lenalidomide (Revlimid® Celgene Corporation) and thalidomide (Thalomid® Celgene Corporation) may also be used in its treatment, though peripheral neuropathy can be a troublesome side effect.

Chronic myelomonocytic leukemia. Chronic myelomonocytic leukemia, or CMML, is characterized by increased numbers of monocytes and immature blood cells (blasts) in the peripheral blood and bone marrow, as well as abnormal appearing cells (dysplasia) in at least one type of blood cell. CMML features characteristics of both a myelodysplastic syndrome, or MDS, as well as a myeloproliferative disorder, or MPD. In the United States, the incidence of CMML is approximately 3,150 individuals per year and the disease affects approximately 9,450 individuals per year. One of the most common symptoms of CMML is splenomegaly, found in approximately half of cases. Other less frequent symptoms consist of anemia, fever, weight loss, night sweats, infection, bleeding, synovitis, lymphadenopathy, skin rashes, pleural effusion, pericardial effusion and peritoneal effusion. CMML can transform into acute myeloid leukemia, or AML, in about 20%-30% of cases. Most cases are dealt with as supportive rather than curative because most therapies do not effectively increase survival. Supportive measures include blood transfusions and growth factors such as erythropoietic and granulocyte-stimulating factor. Reasons for more definitive treatment include the presence of fevers, chills, weight loss, symptomatic organ involvement, increasing blood counts, leukostasis, blood clotting, and/or progressive decreasing blood cell counts. The demethylating agents azacitidine (Vidaza® Celgene Corporation) and decitabine (Dacogen® Otsuka America Pharmaceutical, Inc.) have been used to treat CMML. High dose chemotherapy followed by bone marrow transplantation is also employed to treat CMML, and may provide long term benefit.

Hairy cell leukemia. Hairy cell leukemia, or HCL, is an uncommon hematological malignancy characterized by a clonal accumulation of abnormal B lymphocytes. Approximately 2,000 new cases of HCL occur annually in the United States. The median age at diagnosis is approximately 62 years with male predominance. Although the 6-year overall survival rate has been estimated to be approximately 80% and there are FDA approved therapies for HCL, including cladribine (Litak® Lipomed GmbH and Movectro® Merck KgAA) and pentostatin (Nipent® Hospira, Inc.), there is no permanent cure for the disease.

Acute myeloid leukemia (AML)

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 19,000 new AML cases occur annually in the United States, and approximately 27,000 new cases occur annually in Europe. The average age of an AML patient is 67 years. The National Cancer Institute estimated 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 as cytarabine in combination with an anthracycline such as daunorubicin. In certain circumstances, allogeneic stem cell 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. Despite a moderate to high proportion of patients obtaining a CR with first- and second-line chemotherapy, the high relapse rate and poor OS indicate that most patients harbor drug-resistant CSCs following chemotherapy. 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.

Multiple myeloma (MM)

MM is a hematologic malignancy that is characterized by the dysfunction of plasma cells, which are white blood cells that produce antibodies. During MM, malignant plasma cells overproduce abnormal monoclonal antibodies and can interfere with normal blood cell function in the bone marrow leading to immunodeficiency. Other common clinical manifestations of advanced MM include osteolytic bone lesions and renal disease. The bone marrow, or BM, microenvironment confers growth, survival, and drug resistance of MM cells, and it has recently been shown that plasmacytoid dendritic cells, or pDCs, which express high levels of IL-3R, are significantly increased in the BM of patients with MM and promote MM proliferation. Approximately 22,000 new cases of MM are reported annually in the United States and approximately 33,000 new MM cases are reported annually in Europe. The median age at diagnosis is approximately 62 years for men and 61 years for women. The median overall survival after conventional treatments is 3-4 years, but high-dose treatment followed by autologous stem cell transplantation can extend the median survival to 5-7 years. Despite FDA approved therapies for MM, including thalidomide (Thalomid®), lenalidomide (Revlimid®), bortezomib (Velcade® Millenium Pharmaceuticals, Inc., part of Takeda Pharmaceutical Company Limited), dexamethasone (Decadron® Medimetriks Pharmaceuticals, Inc.), carfilzomib (Krypolis® Onyx Pharmaceuticals Inc., an Amgen Subsidiary), and pomalidomide (Pomalyst® Celgene Corporation), most patients invariably relapse from the disease.

Myelodysplastic syndrome (MDS)

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 such as erythropoietic and granulocyte-stimulating factor, chemotherapy, and stem cell transplantation in certain cases. We believe that a large number of 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 (CML)

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® Novartis AG) and dasatinib (Sprycel® Bristol-Myers Squibb Company). 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.

Hodgkin's lymphoma (HL)

Hodgkin's lymphoma, or HL, is a cancer of the lymphatic system that commonly affects lymph nodes in the neck or the area between the lungs and behind the breastbone. Approximately 9,000 new HL cases occur annually in the United States and approximately 12,000-17,000 cases occur annually in Europe. The disease has four subtypes, including nodular sclerosis, lymphocyte-rich, mixed cellularity, and lymphocyte-depleted HL, all of which produce increased numbers of a unique cell type called "Reed-Sternberg" cells. These cells are considered to be the clonal tumor cells of HL and are known to express the IL-3R. Although combination chemotherapy and/or radiation therapy are affective at combating this disease, 20-30% of patients relapse after initial treatment or have primary refractory disease. Of these patients, those who do not obtain a complete remission, or CR, prior to transplantation, or who relapse after second line therapy, have few effective therapeutic options. Recently, brentuximab vedotin (Adcentris® Seattle Genetics, Inc.) received regulatory approval in the United States and elsewhere for the treatment of recurrent or refractory HL.

Design of SL-401 and mechanism of action

SL-401 is a biologic targeted therapy directed to the IL-3R. SL-401 consists of IL-3 recombinantly fused to a truncated diphtheria toxin payload. Mechanistically, the IL-3 domain of SL-401 directs the cytotoxic payload to IL-3R+ cells. SL-401 is then internalized by target cells, leading to intracellular release of the payload, inhibition of protein synthesis and cell death, or apoptosis. Accordingly, the targeting and mechanism by which SL-401 kills cells differs from therapeutics that are commonly used to treat hematologic malignancies. Traditional therapies, such as chemotherapy, largely target rapidly dividing cells, whether malignant or normal, by interfering with DNA replication and other processes. SL-401, in contrast, is a targeted therapy that specifically recognizes and binds to cells expressing IL-3R, a target which is overexpressed on leukemia cells relative to normal cells. Thus, SL-401 preferentially

targets malignant, not normal cells, a feature expected to result in fewer toxicities relative to traditional therapies. Moreover, by inhibiting protein synthesis, we believe that SL-401 is able to kill not just rapidly dividing cells, but also slower-growing cells such as CSCs. In addition, the SL-401 payload does not appear to be subject to multi-drug resistance proteins highly expressed on CSCs and tumor bulk. Therefore, unlike traditional therapies which largely target and kill tumor bulk only, SL-401 is designed to target and kill both CSCs and tumor bulk.

IL-3R is normally expressed on certain maturing hematopoietic cells, including maturing myeloid cells, B cells, dendritic cells, mast cells, basophils and eosinophils, and appears to be involved in cell maturation, differentiation, and survival. Importantly, IL-3R is not expressed to a significant degree on normal hematopoietic stem cells. IL-3R is, however, overexpressed on multiple hematological malignancies including AML, BPDCN, MDS, CML, B cell acute lymphoid leukemia, Hodgkin's and certain aggressive non-Hodgkin's lymphomas, hairy cell leukemia, and rare malignancies and myeloproliferative disorders involving mast cell, basophilic and eosinophilic lineages including mastocytosis and hypereosinophilic syndrome. In addition to expression on tumor bulk, IL-3R is also expressed on the CSCs of multiple hematologic cancers including 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. We believe that these findings further validate that IL-3R is an important oncology target.

SL-401 preclinical activity

SL-401 has demonstrated preclinical *in vitro* and *in vivo* activity against a wide range of hematologic cancer types. In AML, SL-401 is highly active 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 concentrations that inhibit the growth of fifty-percent (50%) of cells, or an IC_{50}, in the low picomolar range. Notably, normal bone marrow stem 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 the incorporation 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.

In addition, SL-401 demonstrated very high potency against BPDCN cells from patients, with an IC_{50} in the femtomolar (10^{-15} molar) range. SL-401 has also demonstrated preclinical activity against a variety of additional hematologic cancers including certain rare IL-3R+ malignancies such as chronic eosinophilic leukemia, where it produced IC_{50} values in the low single-digit picomolar (10^{-12} molar) range. SL-401 has also shown potent *in vitro* anti-leukemia activity against CML tumor bulk and CML CSCs, and increased survival in mouse models of human CML taken from patients who were resistant to tyrosine kinase inhibitors, or TKIs. SL-401 has also been shown to possess a synergistic anti-CML effect when used in combination with certain TKIs. SL-401 has also demonstrated potent *in vitro* anti-tumor activity against several lymphoid cancer types, including lymphoid leukemia (e.g. T cell acute lymphoid leukemia, or T-ALL), Hodgkin's and non-Hodgkin's lymphoma, and multiple myeloma, or MM. Interestingly, SL-401 appears to have both a direct as well as an indirect anti-MM effect, the latter seemingly caused by SL-401's ability to target IL-3R+ hyperproliferative dendritic cells (the cells of origin of BPDCN) that appear to provide a microenvironmental growth stimulus to their neighboring MM cells. This is notable for several reasons including the drug's novel mechanism of anti-MM action as well as linking the MM and BPDCN diseases via a common plasmacytoid dendritic cell, and IL-3R, target. SL-401 has also been shown to have a synergistic effect against MM when combined with existing therapies including lenalidomide (Revlimid®) and bortezomib (Velcade®). These findings warranted clinical investigation of SL-401.

Phase 1/2 clinical trial—advanced hematologic cancers

Overview

SL-401 demonstrated single agent clinical efficacy, including durable CRs, in a multi-center investigator sponsored Phase 1/2 clinical trial of patients with advanced hematologic cancers, which we refer to as the 401-AHC Study. Specifically, an interim analysis of this trial presented at the annual meeting of the American Society of Hematology (ASH) in December 2013 showed that a single cycle of single agent SL-401 induced seven CRs: five CRs in BPDCN and two CRs in relapsed or refractory AML. Although the study was designed so that all patients received only a single cycle of SL-401 treatment, the median OS, relative to historical data, was improved in the 16 most heavily pretreated AML patients who had failed at least two previous therapies (i.e., third-line or greater) and were treated with therapeutically relevant doses, with only a single cycle. 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 has not

resulted in the protracted hematologic toxicity associated with traditional chemotherapy, which we believe is a key differentiating feature relative to other hematologic cancer therapies.

This 401-AHC Study was undertaken in 84 patients with advanced hematologic cancers, including relapsed or refractory AML patients (n=59), AML patients who were poor risk and not candidates for chemotherapy (n=11), high risk MDS patients (n=7), or patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) (n=7, with "n" representing the number of patients). The median patient age was 65 years, with a range of seven to 84 years of age. Patients received a single cycle of single-agent SL-401 of doses ranging from 4.0 to 22.1 µg/kg/day, 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. Participating sites in the 401-AHC Study were MD Anderson Cancer Center (Houston, TX), Duke University (Durham, NC), the Scott and White Cancer Research Institute/Texas A&M (Temple, TX), the University of Texas Southwestern (Dallas, TX), and the British Columbia Cancer Agency (Vancouver, Canada). Results from the 401-AHC Study, which are set forth below, were presented at the annual meetings of the American Society of Clinical Oncology (ASCO) in June 2013 and ASH in December 2013.

Well-tolerated at clinically active doses

SL-401 was well-tolerated at clinically active doses and had a generally acceptable side effect profile relative to other agents used for advanced hematologic cancers. This included largely transient transaminitis, hypoalbuminemia, edema, thrombocytopenia, fever and chills. This is largely similar to that reported with denileukin diftitox (Ontak® Eisai, Inc), a compound comprised of human interleukin-2 linked to a truncated diphtheria toxin payload, which is FDA approved and has been marketed for certain forms of cutaneous T-cell lymphoma for over a decade. Of note, many of the side effects of Ontak® have been reported to decrease with each successive cycle administered. Importantly, however, the anticancer activity of Ontak® appears to be maintained, and even augmented, with each successive cycle. In particular, patients who do not respond to an initial cycle have been shown capable of responding to later cycles, and patients who partially responded to an initial or early cycle have also been shown capable of converting to complete responders in subsequent cycles. Ontak® is approved on a daily-for-five-days schedule for eight cycles.

The maximum tolerated dose, or MTD, of SL-401 was 16.6 µg/kg/day for five consecutive days, with tolerable and active doses at 16.6 µg/kg/day as well as 12.5, 9.4, and 7.1 µg/kg/day.

Anti-tumor activity

In the 401-AHC Study, to date, one cycle of SL-401 has demonstrated robust single agent activity, including a 78% overall response rate, or ORR, including 5 CRs, in 9 evaluable BPDCN patients. Additionally, SL-401 reduced leukemia blast counts in the bone marrow (i.e., reduced tumor bulk) or stabilized disease, in approximately half of all treated patients, the majority of whom were heavily pretreated. More specifically, tumor shrinkages or disease stabilizations were seen in 46% of patients with relapsed or refractory AML, 55% of AML who were poor risk and thus not candidates for chemotherapy, 43% of high-risk MDS patients and 78% of BPDCN patients. There were also multiple additional cases of tumor shrinkages in response to a single cycle of SL-401 treatment. Durable CRs were induced in two patients with relapsed or refractory AML.

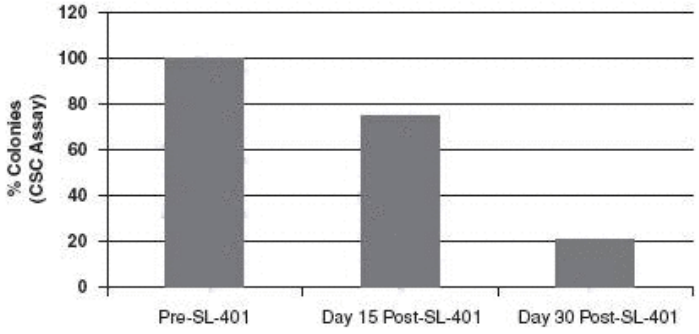
A single cycle of SL-401 administered as a single agent induced major objective anti-tumor responses in 7 of 9 (78%) patients with BPDCN, including 5 CRs and 2 PRs. The median duration of response was 8 months with 2 patients still in remission at 26+ and 16+ months. In addition, a single cycle of SL-401 as a single agent induced durable CRs in advanced AML patients. This included a CR of 25+ months duration in a fourth-line AML patient who had failed three previous treatment regimens, including two treatments with high-dose therapy followed by allogeneic stem cell transplantations, prior to entry into the 401-AHC Study. In addition, a patient with AML that was refractory to standard induction chemotherapy experienced a CR lasting 8 months following treatment with a single cycle of SL-401.

Anti-CSC effect

SL-401 was shown to have potential dual activity not only against tumor bulk (as evidenced by tumor shrinkages and stabilizations) but also against CSCs. Bone marrow samples were collected from three patients both before (day 0) and after SL-401 treatment (day 15 and 30) and were tested for CSC activity in an *ex vivo* colony formation assay (an assay that measures the ability of CSCs to form colonies). As demonstrated by Konopleva in *Blood* in 2010, and as illustrated below, a considerable decrease in CSC activity was noted at 15 and 30 days after patients were treated with SL-401. At 30 days post-treatment, CSC activity decreased by an average of 79% of that measured at pretreatment, suggesting a clinical anti-CSC effect. We believe that these studies also provide 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 notably outlived the historical median OS of heavily pretreated AML patients, with overall survival values of

7.2 months and 13.6 months, respectively. We intend to follow-up on these positive preliminarily provocative data in future clinical trials.

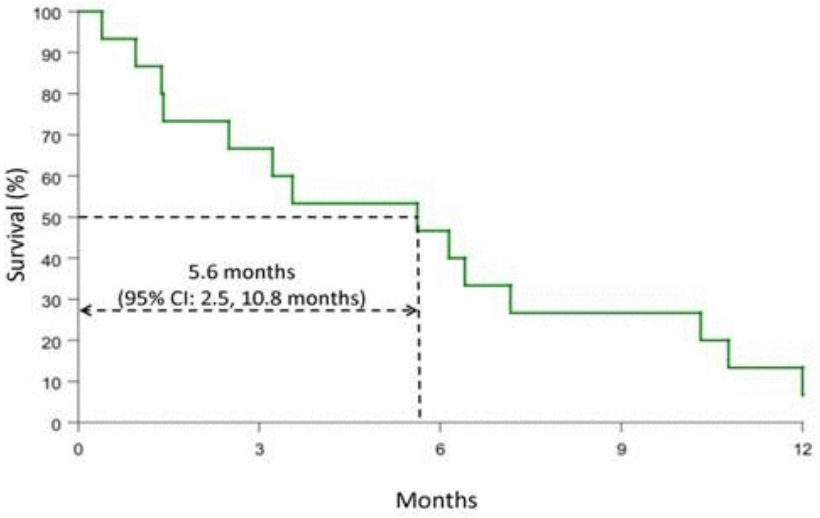
SL-401 demonstrates clinical anti-CSC effect
(adapted from Konopleva et al. Blood 2010; 116:21: Abstract #3298)



Survival signal

In the 401-AHC Study, the median overall survival, or OS was 5.6 months (95% CI: 2.5, 10.8 months) in the 16 most heavily pretreated AML patients treated with therapeutically relevant doses of single cycle SL-401, which is an improvement of several months over historical data reported by Giles et al. in *Cancer* in 2005.

Overall survival signal in AML patients (≥3rd line) treated with only a *single cycle* of SL-401 (at therapeutically relevant doses*; n = 16 patients)
(Konopleva et al. American Society of Hematology 2012 Abstract #3625)



*Patients received the MTD (16.6 µg/kg/d) or one or two doses below the MTD (9.4 and 12.5 µg/kg/d)

Notably, these results derive from the 401-AHC Study wherein only a single cycle regimen of SL-401 was utilized. We believe that a 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 all of our planned clinical trials of SL-401.

Clinical and regulatory strategy for SL-401

Three multicenter clinical trials with SL-401 are currently open in the following indications: 1) blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed/refractory acute myeloid leukemia (AML), which may serve as a registration trial for BPDCN; 2) AML patients in first complete remission (CR) with minimal residual disease (MRD); and 3) four types of advanced high-risk myeloproliferative neoplasms (MPN), including systemic mastocytosis, advanced symptomatic hypereosinophilic disorder, myelofibrosis, and chronic myelomonocytic leukemia. Additional SL-401 studies are currently planned in other indications including myeloma and certain other lymphomas and leukemias.

SL-701

Overview

SL-701 is an enhanced immunotherapy designed to direct the immune system to attack targets present on brain cancer. High-grade gliomas, or HGGs, are the most aggressive brain cancers and have a poor prognosis. Treatment options are limited, particularly for adult patients with recurrent or refractory HGG, including glioblastoma multiforme, or GBM, and pediatric patients with HGG, including brainstem glioma, or BSG, and non-brainstem glioma, indications. In two completed investigator sponsored Phase 1/2 clinical trials, an earlier version of this therapy demonstrated single agent anti-tumor activity, including multiple tumor shrinkages, disease stabilizations, and an overall survival signal. Tumor shrinkage or stabilization was noted in 59% (13/22) of HLA-A2+ (as defined below) adult patients with recurrent or refractory HGG (the 701-Adult-RHGG Study), and 87% (26/30) of HLA-A2+ pediatric glioma patients (the 701-Ped-G Study). To date, there have been eight major objective tumor responses (i.e., tumor regressions) in these two studies, consisting of two CRs and six PRs. An additional tumor shrinkage, in the form of a minor response, or MR, and a

prolonged disease free survival following complete surgical resection (i.e. a clinical complete response, or CCR) were also noted in these studies.

In April 2014, we opened a corporate sponsored IND with the FDA. We have advanced SL-701 into a corporate sponsored trial in adult patients with recurrent GBM, following initial treatment with surgery, radiation, and chemotherapy. We also plan to pursue a trial of SL-701 in pediatric patients with brainstem and non-brainstem high-grade glioma.

In January 2015, SL-701 was awarded Orphan Drug designation from the FDA for the treatment of glioma.

High-grade glioma (including adult glioblastoma and pediatric non-brainstem and 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 WHO classifications, with grade 4 glioma (i.e., glioblastoma, or GBM) and grade 3 glioma (i.e., anaplastic glioma, 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 in adults 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. Bevacizumab (Avastin® Roche AG) received accelerated, but not full, approval for adults with recurrent or refractory adult GBM based, in part, on a response rate endpoint. However, most recurrent patients receiving bevacizumab (Avastin®) do not have durable clinical benefit, and the median OS for these second-line patients is approximately eight to nine months. Currently, no therapies have been approved for GBM patients who fail bevacizumab, which carries a median OS of three to four months.

Pediatric HGG, which includes non-brainstem HGG and brainstem glioma, or BSG, 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 HGG are typically treated with surgery, chemotherapy and/or radiation and have an expected median OS from diagnosis of less than one year.

Design of SL-701 and mechanism of action

SL-701 is an enhanced immunotherapy comprised of several short synthetic peptides that correspond to epitopes of targets including IL-13Rα2, EphA2, and survivin, present on the tumor bulk and/or CSCs of brain cancer. The synthetic peptides that correspond to IL-13Rα2 and survivin are novel artificially constructed mutants designed to be immunogenic to amplify the clinical anti-tumor immune response.

SL-701 is combined with additional elements designed to promote an immune response, such as 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 administered to the patient concurrently with SL-701 administration. Whereas the previous studies have used poly-ICLC as an adjuvant, we are using granulocyte macrophage-colony-stimulating factor or GM-CSF, and imiquimod, a toll-like receptor 7, or TLR7, agonist, which we believe are commercially viable and state-of-the-art adjuvants.

Phase 1/2 clinical trial—adult recurrent or refractory high-grade glioma

In an investigator sponsored Phase 1/2 clinical trial, an earlier version of this therapy was evaluated in adult patients with recurrent or refractory HGG. This study, which we refer to as 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 bevacizumab (Avastin®). The therapy was loaded *ex vivo* onto dendritic cells that had been removed from the patient, 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 and 701-Adult-LGG Study, in which the therapy was administered to patients and demonstrated activity as a direct subcutaneous injection. The 701-Adult-RHGG Study was a single-arm trial whose objectives were to determine the general safety, dosage and efficacy.

Well-tolerated at clinically active doses

The therapy was well-tolerated at clinically active doses in the 701-Adult-RHGG Study. 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 bevacizumab (Avastin®), which are mainstay therapies used to treat adult HGG. We believe this implies that the development of SL-701-based combination regimens may be feasible.

Clinical activity

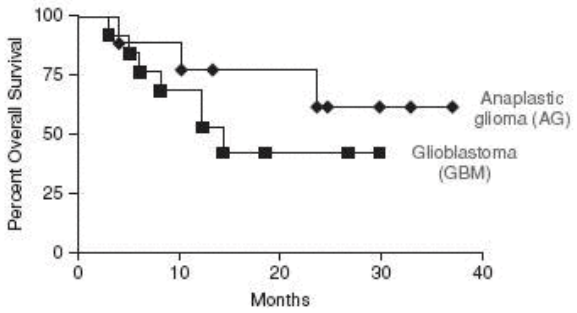
In the 701-Adult-RHGG Study, the therapy demonstrated single agent clinical activity. Forty-six percent (6/13) of refractory or recurrent GBM and 78% (7/9) of recurrent AG patients sustained an anti-tumor response or disease stabilization. This included two durable CRs, one of which occurred in a 62-year-old male GBM patient who was refractory to prior surgical resection, radiation therapy and temozolomide. Following treatment, this patient's gadolinium enhanced tumor mass disappeared, and the patient was determined to have sustained a durable CR that exceeded 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 the therapy. A recurrent AG patient with anaplastic oligoastrocytoma sustained a CR that exceeded 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-therapy brain biopsy from this PR patient demonstrated the presence of macrophages and CD8+ T lymphocytes, which are cells of the immune system, within the tumor. We believe this indicates that the therapy 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. This activity is consistent with the proposed mechanism of action of the therapy wherein it induces the immune system, and cytotoxic T cell in particular, to cross the blood-brain barrier and attack the antigen expressing tumor. A second PR was sustained by a patient with recurrent GBM whose PR exceeded 11 months in duration. The third PR was seen in a recurrent AG patient.

Eighty-one percent (13/16) of evaluable patients had at least one positive immunological assay. We believe this indicates that the therapy stimulated the immune system in a highly specific fashion.

Survival signal

The therapy 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 the therapy, 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 the therapy also experienced an improvement in OS compared with historical results.

Kaplan-Meier survival curve
of recurrent or refractory adult HGG patients treated with an earlier version of SL-701
(Okada et al., Journal of Clinical Oncology 2011; 29:330-336)



Phase 1/2 clinical trial—pediatric glioma

In a completed investigator sponsored Phase 1/2 trial, the therapy was evaluated in pediatric patients with glioma. This study, which we refer to as the 701-Ped-G-Study, was undertaken in 30 HLA-A2+ pediatric patients with glioma. Twenty of these patients had newly diagnosed brainstem glioma, or BSG, four had newly diagnosed non-brainstem HGG, three had recurrent non-brainstem HGG and three had multiply recurrent low-grade glioma, or LGG. Patients received a direct subcutaneous injection of the therapy (without dendritic cells) in the right or left upper arms associated with intact draining auxiliary lymph nodes once every three weeks with a separate concurrent injection of an adjuvant. This 701-Ped-G Study was a single-arm trial whose objectives were to determine the general safety, dosage and efficacy.

Well-tolerated at clinically active doses

The therapy was well-tolerated at clinically active doses in this 701-Ped-G Study. Adverse effects included local injection site reactions and low grade fever in almost all patients, which were generally mild and controlled with analgesics.

Clinical activity

In this 701-Ped-G Study, the therapy demonstrated single agent clinical activity. Eighty seven percent (26/30) of evaluable patients sustained durable tumor reductions or disease stabilizations, including three patients who experienced durable PRs. One of these PR patients is a child with newly diagnosed BSG whose PR demonstrated greater than 50% tumor shrinkage and was 15 months in duration. The second PR occurred in a child with newly diagnosed non-brainstem HGG and was 14 months in duration. The third PR occurred in a child with multiply recurrent LGG and was nine months in duration. Also, a MR was induced in a pediatric patient with non-brainstem HGG. An additional child with newly diagnosed non-brainstem HGG had prolonged disease-free status of 20 months following surgery. In addition, there were four stable disease patients who survived at least 13 months.

In five 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 lasted 15 months is believed to have experienced tumor pseudoprogression prior to the PR**.**

Positive immunological assays (both ELISPOT and tetramer assays) were demonstrated in six of seven evaluable children, including the newly diagnosed BSG pediatric patient who sustained a durable PR that lasted 15 months. We believe that these data indicate that the therapy stimulated the immune system in a highly specific fashion.

Low-grade glioma trial in adult patients

An investigator sponsored study of the therapy was also conducted in adult patients with LGG, which we refer to as the 701-Adult-LGG Study. Twenty-three HLA-A2+ patients have been enrolled, including twelve with newly diagnosed high-risk LGG without prior radiotherapy, one with newly diagnosed high-risk LGG with prior radiotherapy and ten with recurrent LGG. Patients were treated with the therapy via direct subcutaneous injection every three weeks. The therapy was well-tolerated and demonstrated immune responses in high-risk adult patients with LGG. Side effects were minimal with one grade 3 fever. Sustained and specific immune responses, as assessed by ELISPOT assays, were observed in the majority of evaluable patients. A positive correlation between immune response and progression-free survival, or PFS, was noted. Although a thorough evaluation of PFS requires a longer observation period, among 17 patients who completed eight courses, 10 had stable disease.

Clinical and regulatory strategy for SL-701

We have advanced SL-701 into a corporate sponsored trial in adult patients with recurrent GBM, following initial treatment with surgery, radiation, and chemotherapy. We also plan to pursue a trial of SL-701 in pediatric patients with brainstem and non-brainstem HGG.

SL-801

SL-801 is a structurally novel, oral, small molecule that reversibly inhibits XPO1 (Exportin-1), also known as CRM-1 (Chromosome Region Maintenance-1), a nuclear transport protein. XPO1 has been shown to regulate nuclear export of many of the major tumor suppressor proteins and oncogenic cell growth regulators. Overexpression of XPO1 is common in many cancers and is associated with aggressive tumor behavior and poor patient prognosis. Inhibition of XPO1 has been shown to restore tumor suppressor function and proper cell cycle regulation, leading to apoptosis of cancer cells. XPO1 has also been shown to be a clinically validated target in both solid and hematological cancers.

SL-801 has demonstrated broad and potent preclinical activity in a wide array of solid and hematologic tumors in both in vitro and in vivo xenograft experiments. In contrast to the XPO1 inhibitor leptomycin B, which binds irreversibly to XPO1 and caused significant toxicities in Phase 1 trials, SL-801 binding to XPO1 is reversible. SL-801's ability to reversibly bind XPO1 offers the potential to develop flexible dosing schedules that could enable recovery in normal tissues, mitigate side effects, broaden the therapeutic index, and enhance efficacy.

We are conducting IND-enabling work to support entry into clinical trials. We then plan to advance SL-801 into corporate sponsored Phase 1 disease-directed, proof-of-concept trials in both solid and hematologic cancers.

SL-501

SL-501 is a rationally designed, next-generation IL-3R-targeted therapeutic. SL-501 is a variant of SL-401 that binds to the IL-3R with higher affinity and demonstrates enhanced cytotoxicity against hematologic cancer cells in both in vitro and in vivo xenograft experiments, including in AML and CML. In addition, SL-501 possesses preclinical anti-tumor activity against Hodgkin's and non-Hodgkin's lymphoma. SL-501 is currently progressing through IND-enabling studies. Further, we may choose to evaluate the utility of SL-501 in various autoimmune diseases, in which the IL-3R-expressing plasmacytoid dendritic cell (the precursor cell of BPDCN) plays a putative role, such as systemic lupus erythematosus, systemic sclerosis (scleroderma), psoriasis, and rheumatoid arthritis.

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 18 issued patents and 35 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 include issued U.S. Patents 8,470,307 and 7,763,242 covering methods of treating AML and MDS that both expire in 2027, as well as three issued foreign patents. There are additional pending U.S. applications directed to methods of using SL-401 to treat other diseases that, if issued, would also expire in 2027. In addition, we have filed foreign patent applications for the method of using SL- 401 to treat various diseases, although there can be no assurances that such patents will be issued. In addition to patent protection, we also have the exclusivity afforded by the FDA's orphan designation of SL-401 for the treatment of both AML and BPDCN 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-13Rα2 mutant, a non-exclusive worldwide license to SL-701 component, EphA2, and have filed a PCT patent application to SL-701 component, survivin mutant. This intellectual property consists of an issued U.S. composition of matter patent (U.S. Patent 7,612,162) directed to an immunogenic mutant IL-13Rα2 peptide expiring in 2026, issued U.S. method of use patents (U.S. Patents 7,297,337 and 8,114,407) directed to the use of EphA2 peptide expiring in 2024 and 2025, issued U.S. method of use patent (U.S. Patent 8,850,488) directed to the combined use of IL-13Rα2 mutant and EphA2 peptides expiring in 2026, and a pending PCT patent application directed to the use of an immunogenic mutant survivin peptide which, to the extent it issues, would be expected to expire in 2033. We also have additional pending patent applications directed to methods of using SL-701 components to treat certain diseases which if issued, for which there can be no guarantee, would provide additional protection in the United States and certain non-U.S. territories and would expire in 2024, 2025, or 2033. In addition to patent protection, we also have the exclusivity afforded by the FDA's orphan designation of SL-701 for the treatment of glioma 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 (with the exception of Japan, Korea, Taiwan, and China) to SL-801. These patent rights include issued U.S. Patents 8,084,454 and U.S. Patent 8,415,357 covering composition of matter and uses of SL-801 that expire in 2030 and 2028, respectively. We also have additional pending patent applications directed to SL-801 which if issued, for which there can be no guarantee, would provide additional protection in certain non-U.S. territories and would expire in 2028.

We also in-licensed or own certain patent rights, which includes issued patents and pending patent applications in the U.S. and abroad, to our other preclinical assets.

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;

- Seven issued patents that cover methods to treat cancer through use of monoclonal antibodies and other antibody-based compounds directed to nine specific key targets: Frizzled, Glypican-3, Tie-1, CD133, Smoothened, Patched, CD44, ESA, and 67LR. These U.S. Patents are: 7,361,336; 7,427,400; 7,504,103; 7,608,259; 8,715,945; 8,846,325; and 8,784,772. Patent protection extends from 2017, 2019, or 2032, 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-

3Rα as well as composition of matter covering IL-3Rα-targeted antibody conjugates, including U.S. Patent 7,651,678; U.S. Patent 6,733,743; U.S. Patent 8,163,279; U.S. Patent 8,852,551; allowed U.S. Patent application 13/439,453; and other pending applications. Patent protection, to the extent it has or may issue, 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 assess 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 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 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 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 may 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 face patent litigation by the third-party. 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 and/or face a significant monetary damages award. This could have a material adverse effect 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 (Temple, Texas) for SL-401, our biologic targeted therapy directed to the 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 range from the low- to mid-single digits and are 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, 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, the agreement provides for Scott and White to conduct a research program with SL-401. In March 2010, the agreement was amended to further the regulatory advancement of SL-401. We have made certain payments to Scott and White for such research services pursuant to the agreement, which to date total approximately $1.0 million in the aggregate. Additionally, we have been granted the exclusive right of reference to its IND for our own regulatory filings. 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-13Rα2 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-13Rα2, an active ingredient of SL-701, our brain cancer immunotherapy 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 immunotherapies (including SL-701, which has been developed by the University under a separate immunotherapy 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. To date, we have paid an aggregate of approximately $0.6 million in fees to the University under the agreement. We must also pay the University a low-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 $4.2 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-13Rα2 peptide, as well as other immunotherapies 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-13Rα2 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. To date, we have paid an aggregate of approximately $45,000 in fees to the University under the agreement. We must also pay the University a customary low-single digit royalty for the 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 and reference 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-13Rα2 peptide license agreement with the University.

We paid the University an initial license fee, as well as payments following a regulatory milestone. To date, we have paid an aggregate of approximately $27,500 in fees to the University under the agreement. 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-13Rα2 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 of up to an aggregate of $1.7 million upon specified regulatory events, as well as pay royalties of less than 1% 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.

CanBas, Ltd

License for SL-801

On December 26, 2014, we entered into a license agreement with CanBas, Ltd. for SL-801. SL-801 is a small molecule, reversible inhibitor of XPO1. Under the terms of the agreement, CanBas has granted us an exclusive, royalty-bearing, worldwide (excluding Japan, Korea, China and Taiwan) license, under certain patent rights, know-how and materials to research, develop, make, have made, formulate, use, sell, offer to sell and import SL-801, and any products containing or comprising such compound in finished dosage pharmaceutical form, for the treatment of any disease or condition in humans. The patent rights exclusively licensed to us under the agreement are described in more detail above under "Patents and Proprietary Rights Covering CSC-Focused Intellectual Property."

We are responsible to pay annual technical advisory fees over the next four years totaling 430 million Japanese Yen (JPY), if the clinical development continues over this time period. Additionally, we must pay CanBas tiered royalties based on aggregate net sales, by us or our sublicensees, of products containing the licensed compound until the latest date of a period of ten years following the first commercial sale of each product in each country; the date upon which there are no more valid claims or the expiration or termination of the last regulatory exclusivity period. The royalty rates start in the low single digits and are tiered up based on annual net sales. In the future, we may also be responsible, based on the achievement of specific clinical-development, regulatory and sales-based commercial milestones, for certain payments to CanBas of up to $86 million. We have sublicensing rights under the agreement, subject to our paying to CanBas a standard royalty percentage of the 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.

The agreement survives until the later of ten years following the first commercial sale of each product in each country; the date upon which there are no more valid claims; or the expiration or termination of the last regulatory exclusivity period, after which our license becomes fully paid, irrevocable, perpetual, non-exclusive and royalty-free. We may terminate the license for any or no reason upon 60 days advance written notice to CanBas. If either we or CanBas 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.

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 Verastem, Inc., OncoMed Pharmaceuticals, Inc., Dainippon Sumitomo Pharma Co. Ltd., Bionomics Limited and Stem CentRx, Inc. There are also several biopharmaceutical companies that do not appear to be primarily focused on CSCs, but may be developing at least one CSC-directed compound. These companies include Astellas Pharma US, Inc., Boehringer Ingelheim GmbH, Geron Corp.,

GlaxoSmithKline plc, Macrogenics Inc., Micromet, Inc. (an Amgen, Inc. Company), Pfizer Inc., Roche Holding AG, Sanofi U.S. LLC, and others. Additionally, there are a number of companies working to develop new treatments for hematologic cancers, which may compete with SL-401, including Ambit Biosciences Corporation (now a Daiichi Sankyo company), Astex Pharmaceuticals (now an Otsuka Pharmaceutical company), Celator Pharmaceuticals, Inc., Celgene Corporation, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Genzyme Corporation (now a Sanofi company), CSL Limited and Sunesis Pharmaceuticals, Inc., Janssen Pharmaceutical Companies of Johnson and Johnson, 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 Agenus Inc., Bristol-Myers Squibb, Inc., Cortice Biosciences, Inc., Celldex Therapeutics, Inc., CytRx Corporation, GenSpera, Inc., GlaxoSmithKline plc., ImmunoCellular Therapeutics, Ltd., Northwest Biotherapeutics, Inc., Novartis AG, Roche Holding AG and others.

Many of our competitors 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 number of companies working to develop new treatments for AML and other hematologic cancers, including Agios, Inc., Ambit Biosciences Corporation (now a Daiichi Sankyo company), Astex Pharmaceuticals (now an Otsuka Pharmaceutical company), Boehringer Ingelheim, Celator Pharmaceuticals, Inc., Celgene Corporation, Cyclacel Pharmaceuticals, Inc., Eisai Co. Ltd., Epizyme, Inc., Genzyme Corporation (now a Sanofi company), CSL Limited and Sunesis Pharmaceuticals, Inc., Janssen Pharmaceutical Companies of Johnson and Johnson, among others.

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 Agenus Inc., Bristol-Myers Squibb, Inc., Cortice Biosciences, Inc., Celldex Therapeutics, Inc., CytRx Corporation, GenSpera, Inc., GlaxoSmithKline plc., ImmunoCellular Therapeutics, Ltd., Northwest Biotherapeutics, Inc., Novartis AG, Roche Holding AG and others.

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, approval, manufacture, testing, quality control, packaging, labeling, 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 or 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 a clinical hold, refusal to approve pending applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil or criminal penalties, or withdrawal of an approval. Any administrative action 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:

- 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 FDA must clear before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current Good Clinical Practices, or GCPs, and in accordance with human subject protection regulations, 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 pre-approval 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 regulations, or cGMPs, 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 inspection 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 and successful resolution of any questions that arise in the review process.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations post-approval 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; often these are 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, regulations for the protection of human subjects and with applicable cGMP 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 trial recruitment materials and the informed consent form that must be used as part of the informed consent process with 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.

- *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.

- *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. In addition, companies must develop and validate analytical methods for testing the identity, strength, quality and purity of raw materials, in-process material and 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 drug or biologic, proposed packaging and 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 BLAs 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, that covers a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration 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. PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted unless FDA were to issue a regulation to require pediatric assessments.

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 established a performance goal of ten months in which to complete its initial review of a standard NDA or BLA and respond to the applicant, and a performance goal of 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.

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 in the disease area, 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. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies, or REMS, approved by the FDA. The FDA's exercise of this authority can result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products. During the approval process, the FDA will determine whether a REMS is necessary to assure the safe use of the drug or biologic post-approval. 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. Also, in this inspection, FDA seeks to determine whether the manufacturing conforms with application commitments, the authenticity and accuracy of data, and the adequacy of the company's analytical methodology. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with current good clinical practices, or cGCPs. If the FDA determines the application, data, 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 the agency requires 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. In addition, protocol deviations or data discrepancies 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 for the same indication 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 June 2013, SL-401 was awarded Orphan Drug Designation from the FDA for the treatment of BPDCN. Previously, in February 2011, we received Orphan Drug Designation for SL-401 for the treatment of AML. In addition, we received Orphan Drug Designation for SL-701 for the treatment of glioma in January 2015.

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 drug product alone or in combination with one or more other drugs for the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider reviewing sections of the NDA or BLA on a rolling basis before the complete application is submitted. In addition, the sponsor and FDA would agree on a schedule for the submission of the sections of the NDA or BLA. If the FDA agrees to a rolling review of a NDA or BLA, and determines that the schedule is acceptable, 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 with the goal of taking Agency action on a marketing application within 6 months.

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 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, cGMP compliance, record-keeping requirements, reporting of nonconforming distributed products which would require field alert reports (FARs) for NDAs and biological product deviation reports (BPDRs) for BLAs, reporting of adverse events, 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 promotion"), rules for conducting industry-sponsored scientific and educational activities, limitations on comparative or superiority claims and promotional activities involving data presentations. Failure to comply with FDA requirements can have negative consequences, including for cause inspections; warning or untitled letters from the FDA, including demands for correction or removal of noncomplying product; adverse publicity; 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. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract, supplier qualification and periodic audits, but unforeseen circumstances could affect our third-party manufacturers' compliance with applicable regulations and standards. 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 penalties for failure to comply with the terms of the consent decree, audits conducted by outside experts, extensive reporting requirements, and possible withdrawal of the product from the market. Historically, the minimum term of an FDA consent decree has been five years, and violation of consent decree terms results in the extension of the consent decree term.

Major changes to the manufacturing process and other types of major changes, such as adding new indications, require prior FDA approval before being implemented. Moderate and minor changes require FDA notification but not prior 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.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, among other things, renewed the drug user fee program, expanded the FDA's inspection records access and required manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance. On November 27, 2013, the Drug Quality and Security Act, which included the Drug Supply Chain Security Act, was enacted to, among other things, build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Requirements for the tracing of products through the pharmaceutical distribution supply chain took effect on January 1, 2015 for manufacturers and building internal systems to ensure compliance with this law will require dedication of resources. In addition, this law requires engaging in transactions only with authorized trading partners and can limit the pool of available trading partners.

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 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 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 the FY2014 budget proposal President

Obama submitted to Congress in 2013, the Administration requested that reference product exclusivity would decrease from 12 to seven years beginning in 2013. 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 be finalized or what changes the agency may make in its approach to implementation of the BPCIA.

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, if a reference product has been designated for a rare disease or condition the licensure of a biosimilar or interchangeable version of a reference product for such disease or condition 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 a final court decision or dismissal of a patent challenge or, if the applicant has not been sued, after approval. The BPCIA does not prevent a competitor from conducting its own clinical trials and submitting a full BLA on the same or similar product.

There is also currently substantial uncertainty as to how certain terms of the BPCIA will be interpreted by the Courts, which may affect the timing of the entry of a biosimilar or interchangeable product to market, and the required notice that the owner of the reference product exclusivity must be given by the owner of the application of a biosimilar or interchangeable product. Should the courts resolve the interpretation issues in favor of the biosimilar or interchangeable product applicants, the BPCIA may offer more limited exclusivity to the reference product than currently believed.

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, or CMS (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 and the Office of Civil Rights), 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 federal Antikickback Statute, the federal 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, the Veterans Health Care Act of 1992, and the federal Antikickback Statute, each as amended. If products are made available to authorized users of the Federal Supply Schedule (FSS) 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 four federal agencies including the United States Department of Veterans Affairs, the United States Department of Defense, the Coast Guard, the Public Health Service and certain private Public Health Service designated entities (including the Indian Health Service) in order for reimbursement to be available for our product under Medicare and Medicaid. FSS pricing to these four agencies must be equal to or less than the federal ceiling price ("FCP"), which is, at a minimum, 24% off the Non-Federal Average Manufacturer Price for the prior fiscal year. 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. In addition, in August 2013, the federal Physician Payment Sunshine Act took effect and requires annual reporting by prescription drug manufacturers of certain payments and transfers of value made to physicians and teaching hospitals. Post-approval of any of our product candidates, we will need to ensure compliance with annual tracking and reporting of these payments and transfers of value to CMS.

Europe and Worldwide 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 healthcare 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 healthcare 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. For past investigator sponsored studies, all drug substance and drug product for SL-401 and SL-701 was manufactured at academic and contract manufacturing organizations, or CMO, facilities, as directed by our academic collaborators. We have now developed manufacturing processes that are suitable for full-scale cGMP manufacturing. Additionally, we have qualified FDA-audited third-party CMOs to produce sufficient quantities of SL-401 and SL-701 drug substance and drug product of suitable quality for our contemplated corporate sponsored clinical trials and potential commercialization. Our manufacturing programs are being managed

with oversight by our manufacturing team, which is comprised of full-time employees and consultants with experience in manufacturing pharmaceutical drug substance and drug products.

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. For past investigator sponsored studies, SL-401 was manufactured at Wake Forest University. We have optimized the protein expression, generated cGMP master and working cell banks, and developed the fermentation and purification steps of our manufacturing process to be suitable for scale-up in standard manufacturing equipment. This technology has been transferred to a third-party CMO with expertise in bacterial fermentation, which has further optimized and scaled-up the process in their cGMP production suite. The SL-401 drug substance has now met standard industry quality specifications and is adequate to support our planned corporate sponsored clinical trials. The drug product formulation and manufacturing process has been transferred to a third-party CMO with expertise in sterile product manufacture for clinical and commercial supply, and they have successfully produced drug product meeting all cGMP requirements for use in clinical studies.

SL-701 Manufacturing and Supply

SL-701 is an immunotherapy that is comprised of several short synthetic peptides. Each of the component peptides of SL-701 is manufactured individually by solid-phase synthesis and all have been prepared to acceptable quality specifications in cGMP manufacturing equipment by our third-party CMO. The manufacturing scale and product quality is adequate to supply our planned corporate sponsored clinical studies. We have also developed a stable formulation that combines the individual peptides in a single sterile solution to generate SL-701 drug product. This manufacturing process was transferred to a third-party CMO with expertise in sterile product manufacture. This CMO has produced multiple cGMP drug product batches of sufficient quality and quantity to supply our corporate sponsored clinical trials.

Sales and Marketing

We believe that the infrastructure required to commercialize oncology products is relatively limited, which may make 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 potentially 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 to prepare for the commercial launch of an approved product, including preparation of marketing and sales training materials in compliance with legal and regulatory requirements.

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

Research and Development

Company sponsored research and development expenses totaled $21.2 million in 2014, $16.2 million in 2013 and $3.4 million in 2012. “Research and development expenses” consist of costs associated with the development of our product candidates and our platform technology, which include: clinical trial costs, CMC-related costs, nonclinical costs, employee related expenses, external research and development expenses, license fees and milestone payments related to in-licensed products and technology, and facilities, depreciation and other allocated expenses. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview.”

Employees

As of March 12, 2015, we had 22 full-time employees, 6 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.

Item 1A. Risk Factors

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

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

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

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

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

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

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

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

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

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

- delays or failure reaching agreement on acceptable terms with prospective contract manufacturing organizations, or CMOs, contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly depending on the circumstances;

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

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

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

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

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

many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

We may not be able to continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. SL-401 and SL-701 are being developed in hematologic and brain cancers, respectively, both of which are orphan indications (i.e., rare diseases). SL-401 is being developed initially in BPDCN and other rare diseases, including certain myeloproliferative disorders, as well as AML, and SL-701 is being developed in adult and pediatric brain cancer. Some of these represent orphan indications for which there are very limited independently reported data on annual incidences. If the incidences of these diseases are very low, including lower than our estimates or estimates of our third-party contractors, this could significantly delay patient enrollment in any one or more of our ongoing or future clinical trials.

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, conduct, or findings of our clinical trials;

- the FDA may identify protocol deviations or data quality or integrity concerns with our preclinical or clinical trials;

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

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

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

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

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

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

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

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

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

Although we expect to focus a substantial amount of our efforts on the continued clinical testing and potential approval of SL-401 and SL-701, another key element of our strategy is to identify and test additional compounds that target CSCs in a variety of different types of cancer, including SL-501, SL-801, and SL-101. A portion of the research that we are conducting involves new and unproven drug discovery methods, including our proprietary StemScreen platform technology, as well as the testing of new compounds and potential new uses of existing compounds. The drug discovery that we are conducting using our StemScreen platform technology may not be successful in identifying compounds that are useful in treating humans with cancer. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

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

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

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

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

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

Risks Related to Our Financial Position and Capital Requirements

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

We have incurred net losses from operations from our inception through December 31, 2014, of approximately $72.4 million. We do not know whether or when we will become profitable. To date, we have not commercialized any products or generated any revenues from product sales. Our losses have resulted principally from costs incurred in development and discovery activities. We anticipate

that our operating losses will substantially increase over the next several years as we execute our plan to expand our discovery, research, development and potential commercialization activities. We believe that our existing cash, cash equivalents, short-term investments and long-term investments including the cash proceeds received from our Secondary Offering during the first quarter of 2015, will be sufficient to fund our operations and our capital expenditures for at least the next two years. If our cash is insufficient to meet future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third-parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all. In addition, if we do not continue to meet our diligence obligations under our license agreements for our product candidates that we have in-licensed, including SL-401 and SL-701, we will lose our rights to develop and commercialize those product candidates.

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

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

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

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

Our future capital requirements depend on many factors, including:

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

- the timing, receipt and amount of sales of, or royalties on, our future products, if any;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

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

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

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

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

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

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

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

Risks Related to Our Business and Industry

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

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

- execute product candidate development activities;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- maintain, defend, leverage and expand our intellectual property portfolio;
- build and maintain sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners should our products obtain market approval;

- gain market acceptance for our products should they obtain market approval;
- develop and maintain GMP compliant manufacturing and distribution capabilities sufficient to support the intended scope of our pre-clinical and clinical development plans and the potential commercial demand for our product(s);
- develop and maintain any strategic relationships we elect to enter into;
- satisfy our obligations under our license and other agreements; and
- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals, manufacturing and commercialization.

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

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

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

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

Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. In addition, many are farther along in their clinical development programs. We may not be able to compete unless we successfully:

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

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

compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management as well as other employees, consultants and scientific and medical collaborators. As of March 12, 2015, we had 22 full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. Although none of these individuals has informed us to date that he or she intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, completion of our ongoing and future clinical trials or the commercialization of our product candidates.

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

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

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

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

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

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

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, clinical study, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot

successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by healthcare providers, health plans and healthcare clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;

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

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

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

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

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that SL-401 or SL-701 will be approved. For

product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

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

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

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

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

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

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

- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the statute in 2012. A new challenge to the law is currently under review by the Supreme Court with a decision expected in June 2015 that, depending on an outcome we cannot anticipate, could jeopardize access to coverage subsidies to consumers in as many as 34 states and force other changes to the law by a new and expanded majority of Republican ACA opponents in both houses of Congress that came to power in January 2015. Proposals to expand the Medicaid drug rebate program to the Medicare Part D program (or to provide authority for the government to negotiate drug prices under the Medicare Part D program) are likely to be presented to Congress in 2015 by the current Administration, but are unlikely to be implemented by the new Republican Congress. In general, we cannot predict the impact that the ACA or any other legislative or regulatory proposals will have on our business. Regardless of whether or not the ACA is changed or modified by Congress or the Supreme Court, we expect both government and private health plans to continue to require healthcare providers, including healthcare providers that may one day purchase our products, to contain costs and demonstrate the value of the therapies they provide.

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

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

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

Risks Related to Our Dependence on Third-Parties

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

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

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

In April 2014 we opened a corporate sponsored IND with the FDA and have initiated a corporate sponsored clinical trial with SL-701 in adult patients with second-line glioblastoma multiforme, or GBM. In July 2014 we opened a corporate sponsored IND with the FDA and have initiated a corporate sponsored clinical trial with SL-401 in patients with blastic plasmacytoid dendritic cell neoplasm, or BPDCN, and relapsed or refractory acute myeloid leukemia, or AML. In October 2014 we opened an additional corporate-sponsored clinical trial with SL-401 in patients with AML in first complete remission, or CR, following initial therapy with minimal residual disease, or MRD, in their bone marrow and are at high risk of relapse.

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.

Prior to 2014, we relied on academic institutions, CROs, hospitals, clinics and other third-party collaborators who are outside our control to monitor, support, conduct and/or oversee preclinical and clinical studies of our product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we had conducted these trials wholly by ourselves. In our ongoing corporate sponsored trials of SL-401 and SL-701, we have continued to engage various third-parties. If we are unable to maintain or enter into agreements with these third-parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third-parties will devote adequate time and resources to our studies or perform as required by contract or in accordance with regulatory requirements. If these third-parties fail to meet expected deadlines, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended, delayed or terminated, and as a result we may not be able to commercialize our product candidates.

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

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

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

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

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

We do not currently own or operate any manufacturing facilities, and we lack sufficient internal staff and infrastructure to produce clinical and preclinical product candidate supplies ourselves. As a result, we work with third-party contract manufacturing organizations, or CMOs, to produce SL-401 and SL-701 in acceptable quality and quantity for our ongoing and future clinical trials. If we are unable to maintain such third-party manufacturing sources, or fail to do so on commercially reasonable terms or on a timely basis, we may not be able to successfully produce, develop, and market SL-401 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, possibly including SL-101, SL-801 and SL-501. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms or on a timely basis, we may not be able to complete development of such other product candidates or market them.

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

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

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

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

The manufacturers of our product candidates require specialized equipment and utilize complicated production processes that would be difficult, time consuming and costly to duplicate. For each of our product candidates we currently rely on third-party manufacturers to purchase from their third-party vendors the materials necessary to manufacture our product candidates for our clinical studies. Any prolonged disruption in our third-party manufacturers vendor's ability to supply materials for our manufacturing could have a significant negative impact on our ability to manufacture products on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs and timelines and any commercialization costs. In addition, our third-party manufacturers may experience problems not related to their vendors that could also have a significant negative impact on our ability to manufacture products on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs and timelines and any commercialization costs. We may face losses related to the supply of drug

substances, drug product, adjuvants and other components of the product due to third-party distribution and storage of such product. We may suffer losses due to third-party manufacturer shortages or supply shortages of their vendors. We may suffer losses as a result of business interruptions that exceed coverage under our manufacturer's insurance policies. Events beyond our control, such as natural disasters, fire, sabotage or business accidents could have a significant negative impact on our operations by disrupting our product candidate development and commercialization efforts until our third-party manufacturer can repair its facility or we can put in place alternate third-party contract manufacturers to assume this manufacturing role, which we may not be able to do on reasonable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that they can successfully transfer our manufacturing processes to produce product of equivalent quality and quantity. FDA approval of the new manufacturer may also be required. The delays associated with the verification of a new manufacturer or the reverification of an existing manufacturer could negatively affect our ability to develop product candidates or produce approved products in a timely manner. Any delay or interruption in our clinical studies or in the development, validation and commercialization of our product candidates could negatively affect our business**.**

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

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

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

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

Risks Related to Our Intellectual Property Rights

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

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

Our patents and patent applications may not be sufficient to protect our products and product candidates from commercial competition. For example, we cannot obtain a composition of matter patent for SL-401 due to earlier published prior art. We have however obtained U.S. patents for certain methods of using SL-401 to treat AML and MDS. In addition, we have filed additional U.S. and foreign patent applications for the method of using SL-401 to treat AML, MDS, BPDCN, and other diseases although there can be no assurances that such patents will issue. Failure to obtain patents directed to all approved uses of SL-401 would enable a competitor to market SL-401 for such unpatented indication(s), which could lead to price erosion for sales of SL-401 for our patented indications through off-label use. With respect to SL-701, although we have licensed an issued U.S. patent directed to the composition of matter

for the mutant immunogenic IL-13Rα2 peptide, we do not have any foreign composition of matter patent protection. We do not expect that we will be able to obtain such protection outside the U.S. in the future although we do have foreign pending patent applications that seek to cover certain uses of this peptide. While we have a non-exclusive license to issued U.S. patents directed to methods of use for the EphA2 peptide, we do not have any composition of matter patent protection although we do have rights to foreign pending patent applications that seek to cover certain uses of this peptide. While we have filed patent applications directed to methods of use of a new survivin mutant peptide for use in SL-701, we do not have any composition of matter patent protection. While we have patent applications pending in the United States and Canada directed to our StemScreen technology, we currently have no issued patents covering StemScreen.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

The market price of our common stock may be highly volatile, and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in January 2013, the price of our common stock has ranged from $10.00 per share to $47.25 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

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

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

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

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

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

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

- our ability to maintain the license agreements for SL-401, SL-701 and other in-licensed product candidates;

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

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

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

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

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

- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

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

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

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

Our executive officers, directors and principal stockholders beneficially own shares representing approximately 31% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert substantial influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would exert substantial influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our Company on terms that other stockholders may desire.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call special stockholder meetings and the matters transacted at such meetings;

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate and executive office is located in New York, New York. Our New York facility consists of subleased space at 750 Lexington Avenue, Eleventh Floor, New York, New York 10022.

Item 3. Legal Proceedings

We are not a party to, and our property is not the subject of, any material pending legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol "STML" and has been publicly traded since January 31, 2013. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low closing sales prices for our common stock as reported on the NASDAQ Capital Market for the periods indicated.

Fiscal Year Ended December 31, 2014	High	Low
First Quarter	$ 31.48	$ 18.04
Second Quarter	21.28	12.10
Third Quarter	15.87	10.50
Fourth Quarter	17.69	11.00

Holders

The number of record holders of our common stock as of March 13, 2015, was 94. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2014.

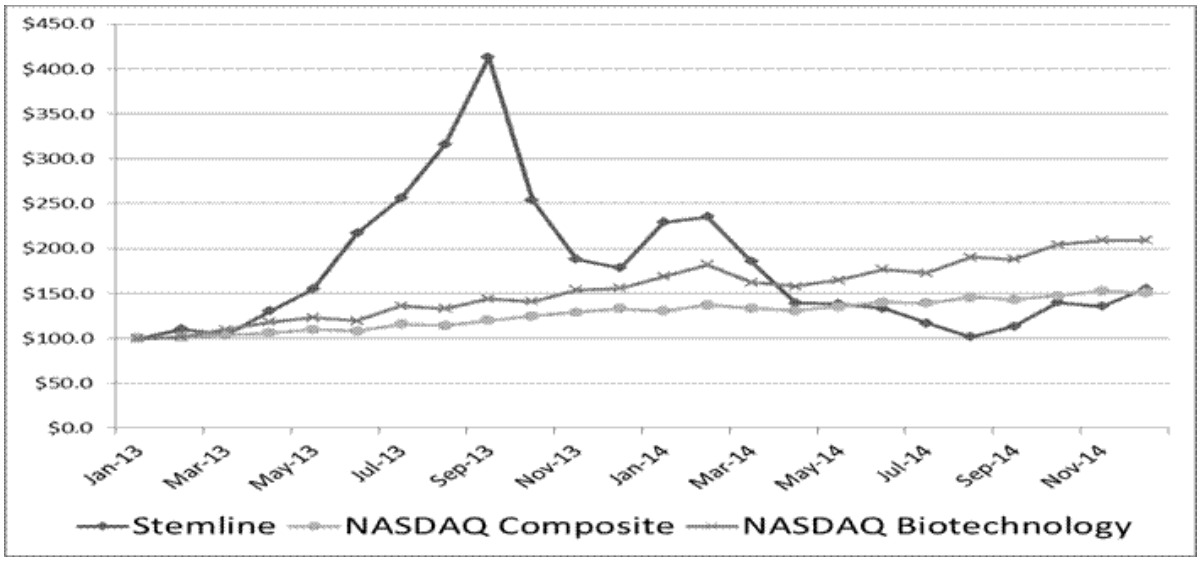
Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
Options	1,643,532	$ 8.64	1,172,264
Restricted stock	283,446	N/A	—
Equity compensation plans not approved by security holders	—	—	—
Total	1,926,978	—	1,172,264

Common Stock Performance Graph

The following graph compares the cumulative total stockholder return on our common stock for the period from January 28, 2013 through December 31, 2014, with the cumulative total return over such period on (i) the U.S. Index of The NASDAQ Stock Market and (ii) the Biotechnology Index of The NASDAQ Stock Market. The graph assumes an investment of $100 on January 28, 2013, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of dividends.

COMPARISON OF 5 YEARS CUMULATIVE TOTAL RETURN*
Among Stemline Therapeutics, Inc., the NASDAQ Composite Index
and the NASDAQ Biotechnology Index



* $100 invested on January 28, 2013 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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Item 6. 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 Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Form 10-K. We have derived the financial information from our audited financial statements. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
Statement of operations data:					
Grant Revenue	$ 335,287	$ 71,000	$ —	$ —	$ —
Operating expenses:					
Research and development	$ 21,240,599	$ 16,178,744	$ 3,376,962	$ 1,629,026	$ 1,329,509
General and administrative	8,084,580	7,871,719	3,090,611	1,088,028	930,331
Total operating expenses	29,325,179	24,050,463	6,467,573	2,717,054	2,259,840
Loss from operations	(28,989,892)	(23,979,463)	(6,467,573)	(2,717,054)	(2,259,840)
Other income:	3,607	280,687	301,684	46,673	484,905
Other expense	—	—	(35)	(9,670)	—
Interest expense	—	(516,871)	(118,765)	(98,643)	(69,493)
Interest income	156,310	19,136	9,907	24,068	43,045
Net loss	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)	$ (2,754,626)	$ (1,801,383)
Less: accretion of preferred stock dividends	—	—	—	—	(239,720)
Add: discount on redemption of preferred stock	—	—	—	—	12,171,765
Net (loss) / income attributable to common stockholders	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)	$ (2,754,626)	$ 10,130,662
Net (loss) / income attributable to common stockholders per common share:					
Basic	$ (2.23)	$ (2.35)	$ (1.82)	$ (0.80)	$ 3.07
Diluted	$ (2.23)	$ (2.35)	$ (1.82)	$ (0.80)	$ 2.81
Weighted average number of common shares:					
Basic	12,936,741	10,317,351	3,441,995	3,441,995	3,298,793
Diluted	12,936,741	10,317,351	3,441,995	3,441,995	3,607,030

	As of December 31,				
	2014	2013	2012	2011	2010
Balance sheet data:					
Cash and cash equivalents	$ 25,007,217	$ 44,200,420	$ 2,025,338	$ 5,829,886	$ 7,226,366
Total assets	$ 60,494,992	$ 85,281,196	$ 5,029,611	$ 6,453,096	$ 7,502,912
Long-term liabilities	$ 607,999	$ 643,000	$ 2,037,296	$ 1,665,346	$ 1,017,033
(Deficit)/earnings	$ (60,195,741)	$ (31,365,766)	$ (7,169,255)	$ (894,473)	$ 1,860,153
Total stockholders' (deficit)/equity	$ 55,413,151	$ 79,624,388	$ (2,508,420)	$ 3,205,340	$ 5,851,561

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Item 1A. Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with "Item 6. Selected financial Data," "Item 8. Financial Statements and Supplementary Data," and our financial statements beginning on page F-1 of this report.

Overview

We are a clinical stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary therapeutics that target cancer stem cells, or CSCs, and tumor bulk. We are currently developing two clinical stage product candidates, SL-401 and SL-701, as well as a pipeline of preclinical candidates that includes SL-801 and SL-501.

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R, present on CSCs and tumor bulk of a variety of hematologic cancers. In July 2014, we opened a corporate sponsored IND with the FDA. Three multicenter clinical trials with SL-401 are currently open in the following indications: 1) blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed/refractory acute myeloid leukemia (AML), the BPDCN portion of which we have designed to serve as a potential registration trial; 2) AML patients in first complete remission (CR) with minimal residual disease (MRD); and 3) four types of advanced high-risk myeloproliferative neoplasms (MPN), including systemic mastocytosis, advanced symptomatic hypereosinophilic disorder, myelofibrosis, and chronic myelomonocytic leukemia. Additional SL-401 studies are currently planned in other indications including myeloma and certain other lymphomas and leukemias.

SL-701 is an enhanced immunotherapy designed to activate the immune system to attack tumors. SL-701 is currently being developed as a single agent in adult patients with second-line glioblastoma multiforme, or GBM. In April 2014, we opened a corporate sponsored IND with the FDA. A multicenter, open-label clinical trial with SL-701 is currently accruing patients with the expectation to enroll approximately 80-100 patients. Previously, an earlier version of the therapy demonstrated clinical activity, including tumor shrinkages, disease stabilizations, and an overall survival signal compared to historical data, in investigator sponsored Phase 1/2 trials in advanced adult and pediatric brain cancers.

We plan to advance our preclinical pipeline of product candidates which includes SL-801. SL-801 is a novel oral small molecule reversible inhibitor of nuclear transport, targeting Exportin-1, or XPO1. We intend to submit an IND for SL-801 and advance this compound into Phase 1disease-directed proof-of-concept studies in both solid and hematologic cancers.

We have devoted substantially all of our resources to developing our product candidates and our platform technology, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. We have generated minimal revenues to date, have not generated any revenue from product sales, and have funded our operations primarily through public and private sales of common stock and private sales of convertible preferred stock to our investors. From inception through December 31, 2014, we have received net proceeds of $101.6 million from the sale of common stock, $12.5 million from the sale of convertible preferred stock and $0.9 million from the issuance of convertible debt. The convertible preferred stock was retired in March 2010 and the convertible debt was converted into common stock in April 2013. Subsequent to December 31, 2014 during the first quarter of 2015, we received additional net cash proceeds of $64.1 million from the underwritten public secondary offering and sale of 4,353,877 shares of our common stock.

We have never been profitable and our net loss from operations was $28.8 million for the year ended December 31, 2014, $24.2 million for the year ended December 31, 2013 and $6.3 million for the year ended December 31, 2012. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through preclinical activities and clinical trials to seek regulatory approval and, if approved, commercialize such product candidates. Furthermore, 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 Operations Overview

Revenue

We have not generated any revenue from product sales and we have generated minimal revenues to date, all relating to a $1.5 million research funding received to date from the Leukemia and Lymphoma Society, or LLS, where we recognized revenue of $0.3 million and $0.1 million during 2014 and 2013, respectively. In the future, we may generate revenue from product sales. In addition, to the extent we enter into licensing or collaboration arrangements, we may have additional sources of revenue.

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

Research and Development Expenses

The following table shows our research and development expenses for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
SL-401	$ 9,171,431	$ 4,880,863	$ 1,628,219
SL-701	3,940,840	1,296,720	126,219
Personnel expenses	7,286,339	7,497,951	1,482,888
Other expenses	841,989	2,503,210	139,636
Total research and development expenses	$ 21,240,599	$ 16,178,744	$ 3,376,962

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

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

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

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

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

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

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

- the potential benefits of our product candidates over other therapies;
- our ability to market and commercialize, either on our own or with strategic partners, and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- the costs, timing and outcome of regulatory approvals; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

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

General and Administrative Expenses

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

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

Interest Income

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

Interest Expense

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

Critical Accounting Policies and Estimates

To understand our financial statements, it is important to understand our critical accounting policies and estimates. We prepare our financial statements in accordance with generally accepted accounting principles, or GAAP. The preparation of financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that 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 Form 10-K. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

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 and CMOs, consultants and other third-party organizations in connection with research and development and administrative activities for which we have not yet been invoiced.

We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs and CMOs 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 may adjust the accrual or prepaid accordingly. There have been no significant adjustments to date. 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 losses, 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, 2014, 2013 and 2012, our deferred tax assets had full valuation allowances on them as we did not have sufficient positive evidence to recognize such deferred tax assets.

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 our ability to utilize these carryforwards. At this time, we have 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 our formation, due to the costs and complexities associated with such a study. We may have experienced various ownership changes, as defined by the Code, as a result of past financing transactions. Accordingly, our 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, we 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 on our deferred tax assets. 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, 2014, we had U.S. federal net operating loss carryforwards of $55.6 million (of which $14.9 million will result in a benefit to additional paid in capital upon realization as they relate to excess benefits from stock option exercises) and research and development credits of $7.0 million which expire in 2024 through 2034.

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 file U.S. income tax returns as well as tax 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

We account for stock-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value calculated by either using a Black-Scholes option pricing model for stock option valuations or the closing stock price on date of grant for restricted stock. Additionally, under the provisions of ASC 718, we are required to include an estimate of the number of awards that will be forfeited in calculating compensation costs. Any changes to the estimated forfeiture rates are accounted for prospectively.

For stock options granted as consideration for services rendered by non-employees, we recognize 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, is re-measured using the fair value of our common stock and the non-cash expense recognized during the period is 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.

Revenue Recognition

We have not yet generated any revenue from product sales. Our sole source of revenue is grant revenue related to $1.5 million of research grants received to date from the Leukemia and Lymphoma Society. Grant payments received prior to our performance of work required by the terms of the research grant are recorded as deferred revenue and recognized as grant revenue once work is performed and qualifying costs are incurred.

Results of Operations

Comparison of Years Ended December 31, 2014 and 2013

Research and development expense. Research and development expense was $21.2 million for the year ended December 31, 2014, compared with $16.2 million for the year ended December 31, 2013, an increase of $5.0 million. The higher costs were primarily attributable to the ramp up in clinical and manufacturing development activities for our SL-401 and SL-701 compounds. The increase in research and development costs associated with SL-401 and SL-701 is primarily driven by higher expenses for CRO services of $4.0 million and $1.2 million in additional costs relating to the manufacturing of SL-401 drug product. As we continue to ramp up our clinical trial activities for SL-401 and SL-701 during 2015, we expect that our research and development expenses will increase compared to prior periods. We expect this increase in costs will continue for the foreseeable future.

General and administrative expense. General and administrative expenses were $8.1 million for the year ended December 31, 2014, compared with $7.9 million for the year ended December 31, 2013, an increase of $0.2 million. The higher expense was driven by an increase in rent, outside legal and audit fees totaling $0.7 million to support the increased governance responsibility of a public company, partially offset by a reduction in financial consulting expenses of $0.6 million.

Interest income. Interest income was $0.2 million for the year ended December 31, 2014, compared with $19,136 for the year ended December 31, 2013. The increase in income of $0.2 million is due to the interest earned from our investments in U.S. Treasury and Agency securities and related money market funds.

Interest expense. Interest expense was $0 for the year ended December 31, 2014, compared with $0.5 million for the year ended December 31, 2013. The decrease in expense of $0.5 million is due to the conversion of our 2.45% convertible notes to common stock in April 2013.

Other income. Other income was $3,607 for the year ended December 31, 2014 and $0.3 million for the year ended December 31, 2013. This income in 2013 was primarily related to the research and development credit refund received from the City of New York.

Comparison of Years Ended December 31, 2013 and 2012

Research and development expense. Research and development expense was $16.2 million for the year ended December 31, 2013, compared with $3.4 million for the year ended December 31, 2012, and increase of $12.8 million. The higher costs were primarily attributable to the ramp up in development activities for our lead compound SL-401. The increase in costs associated with SL-401 includes higher salaries, benefits and non-cash compensation costs of $6.0 million and manufacturing development expenses of $2.4 million. Additionally, the higher expense was partially due to $2.0 million of in-process research and development associated with an

assignment agreement with our chief executive officer. As we begin to initiate clinical trials for SL-401 and SL-701 during 2014, we expect that our research and development expenses will ramp up and increase compared to prior periods. We expect this increase in costs will continue for the foreseeable future.

General and administrative expense. General and administrative expenses were $7.9 million for the year ended December 31, 2013, compared with $3.0 million for the year ended December 31, 2012, an increase of $4.9 million. The higher expenses were driven by increased salary, benefit and non-cash compensation costs of $2.6 million to support the increased governance responsibility of a public company coupled with one-time IPO bonuses. Additionally, we incurred higher expenses for consultants, insurance and rent during 2013.

Interest expense. Interest expense was $0.5 million for the year ended December 31, 2013, compared with $0.1 million for the year ended December 31, 2012. The increase in expense of $0.4 million is due to the amortization of the debt discount of the 2.45% convertible notes and due to the charge to earnings for the beneficial conversion of the 2.45% convertible notes. The 2.45% convertible notes were converted to common stock in April 2014.

Other income. Other income was $0.3 million for both of the years ended December 31, 2013 and December 31, 2012. This income was primarily related to the research and development credit refund received from the City of New York in both years.

Liquidity and Capital Resources

Sources of Liquidity

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

Since inception and through December 31, 2014, we received net proceeds of $101.6 million from the sale of common stock, $12.5 million from the sale of convertible preferred stock and $0.9 million from the issuance of convertible notes. In addition, on January 8, 2015, we completed a follow-on public offering (the "Secondary Offering"), selling 3,800,000 shares at an offering price of $15.75 per share. On February 10, 2015, the underwriters exercised in full their over-allotment option to purchase an additional 553,877 shares at an offering price of $15.75 per share. Aggregate gross proceeds from the Secondary Offering, including the exercise of the over-allotment option, were $68.6 million, and net proceeds received after underwriting fees and offering expenses were approximately $64.1 million.

As of December 31, 2014, our cash, cash equivalents and short and long-term investments totaled $58.6 million. We primarily invest our cash, cash equivalents, short-term investments and long-term investments in 100% U.S. Treasury and Agency securities and related money market funds, with the balance in commercial bank operating accounts. We believe that our existing cash, cash equivalents, short-term investments and long-term investments including the cash proceeds received from our Secondary Offering in the first quarter of 2015, will be sufficient to fund our operations and our capital expenditures for at least the next two years.

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,		
	2014	2013	2012
Net cash used in operating activities	$ (25,713,445)	$ (16,118,487)	$ (4,126,548)
Net cash provided by/ (used) in investing activities	6,384,968	(40,708,687)	—
Net cash provided by financing activities	135,274	99,002,256	322,000
Net increase (decrease) in cash and cash equivalents	$ (19,193,203)	$ 42,175,082	$ (3,804,548)

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for stock-based compensation expense, non-cash depreciation expense and changes in the components of working capital. The net cash used in operating activities increased in 2014, 2013 and 2012 was primarily the result of higher research and development expenses as we ramped up our clinical trial preparations for SL-401 and SL-701. The additional research and development costs also included CMC-related expenses for the manufacture of drug substance and drug product of our product candidates in development.

Investing activities. The net cash provided by financing activities for 2014 reflects sales and maturities of long-term investments within our U.S. Treasury-related investment portfolio net of re-investments. The net cash used in investing activities during 2013 resulted primarily from the purchase of long-term U.S. Treasury Agency securities.

Financing activities. The net cash provided by financing activities for 2014 resulted from the exercise of stock options. The net cash provided by financing activities for 2013 resulted from the net cash proceeds received from our initial public offering in January 2013 and secondary public offering in May 2013. The net cash provided by financing activities for the year ended December 31, 2012 was due to the issuance of $0.4 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 product candidates, SL-401 and SL-701;
- continue the research and development of our other product candidates, including SL-801 and SL-501 and our platform technology;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish, either on our own or with strategic partners, a manufacturing, sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, leverage and expand our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

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

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

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

ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

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

Expected Cash Requirements for Contractual Obligations

The following table presents our expected cash requirements for contractual obligations for each of the following years subsequent to December 31, 2014:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations (1)	$ 911,250	$ 607,500	$ 303,750	$ —	$ —
Investigator initiated clinical trials (2)	1,601,930	391,000	731,000	479,930	—
Clinical trial CRO obligations (3)	21,570,814	8,782,729	10,671,747	2,116,338	—
Bioprocessing Contract (4)	1,482,779	1,482,779	—	—	—
License agreements (5)	4,455,859	1,045,040	1,998,746	1,108,173	303,900
Total	$ 30,022,632	$ 12,309,048	$ 13,705,243	$ 3,704,441	$ 303,900

(1) Operating lease obligations reflects our lease agreement with respect to our corporate offices at 750 Lexington Avenue, New York, New York, for a monthly rent of $50,625. The term of this lease agreement is 36 months and it expires on June 29, 2016.

(2) Reflects our investigator initiated clinical trial agreement with a leading research hospital relating to SL-701 and other health institutions relating to SL-401.

(3) We have agreements in place with three contract research organizations (CRO's) to facilitate research, clinical and data management services in connection with our two clinical-stage product candidates, SL-401 and SL-701.

(4) In February 2013, we entered into a bioprocessing services agreement with a vendor for approximately $2.9 million if all services are performed under the contract. We have subsequently entered into additional contract work orders with this vendor for services under this contract amounting to a cost of $4.3 million. These services are expected to be performed throughout 2015.

(5) We have executed several license 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 agreements include the following:

- Under a research and license agreement with Scott and White 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.
- On December 26, 2014, we entered into a license agreement with CanBas, Ltd. for SL-801. SL-801 is a small molecule, reversible inhibitor of XPO1. Under the terms of the agreement, CanBas has granted us an exclusive, royalty-bearing, worldwide (excluding Japan, Korea, China and Taiwan) license, under certain patent rights, know-how and materials to research, develop, make, have made, formulate, use, sell, offer to sell and import SL-801, and any products containing or

comprising such compound in finished dosage pharmaceutical form, for the treatment of any disease or condition in humans. We are required to make milestone payments upon the achievement of various clinical development, regulatory and commercial milestones. Additionally, we are required to pay tiered royalties on net sales of licensed products.

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

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

Tax Loss Carryforwards

As of December 31, 2014, we had federal net operating loss carryforwards of approximately $55.6 million, which are available to reduce future taxable income. We also had federal tax credits of approximately $7.0 million, which may be used to offset future tax liabilities. The net operating loss and tax credit carryforwards will expire at various dates through 2034. Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual utilization limitation pursuant to the change in ownership rules of Internal Revenue Code Section 382 and 383. The amount of the annual limitation is determined based on the value of our Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. At December 31, 2014, we recorded a 100% valuation allowance against our net operating loss and tax credit carryforwards, as we believe it is more likely than not that the tax benefits will not be fully realized.

Amendment to 2012 Equity Incentive Plan and Amended and Restated 2004 Employee, Director and Consultant Stock Plan

On March 13, 2015, the Board of Directors approved an amendment to the Company's 2012 Equity Incentive Plan and the Company's Amended and Restated 2004 Employee, Director and Consultant Stock Plan to provide that, in the event of a change in control of the Company, unless otherwise provided in the applicable award agreement or separate agreement with a participant governing an award:

(A) If awards are not assumed by the surviving entity or otherwise equitably converted or substituted in connection with the change in control in a manner approved by the Compensation Committee or the Board of Directors, then:

(i) all time-based vesting requirements on outstanding awards will be deemed to have been satisfied and vested in full, and

(ii) all performance-based vesting requirements on outstanding awards will be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the change in control.

(B) If awards are assumed by the surviving entity or otherwise equitably converted or substituted in connection with the change in control, but if within two years after the effective date of the change in control a participant's employment is terminated without cause or the participant resigns for good reason, then:

(i) all time-based vesting requirements on outstanding awards will be deemed to have been satisfied and vested in full, and

(ii) all performance-based vesting requirements on outstanding awards will be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the termination of employment.

In either case, awards other than options or stock appreciation rights will pay out within sixty days following the change in control or the termination of employment, as the case may be, unless a later date is required under the plan in connection with Section 409A of the Internal Revenue Code, and any options or stock appreciation rights will thereafter continue or lapse in accordance with the other provisions of the plan and the applicable award agreement.

Copies of the plan amendments are filed as Exhibits 10.31 and 10.32 hereto and are incorporated herein by reference.

Recently Adopted Accounting Standards

See Note 2 to our financial statements for recently adopted accounting standards.

Jumpstart Our Business Startups Act of 2012

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents, short-term investments and long-term investments of $58.6 million as of December 31, 2014, $84.4 million as of December 31, 2013 and $2.0 million as of December 31, 2012, consisting of cash, U. S. Treasury and Agency securities and Treasury-related money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are primarily in Treasury-related debt securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and CMOs. We may be subject to fluctuations in foreign currency rates in connection with these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2014, 2013 and 2012, all of our liabilities were denominated in our functional currency.

Item 8. Financial Statements and Supplementary Data

Our financial statements and the notes thereto, included in Part IV, Item 15(a), part 1, are incorporated by reference into this Item 8.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Accounting Officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Accounting Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process

designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Accounting Officer (principal financial officer), assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth in the *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2014 based on those criteria.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2015 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2015 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2015 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2015 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2015 Annual Meeting of Stockholders.

Part IV

Item 15. Exhibits, Financial Statements Schedules.

(a) 1. Financial Statements

The following financial statements of Stemline Therapeutics, Inc. are filed as part of this report.

2. Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the financial statements or the related notes.

3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Stemline Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 6, 2013 (File No.001-35619) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Stemline Therapeutics, Inc., filed as Exhibit 3.2 to Form 8-K filed on February 6, 2013 (File No. 001-35619) and incorporated herein by reference.
3.3	Certificate of Amendment of Restated Certificate of Incorporation of Stemline Therapeutics, Inc., filed as Exhibit 3.3 to Form 10-Q on August 14, 2013 (File No. 001-35691) and incorporated herein by reference.
4.1	Specimen certificate evidencing shares of common stock, filed as Exhibit 4.1 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
4.2	Form of Representative's Warrant Agreement, filed as Exhibit 4.2 to Form S-1/A filed on November 14, 2012 (File No. 333-180515) and incorporated herein by reference.
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., filed as Exhibit 10.1 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.2†	Exclusive License Agreement between the Company and the University of Pittsburgh, dated September 30, 2009, filed as Exhibit 10.2 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.3†	Exclusive Patent and Non-Exclusive Know-How License Agreement between the Company and Cambridge University Technical Services Limited, commenced September 16, 2004, filed as Exhibit 10.3 to Form S-1/A filed

Exhibit No.	Description
	on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.4†	Non-Exclusive License Agreement between the Company and the University of Pittsburgh, dated March 30, 2012, filed as Exhibit 10.4 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.5†	Non-Exclusive License Agreement between the Company and the University of Pittsburgh, dated March 21, 2012, filed as Exhibit 10.5 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.6*	Employment Agreement, dated November 6, 2011, between the Registrant and Eric K. Rowinsky, M.D., filed as Exhibit 10.6 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.7*	Employment Agreement, dated March 27, 2012, between the Company and John T. Cavan, filed as Exhibit 10.7 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.8*	Employment Agreement, dated June 15, 2012, between the Registrant and Ivan Bergstein, M.D., filed as Exhibit 10.8 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.9*	Form of Indemnification Agreement between the Registrant and each director, filed as Exhibit 10.9 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.10*	Amended and Restated 2004 Employee, Director and Consultant Stock Plan, filed as Exhibit 10.10 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.11*	Form of Incentive Stock Option Agreement under Amended and Restated 2004 Employee, Director and Consultant Stock Plan, filed as Exhibit 10.11 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.12*	Form of Non-qualified Stock Option Agreement under Amended and Restated 2004 Employee, Director and Consultant Stock Plan, filed as Exhibit 10.12 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.13*	2012 Equity Incentive Plan, filed as Exhibit 10.13 to Form S-1/A on July 19. 2012 (File No. 333-180515) and incorporated herein by reference.
10.14*	Form of Incentive Stock Option Agreement under 2012 Equity Incentive Plan, filed as Exhibit 10.14 to Form S-1/A on July 19. 2012 (File No. 333-180515) and incorporated herein by reference.
10.15*	Form of Nonstatutory Stock Option Agreement under 2012 Equity Incentive Plan, filed as Exhibit 10.15 to Form S-1/A on July 19. 2012 (File No. 333-180515) and incorporated herein by reference.
10.16*	2011 Employee Cash Bonus Plan, filed as Exhibit 10.16 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.17	Senior Unsecured Convertible Note issued by the Company in favor of NB Athyrium LLC, dated March 16, 2010, filed as Exhibit 10.17 to Form S-1 filed on April 2, 2012 (File No. 333-180515) and incorporated herein by reference.
10.18	Exclusive License Agreement between the Company and Dr. Ivan Bergstein M.D., effective as of December 1, 2003, filed as Exhibit 10.18 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.19*	Amended and Restated 2011 Employee Cash Bonus Plan, filed as Exhibit 10.19 to Form S-1/A filed on May 21, 2012 (File No. 333-180515) and incorporated herein by reference.
10.20	Assignment Agreement between the Company and Ivan Bergstein, M.D., effective as of June 15, 2012, filed as Exhibit 10.20 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.

Exhibit No.	Description
10.21*	Offer Letter between the Company and Eric L. Dobmeier, dated April 25, 2012, filed as Exhibit 10.21 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.22*	Offer Letter between the Company and J. Kevin Buchi, dated March 2, 2012, filed as Exhibit 10.22 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.23*	Offer Letter between the Company and Kenneth Zuerblis, dated March 8, 2012, filed as Exhibit 10.23 to Form S-1/A filed on June 20, 2012 (File No. 333-180515) and incorporated herein by reference.
10.24	Amendment, dated July 26, 2012, to Senior Unsecured Convertible Note issued by the Company in favor of NB Athyrium LLC, filed as Exhibit 10.24 to Form S-1/A on July 27, 2012 (File No.333-180515) and incorporated herein by reference.
10.25*	Letter Agreement between the Company and John T. Cavan, dated July 26, 2012, filed as Exhibit 10.25 to Form S-1/A on July 27, 2012 (File No.333-180515) and incorporated herein by reference.
10.26	Amendment No. 1 to Assignment Agreement between the Company and Ivan Bergstein, M.D., dated as of November 7, 2012, filed as Exhibit 10.26 to Form S-1/A on November 14, 2012 (File No. 333-180515) and incorporated herein by reference.
10.27	Amendment No. 2 dated November 14, 2012, to Senior Unsecured Convertible Note issued by the Company in favor of NB Athyrium LLC, filed as Exhibit 10.27 to Form S-1/A on November 14, 2012 (File No. 333-180515) and incorporated herein by reference.
10.28*	Offer Letter between the Company and Stephen P. Hall, dated October 1, 2012, filed as Exhibit 10.28 to Form S-1/A on January 8, 2013 (File No. 333-180515) and incorporated herein by reference.
10.29*	Employment Agreement between the Company and David G. Gionco, dated January 16, 2014, filed as Exhibit 10.1 to Form 8-K on January 23, 2014 (File No. 001-35619) and incorporated herein by reference.
10.30**	License Agreement by and between Stemline Therapeutics, Inc. and the CanBas Co., Ltd, dated December 26, 2014.
10.31*	Amendment No.1 to the 2012 Equity Incentive Plan, adopted March 13, 2015.
10.32*	Amendment No.1 to the Amended and Restated 2004 Employee, Director and Consultant Stock Plan, adopted March 13, 2015.
21.1	List of subsidiaries of Stemline Therapeutics, Inc.
23.1	Consent of Ernst & Young, LLP.
24.1	Power of Attorney (included on signature page).
31.1	Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of principal executive officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certificate of principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from Stemline Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.

† Confidential treatment has been granted with respect to the omitted portions of this exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
* Management contract or compensatory plan, contract or agreement.
**CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

STEMLINE THERAPEUTICS, INC.

Index to Financial Statements

Contents

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. as of December 31, 2014 and 2013, and the related statements of operations, comprehensive loss and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 16, 2015

STEMLINE THERAPEUTICS, INC.
Balance Sheets

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 25,007,217	$ 44,200,420
Short-term investments	28,976,147	—
Related party receivable	—	199,615
Prepaid expenses and other current assets	1,636,808	292,916
Total current assets	55,620,172	44,692,951
Furniture and fixtures, net	230,000	383,333
Long-term investments	4,644,820	40,204,912
Total assets	$ 60,494,992	$ 85,281,196
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,473,842	$ 5,013,808
Total current liabilities	4,473,842	5,013,808
Deferred grant revenue	607,999	643,000
Total liabilities	5,081,841	5,656,808
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2014 and 2013	—	—
Common stock $0.0001 par value, 33,750,000 shares authorized at December 31, 2014 and 2013. 13,285,232 shares issued and outstanding at December 31, 2014 and 13,114,306 shares issued and outstanding at December 31, 2013	1,329	1,310
Additional paid-in capital	115,604,563	111,032,619
Accumulated other comprehensive income (loss)	3,000	(43,775)
Accumulated deficit	(60,195,741)	(31,365,766)
Total stockholders' equity (deficit)	55,413,151	79,624,388
Total liabilities and stockholders' equity (deficit)	$ 60,494,992	$ 85,281,196

See accompanying notes.

STEMLINE THERAPEUTICS, INC.
Statements of Operations

	Year Ended December 31,		
	2014	**2013**	**2012**
Revenues:			
Grant revenue	$ 335,287	$ 71,000	$ —
Operating expenses:			
Research and development	21,240,599	16,178,744	3,376,962
General and administrative	8,084,580	7,871,719	3,090,611
Total operating expenses	29,325,179	24,050,463	6,467,573
Loss from operations	(28,989,892)	(23,979,463)	(6,467,573)
Other income	3,607	280,687	301,684
Other expense	—	—	(35)
Interest expense	—	(516,871)	(118,765)
Interest income	156,310	19,136	9,907
Net loss	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)
Net loss per common share:			
Basic and Diluted	$ (2.23)	$ (2.35)	$ (1.82)
Weighted-average shares outstanding:			
Basic and Diluted	12,936,741	10,317,351	3,441,995

See accompanying notes.

Stemline Therapeutics, Inc.
Statements of Comprehensive Loss

	Year Ended December 31		
	2014	2013	2012
Net loss	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)
Other comprehensive loss:			
Unrealized gain (loss) on investments	50,287	(43,775)	—
Reclassification adjustment for gain on investments included in net loss	(3,512)	—	—
Other comprehensive gain (loss)	46,775	(43,775)	—
Comprehensive loss	$ (28,783,200)	$ (24,240,286)	$ (6,274,782)

Stemline Therapeutics, Inc.
Statements of Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Earnings (Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Capital				
Balance, December 31, 2011	3,441,995	344	4,099,469	—	(894,473)	3,205,340
Stock-based compensation	—	—	561,022	—	—	561,022
Restricted stock grants	34,506	3	(3)	—	—	—
Net loss	—	—	—	—	(6,274,782)	(6,274,782)
Balance, December 31, 2012	3,476,501	347	4,660,488	—	(7,169,255)	(2,508,420)
Issuance of common stock for cash in connection with initial and secondary public offerings, net of issuance costs	8,573,911	857	97,707,649	—	—	97,708,506
Restricted stock grants	304,528	30	(30)	—	—	—
Forfeiture of restricted stock grants	(43,982)	(4)	4	—	—	—
Stock-based compensation	—	—	4,847,086	—	—	4,847,086
Issuance of common stock in connection with the exercise of stock options	550,801	56	1,293,694	—	—	1,293,750
Issuance of common stock in connection with the conversion of convertible notes	252,547	24	2,101,080	—	—	2,101,104
Beneficial conversion related to interest expense	—	—	422,648	—	—	422,648
Net loss	—	—	—	—	(24,196,511)	(24,196,511)
Change in unrealized gain (loss) on available for sale securities	—	—	—	(43,775)	—	(43,775)
Balance, December 31, 2013	13,114,306	$ 1,310	$ 111,032,619	$ (43,775)	$ (31,365,766)	$ 79,624,388
Restricted stock grants	138,663	16	(16)	—	—	—
Forfeiture of restricted stock grants	(777)	(0)	0	—	—	—
Stock-based compensation	—	—	4,436,689	—	—	4,436,689
Issuance of common stock in connection with the exercise of stock options	33,040	3	135,271	—	—	135,274
Net loss	—	—	—	—	(28,829,975)	(28,829,975)
Change in unrealized gain (loss) on available for sale securities	—	—	—	46,775	—	46,775
Balance, December 31, 2014	13,285,232	$ 1,329	$ 115,604,563	$ 3,000	$ (60,195,741)	$ 55,413,151

See accompanying notes.

STEMLINE THERAPEUTICS, INC.
Statements of Cash Flows

	Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities			
Net loss	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	153,333	76,667	—
Stock-based compensation expense	4,436,689	4,847,086	561,022
Amortization of premium paid on marketable securities	249,264	—	—
Net gain on sale of marketable securities	(3,512)	—	—
Non-cash interest expense	—	94,223	118,765
Mark-to-market of put option liability	—	(30,415)	(68,815)
Beneficial conversion of convertible interest	—	422,648	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,343,892)	6,173	(75,879)
Related party receivable	199,615	(199,615)	—
Accounts payable and accrued expenses	(539,966)	2,218,257	1,613,141
Deferred grant revenue	(35,001)	643,000	—
Net cash used in operating activities	(25,713,445)	(16,118,487)	(4,126,548)
Cash flows from investing activities			
Purchase of furniture and fixtures	—	(460,000)	—
Purchase of marketable securities	(16,246,878)	(40,248,687)	—
Sale and maturities of marketable securities	22,631,846	—	—
Net cash used in investing activities	6,384,968	(40,708,687)	—
Cash flows from financing activities			
Proceeds from issuance of common stock, net	—	97,708,506	—
Proceeds from exercise of stock options	135,274	1,293,750	—
Proceeds from issuance of convertible notes	—	—	322,000
Net cash provided by financing activities	135,274	99,002,256	322,000
Net increase (decrease) in cash and cash equivalents	(19,193,203)	42,175,082	(3,804,548)
Cash and cash equivalents at beginning of period	44,200,420	2,025,338	5,829,886
Cash and cash equivalents at end of period	$ 25,007,217	$ 44,200,420	$ 2,025,338
Supplementary Information			
Other information:			
Income tax paid	—	—	—
Interest paid	—	—	—

See accompanying notes.

STEMLINE THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS
December 31, 2014

1. Organization and Basis of Presentation

Organization

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

Stemline Therapeutics, Inc. has incurred losses from operations since inception of $72.4 million. Since its inception, most of its resources have been dedicated to the discovery, acquisition and preclinical and clinical development of its product candidates. In particular, it has expended and will continue to expend substantial resources for the foreseeable future developing its clinical candidates, SL-401 and SL-701, as well as its preclinical product candidates and drug discovery and acquisition efforts. These expenditures will include costs associated with general and administrative costs, facilities costs, research and development, acquiring new technologies, manufacturing product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products approved for sale. 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 expects its research and development expenses to increase significantly in connection with its ongoing and planned clinical trials. As a result, the Company expects to continue to incur significant and increasing operating losses for the foreseeable future.

Initial Public Offering

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

Secondary Public Offerings

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

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.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the US (US GAAP) requires management to make estimates and assumptions that affect the reported financial position at the date of the financial statements and the reported results of operations during the reporting period. Such estimates and assumptions affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash Equivalents

Cash equivalents consist of highly liquid instruments purchased with an original maturity of three months or less. At December 31, 2014 and 2013, 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.

Investments

The Company's investments are considered to be available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity (deficit) and are not reflected in the statements of operations until a sale transaction occurs or when declines in fair value are deemed to be other-than-temporary ("OTT"). The cost of investments classified as available-for-sale are adjusted for the amortization of premiums and accretion of discounts to maturity and recorded in other expense and other income, respectively. Realized gains and losses, if any, are determined using the specific identification method and are included in other income and other expense, respectively. Investments with original maturities beyond 90 days at the date of purchase and which mature at, or less than twelve months from, the balance sheet date are classified as current. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term.

2. Summary of Significant Accounting Policies (continued)

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, investments, other current assets, accounts payable and accrued liabilities. Cash and cash equivalents, and long-term investments are carried at fair value (see Note 6). Financial instruments including other current assets, accounts payable and accrued liabilities are carried at cost, which approximate fair value given their short-term nature.

Other-Than-Temporary Impairment Losses on Investments

The Company regularly monitors its available-for-sale portfolio to evaluate the necessity of recording impairment losses for OTT declines in the fair value of investments. Management makes this determination through the consideration of various factors such as management's intent and ability to retain an investment for a period of time sufficient to allow for any anticipated recovery in market value. OTT impairment losses result in a permanent reduction of the cost basis of an investment. For the years ended December 31, 2014 and 2013 the Company did not realize any investment losses due to OTT declines in fair value.

Furniture and Fixtures

Furniture and fixtures are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, which is three years, using the straight-line method.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, (the Company's furniture and fixtures), for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. The Company purchased fixed assets during 2013. For the years ended December 31, 2014 and 2013 the Company did not realize any impairment losses.

Grant Revenue Recognition

The Company has not yet generated any revenue from product sales. The Company's sole source of revenue is grant revenue related to a $1.0 million research grant received from the Leukemia and Lymphoma Society in October 2013 and an additional $0.5 million that was received during the fourth quarter of 2014 based upon an additional milestone achieved. This research grant was awarded to the Company to support funding some of the costs for the upcoming SL-401 clinical trials. Grant payments received prior to the Company's performance of work required by the terms of the research grant are recorded as deferred revenue and recognized as grant revenue once work is performed and qualifying costs are incurred. The Company has recognized approximately $0.3 million and $0.1 million of revenue related to the Leukemia and Lymphoma Society grant for the years ended December 31, 2014 and 2013, respectively, which reflect twelve months and three months of revenue recognized, respectively, on a straight line basis, based on the Company's best estimates of the timing of work to be performed and qualifying costs incurred.

Accrued Clinical Development Costs

Outside research costs are a component of research and development expense. These expenses include fees paid to contract research organizations and other service providers that conduct certain clinical and product development activities on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Research and Development Costs

Research and development costs are comprised primarily of costs for personnel, including salaries and benefits; clinical studies adminstered by third parties and managed by Stemline personnel; 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. In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when activities have been performed or when the goods have been received.

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 realizability. 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 12), 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 accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value calculated using a Black-Scholes option pricing model for stock options and the closing stock price on date of grant for restricted stock. Additionally, under the provisions of ASC 718, the Company is required to include an estimate of the number of awards that will be forfeited in calculating compensation costs. Any changes to the estimated forfeiture rates are accounted for prospectively.

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, is re-measured using the fair value of the Company's common stock and the non-cash expense recognized during the period is 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.

Segment information

The Company reports segment information in accordance with applicable guidance on segment disclosures. The Company has one reportable segment.

Recent Accounting Pronouncements

In August 2014, the FASB issued a new Accounting Standards Update *ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 provides guidance on management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The guidance is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted.

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

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

3. Net Loss Per Common Share

The Company accounts for and discloses net loss per share using the treasury stock method. Net loss per common share, or basic loss per share, is computed by dividing net loss by the weighted-average number of common shares outstanding. Since the Company is in a net loss for all periods presented, diluted net loss per share is not presented since the common stock equivalents would have an anti-dilutive effect on the per share calculation.

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

	Year Ended December 31,		
	2014	2013	2012
Basic and Diluted loss per common share calculation:			
Net loss attributable to common shareholders — basic and diluted	$ (28,829,975)	$ (24,196,511)	$ (6,274,782)
Basic and diluted weighted-average common shares	12,936,741	10,317,351	3,441,995
Basic and diluted net loss per share	$ (2.23)	$ (2.35)	$ (1.82)

The difference between basic and diluted weighted-average common shares generally results from the assumption that dilutive stock options outstanding were exercised, dilutive restricted stock has vested, outstanding warrants are issued and the conversion of convertible notes. For the years ended 2014, 2013, and 2012, the Company reported a loss from operations and therefore, all potentially dilutive stock options, restricted stock, outstanding warrants and convertible notes as of such date were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive. The total shares of stock options, restricted stock, outstanding warrants and convertible notes that could potentially dilute earnings per share in the future, but which were not included in the calculation of diluted net loss per share because their affect would have been anti-dilutive were as follows:

	Year Ended December 31		
	2014	2013	2012
Unvested restricted stock	283,446	229,250	34,506
Options outstanding	1,643,532	1,228,486	1,819,839
Warrants	99,529	99,529	—
Convertible notes	—	—	252,547
Total	2,026,507	1,557,265	2,106,892

4. Marketable Investments

The following table summarizes the Company's cash equivalents and available for sale securities:

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 23,012,140	$ —	$ —	$ 23,012,140
Short-term investments:				
Fixed-income treasury portfolio:				
Fannie Mae	4,863,371	2,338	—	4,865,709
Federal farm credit bank	11,432,340	3,575	(73)	11,435,842
Federal home loan bank	6,859,294	2,381	(567)	6,861,108
Freddie Mac	5,811,405	2,133	(50)	5,813,488
Total Short-term investments	28,966,410	10,427	(690)	28,976,147
Long-term investments:				
Fixed-income treasury portfolio:				
Federal farm credit bank	1,000,455	—	(1,126)	999,329
Federal home loan bank	2,250,965	—	(3,426)	2,247,539
Freddie Mac	1,400,136	—	(2,184)	1,397,952
Total Long-term investments	4,651,556	—	(6,736)	4,644,820
Total	$ 56,630,106	$ 10,427	$ (7,426)	$ 56,633,107

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

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

There were no available-for-sale securities in a continuous unrealized loss position for greater than twelve months at December 31, 2014 and December 31, 2013. The Company has the ability to hold such securities with an unrealized loss until its forecasted recovery. The Company determined that there was no material change in the credit risk of the above investments. As a result, the Company determined it did not hold any investments with an other-than-temporary impairment as of December 31, 2014.

5. Prepaid Expenses and Other Current Assets

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

	December 31, 2014	December 31, 2013
Prepaid third party vendor costs	$ 1,483,817	$ 39,630
Prepaid insurance	46,748	43,321
Deposits	106,243	209,965
Total	$ 1,636,808	$ 292,916

6. Furniture and Fixtures

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

	December 31, 2014	December 31, 2013
Office furniture and fixtures	$ 460,000	$ 460,000
Less accumulated depreciation	(230,000)	(76,667)
Furniture and fixtures, net	$ 230,000	$ 383,333

Depreciation expense was $153,333 and $76,667 for the years ended December 31, 2014 and 2013, respectively.

7. Fair Value Measurements

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

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, 2014 and 2013:

	December 31, 2014			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance at December 31, 2014
Assets:				
Cash and cash equivalents	$ 25,007,217	$ —	$ —	$ 25,007,217
Short-term investments	28,976,147			28,976,147
Long-term investments	4,644,820	—	—	4,644,820
Total assets at fair value	$ 58,628,184	$ —	$ —	$ 58,628,184

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

There were no transfers between levels in the fair value hierarchy during any of the periods presented herein.

Level 3 Disclosures

The changes in fair value of the Company's Level 3 put option liability during the years ended December 31, 2014, December 31, 2013 and December 31, 2012 were as follows:

	Level 3
Balance at December 31, 2011	$ 99,230
Fair value adjustment to put option liability included in other income	(68,815)
Balance at December 31, 2012	30,415
Fair value adjustment to put option liability included in other income	(30,415)
Balance as of December 31, 2013	—
Fair value adjustment to put option liability included in other income	—
Balance as of December 31, 2014	$ —

For the year ended December 31, 2013, the changes in the fair value of the put option liability resulted from the expiration of the put option in conjunction with the conversion of half of the principal of the 2.45% convertible note, along with accrued interest, into common stock as a result of the IPO. The balance of the note was converted into common stock in April 2013. No other changes in valuation techniques or inputs occurred during the year ended December 31, 2013.

For the year ended December 31, 2012, the changes in the fair value of the put option liability resulted from an adjustment to the remaining period to the expected outcome and taking into consideration the July 26, 2012 and November 14, 2012 amendments to the 2.45% convertible note. No other changes in valuation techniques or inputs occurred during the year ended December 31, 2012.

The fair value of the put option liability was determined utilizing a probability weighted discounted financial model based on management's assessment of the likelihood of achievement of certain outcomes based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the put option liability uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31,	
	2014	2013
Accrued research and development costs	$ 1,762,997	$ 1,966,360
Accrued compensation	1,696,728	2,043,704
Short-term portion of deferred revenue	485,714	286,000
Accrued legal	164,389	372,267
Other accrued liabilities	364,014	345,477
Total accounts payable and accrued expenses	$ 4,473,842	$ 5,013,808

9. Capital Structure

Common Stock

At the 2013 annual meeting of stockholders held on June 19, 2013, the stockholders voted in favor of an amendment to the Company's Restated Certificate of Incorporation to increase the Company's authorized share capital by 11,250,000 shares of common stock. As of December 31, 2014 and 2013, the Company was authorized to issue 33,750,000 shares of common stock.

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

Representative's Warrants

On October 1, 2012, the Company agreed to issue to the representative of the underwriters in the IPO warrants to purchase up to 99,529 shares of the Company's common stock in the event of a successful public offering. The warrants are exercisable for cash or on a cashless basis at a price per share equal to $15.00. The term of the warrants is four years and they expire on January 28, 2018. Based on a successful public offering in January of 2013, these warrants were issued and accounted for as a cost of issuance. The Company has determined, based upon a Black-Scholes model, that the fair value of the warrants on the date of IPO was $413,146. The Company has accounted for the fair value of the warrants as a cost of issuance of common stock from the IPO resulting in a charge directly to stockholder's equity.

10. Grant Revenue

In October 2013, the Company entered into an award contract ("the Agreement") with The Leukemia and Lymphoma Society (LLS). LLS is a national voluntary health agency which, among other activities encourages and sponsors research relating to Leukemia, lymphoma, Hodgkin's disease and myeloma to develop therapies to cure or mitigate these Disease's. To further its mission, LLS provides research funding to entities that can demonstrate after LLS's review process that their proposed research projects have scientific promise to advance LLS's effort to find treatments and cures for the above Diseases and their complications. Pursuant to the Agreement LLS agreed to provide funding to the Company not to exceed $3.5 million to fund the Company's development program related to the Company's pre-clinical and clinical product development activities. The Company received $1.0 million in October 2013, upon execution of the Agreement and received an additional $0.5 million during the fourth quarter of 2014 based upon an additional milestone achieved. The Company could receive the additional $2.0 million based on the completion of certain milestone events. The Company has recognized approximately $0.3 million and $0.1 million of revenue related to the Leukemia and Lymphoma Society grant for the years ended December 31, 2014 and 2013, which reflects twelve months and three months of revenue recognized, respectively, on a straight line basis, based on the Company's best estimates of work performed and qualifying costs incurred. The agreement terminates when there are no longer any payment obligations.

11. Stock-Based Compensation

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

As of December 31, 2014, there were 1,172,264 shares of common stock available for future grants under the 2012 Plan.

Total compensation cost that has been charged against operations related to the above plans was approximately $4.4 million, $4.8 million and $0.6 million for the years ended December 31, 2014, 2013 and 2012, respectively. The exercise of stock options and the vesting of restricted stock during the year ended December 31, 2014 generated an income tax deduction of approximately $1.7 million. The Company does not recognize a tax benefit with respect to an excess stock compensation deduction until the deduction actually reduces the Company's income tax liability. At such time, the Company utilizes the net operating losses generated by excess stock-based compensation to reduce its income tax payable and the tax benefit is recorded as an increase in additional paid-in-capital. No income tax benefit was recognized in the statements of operations for share-based compensation arrangements for the years ended December 31, 2014, 2013 and 2012.

The following table summarizes stock-based compensation related to the above plans by expense category for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
Research and development	$ 2,907,820	$ 3,301,996	$ 412,536
General and administrative	1,528,869	1,545,090	148,486
Total	$ 4,436,689	$ 4,847,086	$ 561,022

Stock Options

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

The weighted-average key assumptions used in determining the fair value of options granted for the years ended December 31, 2014, 2013 and 2012, are as follows:

	Year Ended December 31,		
	2014	2013	2012
Risk-free interest rate	1.97%	2.10%	0.95%
Expected volatility	88.86%	78.23%	78.95%
Dividend yield	—	—	—
Expected life	6.20 years	6.26 years	6.25 years

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

For the years ended December 31, 2014 and 2013 the Company issued 33,040 and 550,801 shares of the Company's common stock, respectively, upon the exercise of outstanding stock options and received proceeds of approximately $135,274 and $1.3 million, respectively. There were no exercises of stock options for the year ended December 31, 2012. For the years ended December 31, 2014, 2013 and 2012 the Company realized no tax benefit from the exercise of stock options. As of December 31, 2014, there was approximately $5.5 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a remaining weighted-average period of approximately 2.3 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures.

The Company's stock options outstanding at December 31, 2014, 2013 and 2012 and changes during the years ended December 31, 2014, 2013 and 2012 are presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2011	1,233,074	$ 2.51		
Options granted	621,828	3.30		
Options exercised	—	—		
Options forfeited	(35,063)	3.30		
Outstanding at December 31, 2012	1,819,839	$ 2.76		
Options granted	159,500	19.08		
Options exercised	(550,801)	2.37		
Options forfeited	(102,052)	2.71		
Outstanding at December 31, 2013	1,326,486	$ 4.89		
Options granted	378,831	21.07		
Options exercised	(33,040)	4.09		
Options forfeited	(28,745)	4.86		
Outstanding at December 31, 2014	1,643,532	$ 8.64	6.81	$ 21,840,758
Options exercisable at December 31, 2014	982,641	$ 4.03	5.70	$ 16,232,198

The aggregate intrinsic value in the previous table reflects the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on December 31, 2014. The intrinsic value of the Company's stock options changes based on the closing price of the Company's common stock. The total intrinsic value of options exercised (the difference in the market price of the Company's common stock on the exercise date and the price paid by the optionee to exercise the option) was approximately $0.4 million and $14.8 million for the years ended December 31, 2014 and 2013, respectively. There were no exercises of stock options for the year ended December 31, 2012.

Restricted Stock

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

The Company's non-vested restricted stock at December 31, 2014, 2013 and 2012, and changes during the years ended December 31, 2014, 2013 and 2012 are presented below:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding at December 31, 2011	—	$ —
Shares granted	34,506	5.97
Shares vested	—	—
Shares forfeited	—	—
Outstanding at December 31, 2012	34,506	$ 5.97
Shares granted	304,528	18.18
Shares vested	(65,802)	11.53
Shares forfeited	(43,982)	23.35
Outstanding at December 31, 2013	229,250	17.34
Shares granted	138,663	21.90
Shares vested	(83,690)	17.99
Shares forfeited	(777)	25.05
Outstanding at December 31, 2014	283,446	$ 19.36

For the year ended December 31, 2014, the Company granted 138,663 shares of restricted stock, at a weighted-average grant date fair value of $21.90 per share amounting to approximately $3.0 million in total aggregate fair value. At December 31, 2014, approximately 283,446 shares remained unvested and there was approximately $3.6 million of unrecognized compensation cost related to restricted stock which is expected to be recognized over a remaining weighted-average period of approximately 2.7 years. The total fair value of restricted stock vested during the year ended December 31, 2014 was approximately $1.5 million. There were no vestings of restricted stock for the year ended 2012.

Performance Share Awards

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

For awards with performance conditions, such as capital raises, an IPO, a change in control or a sale of the company, no expense is recognized, and no measurement date can occur, until the occurrence of the event is probable.

Awards Granted to Non-Employees

The Company periodically re-measures the fair value of stock-based awards issued to non-employees and records expense over the requisite service period. Total compensation cost that has been charged against operations related to options granted to non-employees was approximately $0.1 million, $0.8 million, and $0.1 million for the years ended December 31, 2014, 2013 and 2012, respectively.

12. Income Taxes

The benefit for income taxes consists of the following for the years ended December 31:

	2014	2013	2012
Deferred:			
Federal	$ (14,047,679)	$ (8,861,971)	$ (1,775,748)
State and local	(2,520,711)	(2,813,740)	(1,062,155)
	(16,568,390)	(11,675,711)	(2,837,903)
Increase in valuation allowance	16,568,390	11,675,711	2,837,903
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,		
	2014	2013	2012
Percent of pre-tax income:			
U.S. federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	(8.8)	(11.6)	(11.3)
Permanent items	(14.7)	(2.6)	(0.3)
Change in valuation allowance	57.5	48.2	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,	
	2014	2013
Current deferred tax assets:		
Accrued expenses	$ 1,450,412	$ 1,259,692
Valuation allowance	(1,450,412)	(1,259,692)
Total current deferred tax assets	$ —	$ —
Noncurrent deferred tax assets:		
Net operating loss carryforwards	$ 18,342,986	$ 16,374,002
Research and Development	13,986,047	644,203
Nonqualified stock compensation	3,255,541	2,188,701
	35,584,574	19,206,906
Valuation allowance	(35,584,574)	(19,206,906)
Total noncurrent deferred tax assets	$ —	$ —

In assessing the realizability 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, 2014, 2013 and 2012.

The following table summarizes carryforwards of net operating losses and tax credits as of December 31, 2014:

	Amount	Expiration
Federal net operating losses	$ 55,475,000(A)	2023-2034
State net operating losses	$ 55,534,000(A)	2023-2034
Research and development credits	$ 7,008,000	2023-2034

(A) Of which $14,867,000 will be a benefit to additional paid in capital upon realization as they relate to excess benefits from stock option exercises.

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, 2014 and does not expect this to change significantly over the next twelve months. As of December 31, 2014, 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, 2014 are still subject to examination by major tax jurisdictions.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2014, 2013 and 2012, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss.

For all years through December 31, 2014, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position for these two years. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

13. Commitments and Contingencies

License Agreements

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

Under the Company's license agreements, the Company could be required to pay up to a total of $109.3 million upon achieving certain milestones, such as the initiation of clinical trials or the granting of patents. From inception through December 31, 2014, the Company has paid or accrued $2.4 million in payments resulting from the execution of certain agreements, patent approvals, the initiation of sponsor research agreements, and compound development agreements. Milestone payments will also be due upon the issuance of certain patents, the initiation of certain clinical trials, the submission of regulatory applications and certain regulatory approvals, in addition to sales milestones and single digit royalties payable on commercial sales if any occur.

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, BPDCN, 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 a mutant peptide of IL-13Rα2, an ingredient of SL-701, (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.

In March 2012, the Company entered into a non-exclusive license agreement with UP that covers patent rights claiming the use of a peptide of EphA2, which the Company may use in or packaged with proprietary immunotherapies, including SL-701, for the diagnosis, treatment or prevention of diseases and tumors of the brain. The Company paid UP an initial license fee and will be required to pay UP annual license maintenance fees until the first commercial sale of a licensed product, a customary single digit royalty on sales, and a minimum annual royalty following the first commercial sale of a licensed product. The UP Agreement will expire in its entirety upon the expiration of the last issued patent claiming or covering the product. The Company may terminate the UP Agreement at its sole discretion at any time after a specified number of days following written notice and UP may terminate for a material breach of the agreement by the Company that is not cured within a specified number of days.

In March 2012, the Company also entered into a non-exclusive license agreement with UP for the right to use certain information and data contained in the INDs for the clinical trials relevant to 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-13Rα2 license agreement is terminated.

CanBas, Ltd

On December 26, 2014, we entered into a license agreement with CanBas, Ltd. for SL-801. SL-801 is a small molecule, reversible inhibitor of XPO1. Under the terms of the agreement, CanBas has granted us an exclusive, royalty-bearing, worldwide (excluding Japan, Korea, China and Taiwan) license, under certain patent rights, know-how and materials to research, develop, make, have made, formulate, use, sell, offer to sell and import SL-801, for the treatment of any disease or condition in humans.

We are responsible to pay technical advisory fees over the next four years of 430 million Japanese Yen (JPY), in aggregate, only if the clinical development continues over this time period. Additionally, we must pay CanBas tiered royalties based on aggregate net sales, by us or our sublicensees, of products containing the licensed compound until the latest date of a period of ten years following the first commercial sale of each product in each country; the date upon which there are no more valid claims or the expiration or termination of the last regulatory exclusivity period. The royalty rates range from low single digits and are tiered up based on annual net sales. We also must make certain payments to CanBas of up to $86 million upon the achievement of specific clinical development, regulatory and sales-based commercial milestones. We have sublicensing rights under the agreement, subject to our paying to CanBas a standard royalty percentage of the payments we receive from a sublicensee.

The agreement survives until the later of ten years following the first commercial sale of each product in each country; the date upon which there are no more valid claims or the expiration or termination of the last regulatory exclusivity period, after which our license becomes fully paid, irrevocable, perpetual, non-exclusive and royalty-free. We may terminate the license for any or no reason upon 60 days advance written notice to CanBas. If either we or CanBas 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.

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.

Contractual Agreements

In February 2013, the Company entered into a bioprocessing services agreement with a vendor for approximately $2.9 million if all services are performed under the contract. As of December 31, 2014, the contract services were performed on the initial work order and had been paid by the Company. During 2014, the Company entered into new work order agreements with this vendor totaling approximately $3.4 million, with services to be rendered on these agreements through 2015. The Company has received and paid for services during the twelve months ended December 31, 2014 relating to this agreement in the amount of $1.9 million.

In October 2013, the Company entered into a clinical trial agreement with a leading research hospital and other participating institutions, relating to the performance of our feasibility/pilot study to evaluate the effects of SL-701. Services under this contract are expected to be performed through 2017. The Company's total obligation under the contract is expected to be approximately $1.0 million.

The Company has agreements in place with three contract research organizations (CRO's) to facilitate research and clinical and data management services in connection with our two clinical-stage product candidates, SL-401 and SL-701. The Company's total obligation under these contracts is expected to be approximately $21.6 million through 2018.

Lease Agreement

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

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

2015	$	607,500
2016		303,750
2017		—
	$	911,250

Rent expense charged to operations was approximately $0.6 million and $0.3 million for the years ended December 31, 2014 and 2013, respectively. Rent expense is included in general and administrative expenses in the Company's Statement of Operations.

14. Related Party Items

Receivable from Related Party

In November 2013, the Company recorded a $0.2 million receivable from an executive of the Company related to New York State tax withholdings resulting from an exercise of stock options. This item is reflected on the Company's December 31, 2013 balance sheet as a related party receivable.

Assignment Agreement with the Company's Chief Executive Officer

On June 15, 2012, the Company entered into an assignment agreement with Dr. Bergstein, the Company's Chairman, President and Chief Executive Officer and owner of certain proprietary patent rights and related technology. Pursuant to the assignment agreement, as amended on November 7, 2012, effective immediately prior to the registration statement for the Company's initial public offering being declared effective by the Securities and Exchange Commission, Dr. Bergstein agrees to assign, sell, transfer and convey to the Company all of his right, title and interest in and to these patent rights and related technology in exchange for $2.0 million in cash or a combination of cash and shares of Company common stock, payable only if, within five years of the date of transfer, the Company either (i) has a change in control, as defined in the assignment agreement, or (ii) achieves a market capitalization of at least $200 million for a prescribed period. Under the terms of the assignment agreement, as amended, 50% of such payment shall be paid in cash and the remaining 50% may be paid in shares of Company common stock, or a combination of cash and common stock, as determined by the Company. If the Company elects to settle payment in shares, the Company will value the shares at the date of issuance. None of the assigned patent rights and related technology has alternative future uses, nor have they reached a stage of technological feasibility. The Company accounted for this transaction as an asset acquisition as it achieved a market capitalization of $200 million for the prescribed period because it did not acquire any processes or activities in addition to the assigned rights and technology. The Company has recorded the entire purchase price to acquire in-process research and development expense for the year ended December 31, 2013. The assignment agreement does not contain any vesting or rescission/refund provisions.

15. Other Income

The components of other income for the years ended December 31, 2014, 2013 and 2012 are as follows:

Other Income:	2014	2013	2012
Mark-to-market valuation adjustment to Put Option	$ —	$ 30,415	$ 68,615
New York City Biotechnology R&D tax credit	—	249,477	203,806
Other	3,607	795	29,263
Total other income	$ 3,607	$ 280,687	$ 301,684

Other income includes funds from the City of New York for the 2013 and 2012 Biotechnology Tax Credit program. The income from these programs is a reimbursement of expenses directly related to specific qualifying research programs in accordance with the guidelines of the respective tax credit programs and there are no performance or refund obligations. These expenses were incurred in prior periods and therefore the income was recorded when the funds were received. Other income also includes the mark-to-market of the put option liability associated with the issuance of convertible notes. See Note 6 for further discussion of the Put Option.

16. Subsequent Events

On January 8, 2015, the Company completed a follow-on public offering, selling 3,800,000 shares at an offering price of $15.75 per share. On February 10, 2015, the underwriters exercised their over-allotment option to purchase an additional 553,877 shares at the offering price of $15.75 per share. Aggregate gross proceeds from the Secondary Offering, including the exercise of the over-allotment option, were $68.6 million, and net cash proceeds received after underwriting fees and offering expenses were approximately $64.1 million.

17. Selected Quarterly Financial Data (Unaudited)

	Quarters Ended			
	March 31	June 30	September 30	December 31
2014				
Net loss attributable to common stockholders	$ (8,999,926)	$ (6,012,698)	$ (6,885,157)	$ (6,932,194)
Basic and diluted net loss per common share	$ (0.70)	$ (0.47)	$ (0.53)	$ (0.53)
2013				
Net loss attributable to common stockholders	$ (5,505,646)	$ (5,450,638)	$ (5,573,524)	$ (7,666,703)
Basic and diluted net loss per common share	$ (0.90)	$ (0.55)	$ (0.45)	$ (0.60)

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Index to Exhibits

Exhibit No.	Description
10.30**	License Agreement by and between Stemline Therapeutics, Inc. and the CanBas Co., Ltd, dated December 26, 2014.
10.31	Amendment No.1 to the 2012 Equity Incentive Plan, adopted March 13, 2015.
10.32	Amendment No.1 to the Amended and Restated 2004 Employee, Director and Consultant Stock Plan, adopted March 13, 2015.
21.1	List of subsidiaries of Stemline Therapeutics, Inc.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1	Power of Attorney (included on signature page).
31.1	Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of principal executive officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certificate of principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from Stemline Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

**CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2015

STEMLINE THERAPEUTICS, INC.

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

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POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ivan Bergstein, M.D. his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully 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 any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 16, 2015, and in the capacities indicated:

Signatures	Title
/s/ Ivan Bergstein, M.D. Ivan Bergstein, M.D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)
/s/ David G. Gionco David G. Gionco	Vice President of Finance and Chief Accounting Officer (Principal Financial and Accounting Officer)
/s/ Ron Bentsur Ron Bentsur	Director
/s/ J. Kevin Buchi J. Kevin Buchi	Director
/s/ Eric L. Dobmeier Eric L. Dobmeier	Director
/s/ Kenneth Zuerblis Kenneth Zuerblis	Director

Exhibit 10.30

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

EXECUTION COPY
CONFIDENTIAL

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (the "**Agreement**") is made and entered into as of December 26**,** 2014 (the "**Execution Date**") by and between **CanBas Co., Ltd**, a Japanese corporation, having its principal place of business at 2-2-1 Otemachi, Numazu City, Shizuoka 410-0801 Japan (**"CanBas**"), and **Stemline Therapeutics, Inc.**, a Delaware corporation, having a place of business at 750 Lexington Avenue, 11th Floor New York, NY 10022, USA ("**Licensee**"). CanBas and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, CanBas and its Affiliates Control (as defined below) certain intellectual property with respect to the Licensed Compound (as defined below) and the Licensed Product (as defined below); and

WHEREAS, CanBas desires to grant certain licenses to Licensee, and Licensee desires to obtain those licenses, to develop and commercialize the Licensed Compound and Licensed Product (as defined below) in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained therein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

ARTICLE I
DEFINITIONS

Unless otherwise specifically provided herein, the following terms and their correlatives shall have the following meanings:

1.1 "**Adverse Drug Experience**" shall have the meaning set forth in Section 9.1.

1.2 "**Affiliate**" shall mean, with respect to a Party (or Sublicensee, as applicable), any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party (or Sublicensee, as applicable). For purposes of this definition "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity), provided that if local law restricts foreign ownership, control shall be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

1.3 **"Agreement**" shall have the meaning set forth in the preamble to this Agreement.

1.4 "**Applicable Law**" shall mean applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, which may be in effect from time to time.

1.5 "**Breaching Party**" shall have the meaning set forth in Section 14.2.

1.6 "**Business Day**" shall mean a day other than a Saturday or Sunday on which banking institutions in both Tokyo, Japan and New York, NY are open for business.

1.7 "**Calendar Quarter**" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.8 "**Calendar Year**" shall mean each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.

1.9 "**CanBas**" shall have the meaning set forth in the preamble to this Agreement, and shall include its successors and permitted assigns.

1.10 "**CanBas Distributor**" shall mean a Person, other than a CanBas Licensee or an Affiliate of CanBas, in one or more countries outside the Territory that (a) purchases the Licensed Product from CanBas, an Affiliate of CanBas or a CanBas Licensee for such country(ies), (b) assumes responsibility from CanBas, an Affiliate of CanBas or a CanBas Licensee, as applicable, for all or a portion of the Commercialization of the Licensed Product in such country(ies) and (c) sells Licensed Product in such country(ies).

1.11 "**CanBas Know-How**" shall mean all Information that is Controlled by CanBas or any of its Affiliates as of the Effective Date or during the term of this Agreement that (a) is not generally known and (b) is reasonably necessary or useful for the Exploitation of the Licensed Compound or the Licensed Product (including in each case Improvements thereto), but excluding any Information to the extent claimed by CanBas Patents.

1.12 "**CanBas Licensee**" shall mean any Person, other than Licensee, its Affiliates or Affiliates of CanBas, that is granted a license by CanBas, an Affiliate of CanBas or another CanBas Licensee under any CanBas Patents, CanBas Know-How or any Regulatory Documentation controlled by CanBas or any Affiliates of CanBas, in each case to Exploit the Licensed Compound or the Licensed Product in the Field outside the Territory. For clarity, any CanBas Distributor that is granted such a license limited to the activities contemplated under the definition of CanBas Distributor in Section 1.10 shall not be deemed a CanBas Licensee by virtue of such grant.

1.13 "**CanBas Patents**" shall mean all of the Patents that CanBas or any of its Affiliates Controls, as of the Effective Date or during the term of this Agreement, that claim technology that is reasonably necessary or useful for the Exploitation of the Licensed Compound or the Licensed Product (including in each case Improvements thereto) including those that claim the Licensed Compound or the Licensed Product or the Development or Commercialization thereof. For the avoidance of doubt, the CanBas Patents include, as of the Effective Date, the Patents set forth on Exhibit A.

1.14 "**CanBas Trademarks**" shall mean all Trademarks and Trademark applications for the Licensed Compound or the Licensed Product that CanBas or any of its Affiliates Controls, as of the Effective Date or during the term of this Agreement in the Territory. The CanBas Trademarks are set forth on Exhibit A. For avoidance of doubt, the CanBas Trademarks shall not include the word "CanBas" or any of its variations or any successor name for CanBas.

1.15 "**Clinical Data**" shall mean all information with respect to the Licensed Compound or the Licensed Product made, collected or otherwise generated under or in connection with the Clinical Studies or the Post Approval Studies for the Licensed Compound or the Licensed Product, including any data, reports and results with respect to any of the foregoing.

1.16 "**Clinical Studies**" shall mean Phase I, Phase II, and Phase III trials, and such other tests and studies in patients that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals, but excluding Post Approval Studies.

1.17 "**Combination Product**" shall mean a Licensed Product that contains the Licensed Compound as an active ingredient together with one or more other active ingredients that are sold either as a fixed dose or as separate doses in a single package. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7) in the United States (or its international counterparts).

1.18 "**Commercialization**" shall mean any and all activities (whether conducted before or after Regulatory Approval) directed to the marketing, detailing and promotion of the Licensed Product after Regulatory Approval has been obtained, and shall include pre-launch and post-launch marketing, promoting, detailing, marketing research, distributing, and commercially selling the Licensed Product, importing, exporting or transporting the Licensed Product for commercial sale and regulatory affairs with respect to the foregoing, but shall not include Post Approval Studies or Manufacturing. When used as a verb, "**Commercializing**" means to engage in Commercialization and "**Commercialize**" and "**Commercialized**" shall have corresponding meanings.

1.19 "**Commercially Reasonable Efforts**" shall mean, with respect to the Development or Commercialization of the Licensed Compound or the Licensed Product, that level of efforts and resources commonly dedicated in the biotechnology industry by a company that is similarly situated to Licensee and its Affiliates (taken as a whole) developing and commercializing a product of similar commercial potential at a similar stage in its lifecycle, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then-current competitive environment for such product and the likely timing of such product's entry into the market, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors.

1.20 "**Committee**" shall have the meaning set forth in Section 2.1.5.

1.21 "**Complaining Party**" shall have the meaning set forth in Section 14.2.

1.22 "**Confidential Information**" shall have the meaning set forth in Section 11.1.

1.23 "**Control**" shall mean, with respect to any item of Information, Regulatory Documentation, Patent or Intellectual Property Right, possession by a Person of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in ARTICLE VI), to assign or grant a license, sublicense or other right to or under, or grant access to, such Information, Regulatory Documentation, Patent or Intellectual Property Right, to another Person as provided for herein without violating the terms of any written agreement or other binding arrangement with any Third Party at the time such assignment or grant is first required hereunder. For clarity and without limitation, it is understood and agreed that, pursuant to such Third Party agreements or arrangements, any of the foregoing may be partially and not fully "Controlled" for purposes of the licenses and other rights granted herein (e.g., CanBas may only have a covenant not to sue or other non-exclusive right or license to a Patent or Information, or may not have all the rights specified in the prosecution and enforcement provisions set forth in ARTICLE VIII for any Patent), in which case the item in question shall be licensed or otherwise made available, as applicable, to such other Person hereunder to the extent and only to the extent permitted by such Third Party agreements and arrangements.

1.24 "**Corporate Names**" shall mean such Trademarks, including the CanBas Trademarks and the Stemline Trademarks, and corporate names and logos Controlled by either CanBas or Licensee as either Party may designate in writing from time to time together with any variations and derivatives thereof.

1.25 "**Data Exchange Agreement**" shall have the meaning set forth in Section 9.2.

1.26 "**Development**" shall mean any and all activities related to research, preclinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, Clinical Studies and Post Approval Studies, including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, in each case with respect to the Licensed Compound or the Licensed Product. When used as a verb, "**Develop**" shall mean to engage in Development.

1.27 "**Joint Development Committee**" shall have the meaning set forth in Section 2.1.5(i).

1.28 "**Joint Marketing Committee**" shall have the meaning set forth in Section 2.1.5(ii).

1.29 "**Dispute**" shall have the meaning set forth in Section 15.6.

1.30 "**Distributor**" shall mean a Person, other than Licensee, a Sublicensee, or an Affiliate of either Licensee or a Sublicensee, in one or more countries in the Territory that (a) purchases the Licensed Product from the Licensee, its Affiliates or Sublicensees for such country(ies), (b) assumes responsibility for all or a portion of the Commercialization of the

Licensed Product in such country(ies) and (c) sells Licensed Product in such country(ies).

1.31 **"Drug Approval Application**" shall mean a Biological License Application or New Drug Application as defined in the FFDCA and the regulations promulgated thereunder, or any corresponding foreign application, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.32 "**Drug Master File**" shall mean any drug master files filed with the FDA or equivalent regulatory body with respect to the Licensed Compound or Licensed Product and any equivalent filing in other countries or regulatory jurisdictions.

1.33 "**Effective Date**" shall have the meaning set forth in Section 14.1.

1.34 "**EMA**" shall mean the European Medicines Agency and any successor agency thereto.

1.35 "**European Union**" shall mean the organization of member states as it may be constituted from time to time, which, as of the date hereof, consists of Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland and a portion of Cyprus.

1.36 "**Execution Date**" shall have the meaning set forth in the preamble to this Agreement.

1.37 "**Exploit**" shall mean to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, hold or keep (whether for disposal or otherwise), export, transport, distribute, promote, market or otherwise dispose of, and cause or contract for other Persons to do the same.

1.38 "**Exploitation**" shall mean the act of Exploiting a product or process.

1.39 "**Field**" shall mean all pharmaceutical uses in humans.

1.40 "**FDA**" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.41 "**FFDCA**" shall mean the United States Food, Drug, and Cosmetic Act, as amended from time to time.

1.42 "**First Commercial Sale**" shall mean the first sale for use or consumption by the general public of the Licensed Product in a country in the Territory after all required Regulatory Approvals for commercial sale of the Licensed Product have been obtained in such country.

1.43 "**Improvement**" shall mean any modification to a compound, product or technology or any discovery, technology, device or process or formulation related to such compound, product or technology, whether or not patented or patentable, including any enhancement in the efficiency, operation, manufacture (including any manufacturing process), ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of such compound, product or technology, any discovery or development of any new or expanded indications for such compound, product or technology or any discovery or development that improves the stability, safety or efficacy of such compound, product or technology.

1.44 "**Indemnification Claim Notice**" shall have the meaning set forth in Section 13.3.

1.45 "**IND**" shall mean an investigational new drug application filed with the FDA for authorization to commence Clinical Studies or Post Approval Studies and its equivalent in other countries or regulatory jurisdictions.

1.46 "**Indemnified Party**" shall have the meaning set forth in Section 13.3.

1.47 "**Information**" shall mean all commercial, technical, scientific and other know- how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material (including all tangible biological or chemical materials), including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; in all cases, whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed, but excluding the Regulatory Documentation.

1.48 "**Intellectual Property Rights**" shall mean Trademarks, service marks, trade names, registered designs, design rights, copyrights (including rights in computer software), database rights, trade secrets and any rights or property similar to any of the foregoing (other than Patents) in any part of the world whether registered or not registered together with the right to apply for the registration of any such rights.

1.49 "**Knowledge**" shall mean the collective good faith understanding of each of the officers, directors, employees and consultants of a Party of the facts and information then in their possession without any duty to conduct any investigation with respect to such facts and information.

1.50 "**Licensed Compound**" shall mean *, all analogues and derivatives thereof, and all Improvements to each of the foregoing.

1.51 "**Licensed Product**" shall mean any formulation or dosage of pharmaceutical composition or preparation in finished form labeled and packaged for sale by prescription, over- the-counter or any other method that contains the Licensed Compound as an active ingredient (including Combination Products), and any Improvements thereto.

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*Confidential material redacted and filed separately with the Commission.

1.52 "**Licensee**" shall have the meaning set forth in the preamble to this Agreement, and shall include its successors and permitted assigns.

1.53 "**Losses**" shall have the meaning set forth in Section 13.1.

1.54 "**MAA**" shall mean Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.55 "**Manufacture**" **and** "**Manufacturing**" shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Licensed Compound or the Licensed Product or any intermediate thereof, including chemistry manufacturing and controls processes, process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, release and stability testing, quality assurance and quality control.

1.56 "**NDA**" shall mean a New Drug Application as defined in the FFDCA and the regulations promulgated thereunder.

1.57 **"Net Sales"** means the total invoiced sales of product by Licensee, its Affiliates, and Sublicensees and their Affiliates, less the total of charges or expenses actually applied, both as determined in accordance with US Generally Accepted Accounting Principles, or GAAP. The following are charges and expenses allowable to be applied as an offset to the revenues derived by sales of product: *

With respect to a Licensed Product that is a Combination Product, "Net Sales" shall include that percentage of the Net Sales of such Combination Product (as determined in accordance with the

*Confidential material redacted and filed separately with the Commission.

foregoing paragraph) as Licensee may reasonably determine based on the wholesale acquisition costs of the Licensed Compound contained in a Licensed Product and the other active ingredient(s) in such Combination Product when sold separately, or other similar approach. In the case of any revision to Net Sales under this Agreement in connection with sales of a Combination Product, Licensee shall provide CanBas with a written statement of how such adjustment was calculated. Net Sales shall be determined from books and records maintained in accordance with U.S. GAAP, as consistently applied by Licensee with respect to sales of the Licensed Product.

Licensee's or any of its Affiliates' or Sublicensees' transfer of Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless the Licensed Product is consumed by such Affiliate or Sublicensee in the course of its Commercialization (but not Development) activities. Licensee's or any of its Affiliates' or Sublicensees' sales or transfers of Licensed Product to Distributors (including wholesalers), and any consideration of any kind received in connection with such sales or transfers (including royalties, commercial rebates or commissions) shall be included in the calculation of Net Sales. Net Sales shall be determined in accordance with the local generally accepted accounting principles.

1.58 "**Notice Period**" shall have the meaning set forth in Section 14.2.

1.59 "**Party**" **and** "**Parties**" shall have the meaning set forth in the preamble to this Agreement, and shall not include any Affiliates of CanBas or Licensee.

1.60 "**Patents**" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority, directly or indirectly, from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the patent applications described in the foregoing clauses (a) and (b), and any foreign counterparts thereof, including utility models, petty patents, design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the patents or patent applications described in the foregoing clauses (a), (b) and (c), and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents, including any rights that give rise to Regulatory Exclusivity Periods.

1.61 "**Payments**" shall have the meaning set forth in Section 7.7.

1.62 "**Person**" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.63 "**Phase I**" shall mean a human clinical trial of the Licensed Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients or a similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended.

1.64 "**Phase II**" shall mean a human clinical trial of the Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended.

1.65 "**Phase III**" shall mean a human clinical trial of the Licensed Product designed to establish that a pharmaceutical product is safe and efficacious for its intended use and to determine warnings, precautions and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which trial is intended to support marketing approval of the Licensed Product, including all tests and studies that are required by the FDA from time to time, pursuant to Applicable Law or otherwise.

1.66 "**Post Approval Studies**" shall mean studies conducted with a Licensed Product after the receipt of the first Regulatory Approval of such Licensed Product.

1.67 "**Product Labeling**" shall mean, with respect to a country, (a) the full prescribing information for the Licensed Product approved by the relevant Regulatory Authority for such country, including any required patient information; and (b) all labels and other written, printed or graphic matter upon an container, wrapper or any package insert utilized with or for the Licensed Product.

1.68 "**Reference Date**" shall mean the due date of each Reference Milestone as reasonably created or amended by Licensee pursuant to this Agreement and for the term of this Agreement as set forth in Exhibit E.

1.69 "**Reference Milestones**" shall mean each development milestone as reasonably created or amended by Licensee pursuant to this Agreement and for the term of this Agreement as set forth in Exhibit E.

1.70 "**Regulatory Approval**" shall mean, with respect to a country, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market the Licensed Product in such country, including, where applicable and as required, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), (c) labeling approval and (d) technical, medical and scientific licenses.

1.71 "**Regulatory Authority**" shall mean any supra-national, federal, national, regional, state, provincial or local governmental regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Compound or the Licensed Product, including the FDA and EMA.

1.72 "**Regulatory Documentation**" shall mean all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to the Licensed Compound or the Licensed Product, whether in draft or final form, and all data contained in any of the foregoing, including all INDs, Drug Approval Applications, regulatory drug lists, advertising and promotion documents, Manufacturing data, Drug Master Files, chemistry manufacturing and control data, Clinical Data, adverse event files and complaint files.

1.73 **"Regulatory Exclusivity Periods"** shall mean, with respect to any country in the Territory, a period of exclusivity, granted or afforded by Applicable Law or by a Regulatory Authority in such country, which either confers exclusive marketing rights with respect to a product or prevents another party from using or otherwise relying on the data supporting the approval of a new Drug Approval Application for a product without the prior written authorization of the Drug Approval Application-holder for an already-approved product, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, non-patent-related pediatric exclusivity, or any other applicable marketing or data exclusivity, including any such periods under national implementations in the EU of Article 10 of Directive 2001/83/EC, Article 14(11) of Parliament and Council Regulation (EC) No 726/2004, Parliament and Council Regulation (EC) No 141/2000 on orphan medicines, Parliament and Council Regulation (EC) No 1901/2006 on medicinal products for pediatric use and all international equivalents.

1.74 "**sNDA**" shall mean a Supplemental New Drug Application as defined in the FFDCA and the regulations promulgated thereunder.

1.75 **"Special Committee"** shall mean a special committee composed of the Chief Executive Officer of CanBas and the Chief Executive Officer of Licensee and, in addition, at least one (1) additional senior manager from each Party, and convened by the Parties pursuant to Section 2.1.3 and prior to the creation of any new Reference Milestones amending Exhibit E.

1.76 "**Stemline Trademarks**" shall mean all Trademarks and Trademark applications for the Licensed Compound or the Licensed Product that Licensee or any of its Affiliates Controls, as of the Effective Date or during the term of this Agreement in the Territory. The Stemline Trademarks are set forth on Exhibit C. For avoidance of doubt, the Stemline Trademarks shall not include the word "Stemline" or any of its variations or any successor name for Licensee.

1.77 **"Sublicense Income"** shall mean upfront and milestone payments received by Licensee from its Sublicensees in consideration of the grant of a sublicense of the license granted to Licensee under Section 5.1.1. For avoidance of doubt, Sublicense Income shall not include payments to reimburse Licensee for out-of-pocket expenses incurred for research and development or payments based on sales of Licensed Compound or Licensed Product (i.e., royalty payments). In case Licensee enters into an agreement under which Licensee receives payments for research and development, Licensee shall so inform CanBas in writing and the

Parties shall negotiate in good faith towards an agreed portion of such amount to be included as Sublicense Income.

1.78 **"Sublicensee**" shall mean any Person, other than an Affiliate of Licensee, that is granted a sublicense by Licensee, any Affiliate of Licensee or any other Sublicensee as provided in Section 6.3. For clarity, any Distributor that is granted such a license limited to the activities contemplated under the definition of Distributor in Section 1.29 shall not be deemed a Sublicensee by virtue of such grant**.**

1.79 "**Territory**" shall mean all countries in the world except for Japan, China, Taiwan and Korea.

1.80 "**Third Party**" shall mean any Person other than CanBas, Licensee and their respective Affiliates.

1.81 "**Third Party Claims**" shall have the meaning set forth in Section 13.1.

1.82 "**Trademark**" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.83 "**United States**" **or** "**U.S.**" shall mean the United States of America, including its territories and possessions, the District of Columbia and Puerto Rico.

1.84 "**Valid Claim**" shall mean, with respect to a particular country, (a) any claim of an issued and unexpired Patent and/or any restored patent period thereof in such country that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country; or (b) a claim of a pending Patent application, which claim has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

1.85 **"VAT**" shall have the meaning set forth in Section 7.7.

ARTICLE II
DEVELOPMENT AND REGULATORY MATTERS

2.1 **Development of the Licensed Product**.

2.1.1. **Ongoing Development**. CanBas represents that, prior to the Effective Date, CanBas has, to its knowledge, delivered to Licensee copies of Clinical Data, Regulatory Documentation and other Information related to Development in or outside the Territory that as of the Effective Date was Controlled by CanBas, including, but not limited to, all safety information relating to the Licensed Compound and the Licensed Product Controlled by CanBas, to enable Licensee's Development and Commercialization efforts. In the event CanBas is aware of any such Clinical Data, Regulatory Documentation and other Information related to Development of the Licensed Compound or the Licensed Product that it does not Control,

CanBas will so notify Licensee and shall make reasonable efforts to acquire Control over such Clinical Data, Regulatory Documentation and other Information so that it can be made available to Licensee. In addition, during the term of this Agreement, when and as such Clinical Data, Regulatory Documentation and other Information comes to be Controlled by CanBas, CanBas shall deliver such Clinical Data, Regulatory Documentation and other Information to Licensee, including but not limited to (i) Clinical Study results, preclinical study results and resultant data analyses, (ii) regulatory submissions or draft regulatory submissions made or to be made to any Regulatory Authority by or on behalf of CanBas with respect to the Licensed Compound or the Licensed Product, (iii) protocols for any ongoing Clinical Studies and proposed designs for any anticipated Clinical Studies with respect to the Licensed Compound or the Licensed Product, in each case in the English language, and (iv) development and manufacturing data and results, including that related to any alternative synthetic approaches. Licensee shall be under a reciprocal duty to deliver any such Clinical Data, Regulatory Documentation and other Information in its control to CanBas, including but not limited to (i) Clinical Study results, preclinical study results and resultant data analyses, (ii) regulatory submissions or draft regulatory submissions made or to be made to any Regulatory Authority by or on behalf of Licensee with respect to the Licensed Compound or the Licensed Product, (iii) protocols for any ongoing Clinical Studies and proposed designs for any anticipated Clinical Studies with respect to the Licensed Compound or the Licensed Product, in each case in the English language, and (iv) development and manufacturing data and results, including that related to any alternative synthetic approaches

2.1.2. Diligence and Compliance. As between the Parties, Licensee shall have sole responsibility and right, at its own expense, for Developing and seeking Regulatory Approval for the Licensed Product in the Field in the Territory and in compliance with Applicable Law. Without limiting the foregoing, Licensee (and such other entities, as applicable) shall use Commercially Reasonable Efforts (a) to achieve each of the Reference Milestones within the specified Reference Date in Exhibit E; (b) to Develop a Licensed Product in the Field in the Territory in accordance with the terms and conditions of this Agreement; and (c) to seek and maintain Regulatory Approval(s) with respect to a Licensed Product in the Field in the Territory.

2.1.3. *

2.1.4. *

2.1.5. Development and Marketing Committee. The Parties shall establish two committees (each a "Committee" and collectively the "Committees") as follows:

(i) The Parties shall establish a development committee (a "**Joint Development Committee**" or "**JDC**") composed of representatives of Licensee and CanBas for the purpose of exchanging information between Parties. Each Party shall consider any suggestions relating to the development of the Licensed Compound or Licensed Product provided by the other Party to the JDC. However, and for the avoidance of doubt, Licensee shall have complete decision-making authority relating to such development in the Territory and CanBas shall have complete decision-making authority relating to such development outside of the Territory. Any final determination as to development in the Territory shall (a) be consistent with the terms of this Agreement; and (b) not materially affect the rights and obligations of CanBas under this Agreement without CanBas's consent.

*Confidential material redacted and filed separately with the Commission.

(ii) The Parties shall establish in due time a marketing committee ("**Joint Marketing Committee**" or "**JMC**") of representatives of Licensee and CanBas for the purpose of exchanging information between the Parties. Each Party shall consider any suggestions relating to the marketing of the Licensed Product provided by the other Party to the JMC. However, and for the avoidance of doubt, Licensee shall have complete decision-making authority relating to marketing and sales strategies and efforts in the Territory and CanBas shall have complete decision-making authority relating to such marketing and sales strategies and efforts outside of the Territory. Any final determination as to marketing in the Territory shall (a) be consistent with the terms of this Agreement; and (b) not materially affect the rights and obligations of CanBas under this Agreement without CanBas's consent.

(iii) Meetings. The JDC and the JMC shall each meet biannually, whether face-to-face or electronically, as agreed from time-to-time.

2.2 Regulatory Matters in the Territory.

2.2.1. Regulatory Responsibilities.

(i) As between the Parties, Licensee shall have sole responsibility for preparing and maintaining all Regulatory Documentation with respect to (a) Regulatory

Approvals, including Drug Approval Applications, for the Licensed Product in the Territory and (b) Development activities for the Licensed Product that are conducted in support of Regulatory Approvals for the Licensed Product or Commercialization of the Licensed Product in the Territory. Licensee will notify CanBas seven (7) Business Days in advance (as a general rule) of any meetings with the FDA or any other regulators related to the foregoing and CanBas shall have the right to participate in its sole discretion but solely as an observer. Subject to ARTICLE XIV, all Regulatory Approvals and related Regulatory Documentation within the Territory relating to the Licensed Product shall be the sole property of Licensee and held in the name of Licensee (or in each such case Licensee's Affiliate or Sublicensee).

(ii) As between the Parties, CanBas shall have sole responsibility for preparing and maintaining all Regulatory Documentation with respect to (a) Regulatory Approvals, including Drug Approval Applications, for the Licensed Product outside the Territory and (b) Development activities for the Licensed Product that are conducted in support of Regulatory Approvals for the Licensed Product or Commercialization of the Licensed Product outside the Territory. CanBas will notify Licensee seven (7) Business Days in advance (as a general rule) of any meetings with the Regulatory Authorities related to the foregoing and Licensee shall have the right to participate in its sole discretion but solely as an observer. Subject to ARTICLE XIV, all Regulatory Approvals and related Regulatory Documentation outside the Territory relating to the Licensed Product shall be the sole property of CanBas and held in the name of CanBas (or in each such case CanBas's Affiliate or Sublicensee).

2.2.2. Regulatory Data. Licensee shall provide CanBas, *, with copies of Clinical Data and Regulatory Documentation necessary for CanBas's regulatory filings and developed by or on behalf of Licensee pursuant to this Agreement during the term of this Agreement. Each Party shall support the other, as may be reasonably necessary, in the clinical and regulatory development including obtaining Regulatory Approvals for the Licensed Product, including providing necessary documents or other materials required by Applicable Law to obtain Regulatory Approvals, in each case in accordance with the terms and conditions of this Agreement and the Development.

2.2.3. Communications with Regulatory Authorities. As between the Parties, Licensee shall be responsible for all communications with the Regulatory Authorities in the Territory during the term of this Agreement relating to the Licensed Product. CanBas shall not initiate any communications with any such Regulatory Authority concerning the Licensed Compound or the Licensed Product without first obtaining prior written approval of Licensee.

2.3 Disclosures.

2.3.1. CanBas shall disclose to Licensee in writing (in the English language if available, otherwise in whatever language available) any and all CanBas Know-How, CanBas Patents and Regulatory Documentation developed or prepared or otherwise Controlled by CanBas or any of its Affiliates or CanBas Licensees, as soon as reasonably practicable after the Effective Date, or if applicable, after the development or preparation or acquisition thereof, in each case as reasonably necessary or useful for Licensee to exercise the license granted to it pursuant to Section 6.1.

*Confidential material redacted and filed separately with the Commission.

2.3.2. Licensee shall disclose to CanBas in writing (in the English language if available, otherwise in whatever language available) additions or improvements to the CanBas Know-How and CanBas Patents and any Regulatory Documentation developed or prepared or otherwise Controlled by Licensee or any of its Affiliates or Sublicensees, as soon as reasonably practicable after such items come into Licensee's Control, in each case as reasonably necessary or useful for CanBas to exercise the license granted to it pursuant to Section 6.1.2.

ARTICLE III
MANUFACTURING AND SUPPLY

3.1 Manufacturing Development. Licensee shall have the right to perform the activities relating to Manufacturing process development and scale-up of Manufacturing of the Licensed Compound and the Licensed Product. Such right shall be exclusive (except as to CanBas and its Affiliates, and CanBas Sublicensees and their Affiliates) in the Territory and non-exclusive outside the Territory. Without limiting the foregoing, upon Licensee's request, CanBas shall transfer to Licensee relevant materials, protocols, raw material, in-process and final specifications, assays and standard operating procedures under its or any of its Affiliates' or CanBas Licensees' Control in order to enable Licensee to conduct any of the Manufacturing activities contemplated hereunder.

3.2 Supply.

3.2.1. Material Transfer. Promptly following the Effective Date, upon receipt of written request from Licensee, CanBas will transfer to Licensee active pharmaceutical ingredient ("API") with the total quantity of *(*) * consisting of both a) *(*) *of API and b) *(*) *of a reference standard for the Licensed Product owned or available to CanBas in accordance with packaging and shipping instructions provided by Licensee in its written request. In return, Licensee shall pay CanBas $* USD *. Such API shall be accompanied by the results of all in-process and release testing and certification of compliance to all applicable specifications. Licensee shall reimburse CanBas for out-of-pocket expenses actually incurred in shipping the API to Licensee. CanBas will further transfer all right and license to any raw materials, starting materials, intermediates or works in process held at any third party under contract to CanBas.

3.3 Commercial Supply. As between the Parties, Licensee shall have the exclusive right to Manufacture the Licensed Compound or the Licensed Product in and for the Territory. Licensee may elect to Manufacture commercial supplies of the Licensed Compound or the Licensed Product itself or through its Affiliates or Third Party suppliers (including Sublicensees). Licensee agrees to comply, and use reasonable efforts to cause its Affiliates or Third Party suppliers (including Sublicensees) to comply, with separate agreements governing confidentiality, quality and volume controls, and purchasing obligations/restrictions with all Affiliates or Third Party suppliers (including Sublicensees) to be engaged in the Manufacture of the Licensed Compound or the Licensed Product. CanBas will introduce Licensee to CanBas's current contract manufacturers of the Licensed Compound and the Licensed Product and hereby consents to such parties performing Manufacturing or related services for Licensee should Licensee, in its sole discretion, elect to so engage such parties. *

*Confidential material redacted and filed separately with the Commission.

ARTICLE IV
TECHNICAL ASSISTANCE

4.1 Technical Assistance. At Licensee's written request, CanBas agrees to provide technical assistance to Licensee in connection with the performance of the Manufacturing activities contemplated in this Article III at reasonable cost basis (including actual payment to a third party contractors).

ARTICLE V
COMMERCIALIZATION

5.1 Commercialization of the Licensed Product.

5.1.1. In General. As between the Parties, Licensee shall have the exclusive right to Commercialize the Licensed Compound and Licensed Product in the Territory, in compliance with this Agreement and Applicable Law.

5.1.2. Commercialization Obligations. Licensee, directly or through one or more of its Affiliates, Sublicensees or Distributors, shall use Commercially Reasonable Efforts to Commercialize a Licensed Product in the Field and in the Territory.

5.2 Promotional Materials and Activities.

5.2.1. In General. As between the Parties, Licensee shall have the exclusive right, at its sole expense, for preparing all promotional materials used to support the Commercialization of the Licensed Product in the Territory. Each Party shall ensure that all its promotional materials shall be consistent with Applicable Law and with the approved Product Labeling for the Licensed Product. As between the Parties, Licensee shall have the exclusive right to obtain any approvals from the Regulatory Authorities required for the use of any promotional materials in the Territory and shall submit all applicable promotional materials to such Regulatory Authorities as required by Applicable Law.

5.3 Unauthorized Sales.

5.3.1. Unauthorized Sales by Licensee. Licensee (a) shall, and shall cause its Affiliates, Sublicensees and Distributors to, distribute, market, promote, offer for sale and sell the Licensed Product only in the Territory to the extent consistent with Applicable Law, and (b) shall not, and shall not permit its Affiliates and shall use commercially reasonable efforts to not permit Sublicensees or Distributors to, distribute, market, promote, offer for sale or sell the

Licensed Product (i) to any Person outside the Territory or (ii) to any Person inside the Territory that Licensee, or its Affiliates, Sublicensees or Distributors, as applicable, knows (A) is likely to distribute, market, promote, offer for sale or sell the Licensed Product outside the Territory or assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold the Licensed Product outside the Territory or assisted another Person to do so. Such commercially reasonable efforts with respect to Sublicensees and Distributors shall include obtaining their written agreement to an undertaking at least as restrictive with respect to such Sublicensees and Distributors as the preceding sentence is with respect to Licensee and its Affiliates. If Licensee, its Affiliates or any Sublicensees or Distributors receives any orders for the Licensed Product for an area outside the Territory, such orders shall be referred to CanBas.

5.3.2. Unauthorized Sales by CanBas. CanBas (a) shall, and shall cause its Affiliates and CanBas Licensees and CanBas Distributors to, distribute, market, promote, offer for sale and sell the Licensed Product only outside of the Territory to the extent consistent with Applicable Law, and (b) shall not, and shall not permit its Affiliates and shall use commercially reasonable efforts to not permit CanBas Licensees or CanBas Distributors to, distribute, market, promote, offer for sale or sell the Licensed Product (i) to any Person inside the Territory or (ii) to any Person outside of the Territory that CanBas, or its Affiliates, CanBas Distributors or CanBas Licensees, as applicable, knows (A) is likely to distribute, market, promote, offer for sale or sell the Licensed Product insider the Territory or assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold the Licensed Product inside the Territory or assisted another Person to do so. Such commercially reasonable efforts with respect to CanBas Licensees and CanBas Distributors shall include obtaining their written agreement to an undertaking at least as restrictive with respect to such CanBas Licensees and CanBas Distributors as the preceding sentence is with respect to CanBas and its Affiliates. If CanBas, its Affiliates or any CanBas Licensees or CanBas Distributors receives any orders for the Licensed Product for an area is the Territory, such orders shall be referred to Licensee.

5.4 Reporting. Each Party will prepare and provide to the other Party an annual report of each Regulatory Approval of a Licensed Product in the Territory (as relates to Licensee) and outside the Territory (as relates to CanBas). Licensee's report will include sufficient detail to enable CanBas to assess Licensee's compliance with its Commercialization obligations in Section 5.1.2 during the preceding year. Notwithstanding the foregoing, if during the most recent Joint Development Committee meeting sufficient detail in writing was provided, as determined by the reasonable judgment of the recipient Party, no annual report shall be required in that year. The content of such reports shall be deemed Confidential Information of the providing Party hereunder, and the other Party shall not use any information learned by it or disclosed to it pursuant to this Section 5.4 except, in the case of CanBas, as reasonably necessary to assess and enforce Licensee's compliance with Section 5.1.2.

5.5 Cooperation. Subject to Section 2.2.3, each Party shall provide reasonable cooperation to the other Party as necessary to enable such other Party to respond to inquiries relating to the Licensed Compound or the Licensed Product received from Regulatory Authorities in the Territory, in the case of Licensee, or outside the Territory, in the case of CanBas.

ARTICLE VI
GRANT OF RIGHTS

6.1 License Grants.

6.1.1. Grants to Licensee. Subject to the terms and conditions of this Agreement, including Section 6.2, CanBas (on behalf of itself and its Affiliates and CanBas Licensees) hereby grants to Licensee and its Affiliates a perpetual, irrevocable, royalty-bearing license, in accordance with the terms of this Agreement, with the right to grant sublicenses (through multiple tiers) in accordance with Section 6.3, under (a) the CanBas Patents and the CanBas Know-How, and (b) under the Regulatory Documentation Controlled by CanBas, any of its Affiliates or CanBas Licensees (including rights of reference in accordance with Section 6.3), in both cases ((a) and (b)), to Exploit the Licensed Compound and the Licensed Product in the Field in the Territory. The foregoing license shall be: (i) exclusive (even as to CanBas, its Affiliates and CanBas Licensees) for all activities in the Territory other than Manufacturing. With respect to Manufacturing, the license shall be exclusive (except as to CanBas and its Affiliates and Licensees and their Affiliates) in the Territory and non-exclusive outside the Territory. For avoidance of doubt, CanBas expressly reserves the right to Manufacture, and/or cause CanBas's Affiliates and CanBas Licensees and their Affiliates to Manufacture, Licensed Compound or the Licensed Product in the Territory exclusively for the purpose of development and marketing Licensed Product outside of the Territory.

6.1.2. Grants to CanBas. Subject to the terms and conditions of this Agreement, including Section 6.2, Licensee (on behalf of itself and its Affiliates) hereby grants to CanBas and its Affiliates, the exclusive (including with regard to Licensee, its Affiliates and Sublicensees), royalty-free license, with the right to grant sublicenses (through multiple tiers) in accordance with Section 6.3, under (a) the improvements or additions to the CanBas Patents and the CanBas Know-How Controlled by Licensee, and (b) under the Regulatory Documentation Controlled by Licensee or any of its Affiliates (including rights of reference in accordance with Section 6.3), in both cases ((a) and (b)), to Exploit the Licensed Compound and the Licensed Product in the Field outside the Territory. Immediately upon termination, regardless of reason, the license granted pursuant to Section 6.1.2 hereunder shall become a perpetual, irrevocable, and royalty-free license, both in and outside the Territory, with the right to grant sublicenses.

6.2 Retention of Rights. Notwithstanding anything to the contrary in this Agreement, as between the Parties, CanBas and its Affiliates retain all rights (subject to Section 6.1.2) to Exploit the Licensed Compound or the Licensed Product outside the Territory.

6.3 Sublicenses.

6.3.1. In General. The rights and licenses granted to Licensee and its Affiliates under Section 6.1 shall include the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, to Sublicensees or CanBas Sublicensees, respectively, (as part of any license agreements, co-promotion agreements, supply agreements or otherwise). Any such permitted sublicenses shall be consistent with and subject to the terms and conditions of this Agreement. Each Party shall provide advance notification to the other Party, in writing, of any prospective sublicense and the name of subject sublicensee(s).

6.3.2. Surviving Sublicensees. Each sublicense granted to a Sublicensee under any rights licensed hereunder shall terminate immediately upon the termination of the applicable license from CanBas to Licensee with respect to such rights, provided that such sublicensed rights shall not terminate if, as of the effective date of such termination by CanBas such Sublicensee is not in material breach of its obligations to Licensee or its applicable Affiliate under its sublicense agreement, and within thirty (30) days of such termination such Sublicensee agrees in writing to be bound directly to CanBas under a license agreement substantially similar to this Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee for Licensee (each such surviving Sublicensee, a **"Surviving Sublicensee**").

6.4 Use of Trademarks and Corporate Names.

6.4.1. Trademarks. As between the Parties, and subject to the reciprocal grants below, Licensee shall have the sole right to determine and own the Stemline Trademarks to be used with respect to the Commercialization of the Licensed Compound and Licensed Product in the Territory and CanBas shall have the sole right to determine and own the CanBas Trademarks to be used with respect to the Commercialization of the Licensed Compound and Licensed Product outside the Territory.

6.4.2. Stemline Trademarks. Licensee hereby grants to CanBas a royalty free, non-exclusive license (with the right to sublicense) to the Stemline Trademarks listed in Exhibit C hereto, and as amended, during the term of this Agreement, in connection with the manufacture, sale, distribution, advertising, and promotion of the Licensed Compound or the Licensed Product outside of the Territory in the manner provided by this Agreement. This license excludes the right to sell, distribute, advertise and promote the Licensed Product in the Territory via e-commerce. No right, express or implied, is granted to CanBas to transfer the right to use the Licensee Trademarks to third parties, and any such right is expressly withheld from this Agreement.

6.4.3. CanBas Trademarks. CanBas hereby grants to Licensee a royalty free, non-exclusive license, with the right to sublicense, subject to any reservations contained herein, and all of the terms contained in this Agreement, to use the CanBas Trademarks listed in Exhibit A hereto, and as amended, during the term of this Agreement, in the Territory, in connection with the manufacture, sale, distribution, advertising, and promotion of the Licensed Compound or the Licensed Product in the manner provided by this Agreement. This license excludes the right to sell, distribute, advertise and promote the Licensed Compound or the Licensed Product outside the Territory via e-commerce. No right, express or implied, is granted to Licensee to transfer the right to use the CanBas Trademarks to third parties, and any such right is expressly withheld from this Agreement.

6.4.4. Corporate Names. With respect to any Corporate Names licensed to Licensee and its Affiliates under Section 6.1.2, Licensee agrees to comply, and cause its Affiliates to comply, with the customary guidelines of CanBas with respect to manner of use (as provided in writing by CanBas), and to maintain the quality standards of CanBas with respect to the goods sold and services provided in connection with CanBas's Corporate Names.

ARTICLE VII
CONSIDERATION

7.1 Payments.

(i) **Initial Payment**. Licensee shall make an initial non-refundable payment to CanBas (the "Initial Payment") totaling *Japanese Yen (*) upon the Effective Date.

7.1.2. Technical Advisory Fees.

(i) *

7.1.3. Contingent Payments.

(i) *

7.2 Royalties. Subject to Section 7.3 and the other terms and conditions of this Agreement, in partial consideration of the licenses and other rights granted herein, Licensee shall pay to CanBas in cash, royalties based on aggregate Net Sales of such Licensed Product in the Territory during such Calendar Year at the rates set forth below:

7.2.1. as to each Licensed Product and each country in the Territory:

(i) for sales of Licensed Product by Licensee, Licensee's Affiliates and their respective Distributors:

(A) * percent (*%) of annual Net Sales of Licensee and its Affiliates up to *Dollars ($*USD) in any Calendar Year;

(B) * percent (*%) of annual Net Sales of Licensee and its Affiliates over * Dollars ($ * USD) up to * Dollars ($*) in any Calendar Year;

(C) * percent (*%) of Net Sales of Licensee and its Affiliates over * Dollars ($*) up to * Dollars ($* USD) in any Calendar Year; and

(D) * percent (*%) of Net Sales of Licensee and its Affiliates over * Dollars ($* USD) in any Calendar Year

provided, however, (a) that if Licensee is required, in Licensee's reasonable discretion, to make payments to one or more Third Parties in order to Exploit the Licensed Compound or the Licensed Product, Licensee may offset up to * percent (*%) of such Third-Party payments against royalty payments due to CanBas, provided that such offset may not reduce any single royalty payment by more than * percent (*%), and (b) that any royalties are payable to CanBas, as determined on a country-by-country basis, until the latest date of: (i) the date upon which there are no more Valid Claims, (ii) the expiration or termination of the last Regulatory Exclusivity Period pertaining to the Licensed Product in such country, and (iii) the tenth (10^{th}) anniversary of the First Commercial Sale of such Licensed Product in such country.

(ii) Additional Royalty. On a country by country basis, an additional

*Confidential material redacted and filed separately with the Commission.

royalty in addition to the Royalty described in 6.2.1(i) shall apply if, and only if, prior to the end of a Phase I clinical trial, Licensee sublicenses the Licensed Product in a country in the Territory ("Additional Royalty"). The Additional Royalty for that country shall be calculated as follows:

(A) *

Notwithstanding the foregoing, the Additional Royalty for any given period shall be capped at an amount so that CanBas shall never receive greater than * percent (*%) of the royalty received by Licensee from the relevant Sublicensee.

7.3 Royalty Term. Licensee's obligations to pay royalties under this ARTICLE VII shall terminate, on a country-by-country basis and Licensed Product-by-Licensed Product basis pursuant to 7.2. Upon the termination of Licensee's royalty obligations with respect to a Licensed Product in a country, the license grants to Licensee contained in Section 6.1 shall become fully paid-up, royalty-free, perpetual and irrevocable for such Licensed Product in such country.

7.4 Royalty Payments. Running royalties based upon the Net Sales during a * shall be payable by Licensee on a * basis, within * of the following *.

7.5 Royalty Statements. Licensee shall use Commercially Reasonable Efforts to provide to CanBas, within *, but in no case more than * following the end of the relevant *, a statement showing (a) invoiced sales and Net Sales during the relevant *, (b) the number of units of Licensed Product sold on a country-by-country basis during such *, (c) a detailed breakdown of any deductions from the invoiced sales and (d) the amount of royalties due on such Net Sales.

7.6 Mode of Payment. All cash payments to CanBas under this Agreement shall be made by wire transfer of United States Dollars (or Japanese Yen if denominated as such hereunder) in the requisite amount to such bank account as CanBas may from time to time designate by notice to Licensee. Bank handling charges shall be borne by Licensee. With respect to sales outside the United States, payments shall be calculated based on currency exchange rates for the relevant Calendar Quarter, as follows. For each Calendar Quarter and each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates for each Business Day in such Calendar Quarter as set forth in *The Wall Street Journal*, Eastern Edition or, if not available, as otherwise agreed by the Parties. For any late payments, Licensee shall pay interest in arrears at the rate of *% per annum.

7.7 Taxes.

7.7.1. *

7.7.2. *

7.8 Financial Records. Licensee shall, and shall cause its Affiliates, Sublicensees and Distributors to, keep reasonably complete and accurate books and records pertaining to the Commercialization of the Licensed Product, including books and records of the invoiced sales (including any deductions therefrom) and Net Sales, in sufficient detail to calculate the royalties payable under this Agreement. Such books and records shall be retained by Licensee, its Affiliates, Sublicensees and Distributors, until * (*) years after the end of the period to which such books and records pertain.

*Confidential material redacted and filed separately with the Commission.

7.9 **Audit**. At the request of CanBas, Licensee shall, and shall cause its Affiliates, its Sublicensees and Distributors, to permit an independent certified accountant selected by CanBas and acceptable to Licensee, during normal business hours and upon reasonable advance notice, to examine the books and records maintained pursuant to Section 7.8. Such examinations may not (i) be conducted for any * more than *after the end of such *, (ii) be conducted more than once in any * period or (iii) be repeated for any *. Further, (a) all results and the basis for such results of such accountant's audit shall be deemed Confidential Information of Licensee hereunder and (b) CanBas shall not use any information learned by it or disclosed to it pursuant to this Section 7.9 except as reasonably necessary to assess and enforce Licensee's compliance with this ARTICLE VII. Except as provided below in Section 7.10, the cost of this examination shall be borne by CanBas, unless the audit reveals a variance of more than * percent (*%) or * Dollars ($* USD), whichever is greater, from the reported amounts, in which case Licensee shall bear any out-of-pocket costs of CanBas for the audit. Unless disputed pursuant to Section 7.10, if such audit concludes that additional payments were owed or that excess payments were made during such period, Licensee shall pay the additional royalties or CanBas shall reimburse such excess payments, within * after the date on which such auditor's written report is delivered to the Parties, unless either Party disputes such report pursuant to Section 7.10.

*Confidential material redacted and filed separately with the Commission.

7.10 Audit Dispute. In the event of a dispute regarding the results of an audit conducted pursuant to Section 7.9, including the amount of royalties owed to CanBas under this ARTICLE VII, CanBas and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days after receipt of the auditor's written report delivered pursuant to Section 7.9, the dispute shall be submitted for arbitration to a certified public accounting firm selected by each Party's certified public accountants (and different from the one that conducted the applicable audit) or to such other Person as the Parties shall mutually agree (the "**Arbitrator**"). The decision of the Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be allocated between the Parties in such manner as the Arbitrator shall determine. Not later than ten (10) days after such decision, the Parties shall pay or reimburse each other as contemplated by the last sentence of Section 7.9.

7.11 Confidentiality. The receiving Party shall treat all information subject to review under this ARTICLE VII in accordance with the confidentiality provisions of ARTICLE XI and the Parties shall cause any auditor or Arbitrator to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such auditor or Arbitrator, as the case may be, to keep all such financial information confidential, subject to the reporting obligations of the auditor or Arbitrator under Section 7.9 or 7.10, respectively.

7.12 Blocked Payments. In the event that, by reason of Applicable Law in any country, it becomes impossible or illegal for Licensee to transfer, or have transferred on its behalf, Payments owed CanBas hereunder, Licensee shall promptly notify CanBas of the conditions preventing such transfer and such Payments shall be deposited in local currency in the relevant country to the credit of CanBas in a recognized banking institution designated by CanBas or, if none is designated by CanBas within a period of thirty (30) days after receipt of such notice, in a recognized banking institution selected by Licensee and notified to CanBas.

ARTICLE VIII
INTELLECTUAL PROPERTY

8.1 Ownership of Intellectual Property.

8.1.1. Ownership of Technology. Subject to the licenses and rights of reference granted in Section 6.1, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all: (a) inventions or other Information that is conceived, discovered, developed or otherwise made, by or on behalf of such Party or its Affiliates or, in the case of Licensee, Sublicensees, or, in the case of CanBas, CanBas Licensees and sublicensees, under or in connection with this Agreement or the Development or Commercialization of Licensed Compound or Licensed Product, whether or not patented or patentable, and any and all Patent and Intellectual Property Rights claiming or covering the same, and (b) other Information or other inventions and Patent and Intellectual Property Rights that are owned or otherwise Controlled (other than pursuant to the license grants set forth in Section 6.1) by such Party, its Affiliates, its licensees or its sublicensees. If any Patents identified in clause (a) arise in a manner such that both Parties are joint owners thereof, then notwithstanding the foregoing and Section 8.1.2, the Parties shall agree on terms by which the Parties shall Exploit such Patents in a manner consistent with the licenses and other rights and obligations set forth in this Agreement.

This Agreement shall be understood to be a joint research agreement in accordance with 35 U.S.C. § 103(c)(3) to Develop and Commercialize Licensed Compound and Licensed Product.

8.1.2. Ownership of Patents and Know-How. Without limitation of Section 8.1.1, subject to the licenses and rights of reference granted under Section 6.1, as between the Parties, CanBas shall own and retain all right, title and interest in and to all CanBas Patents and CanBas Know-How. As between the Parties, Licensee shall own and retain all right, title and interest in and to any Stemline Trademarks (subject to Section 8.1.4) used in Commercializing the Licensed Product in the Territory. Licensee's use of any CanBas Trademark in the Territory is expressly subject to the reservations contained herein.

8.1.3. Ownership of Regulatory Documentation and Approvals. Subject to the licenses and rights of reference granted hereunder, as between the Parties, each Party shall own all right, title and interest in and to any Regulatory Approvals granted to, and any Regulatory Documentation developed by, or on behalf of such Party, its Affiliates, or, in the case of Licensee, the Sublicensees, or in the case of CanBas, the CanBas Licensees.

8.1.4. Ownership of Corporate Names. As between the Parties, each Party shall retain all right, title and interest in and to its Corporate Names and agrees that it shall not attack, dispute or contest the validity of or ownership of the other Party's Corporate Names or any registrations issued or issuing with respect thereto. Each Party expressly acknowledges and agrees that no ownership rights are vested or created by the limited rights of use granted pursuant to Section 6.1.2 and that all use of the Corporate Names in accordance therewith, including any goodwill generated in connection therewith, inures to the benefit of the respective owner of the Corporate Names and the owner of such Corporate Names may request and receive a confirmatory assignment thereof.

8.2 Maintenance and Prosecution of Patents and Trademarks.

8.2.1. CanBas Patents. Subject to Section 8.2.3, Licensee, through patent attorneys or agents of its choice and at Licensee's sole cost and expense, shall (a) be responsible for obtaining, prosecuting (including any interferences, oppositions, reissue proceedings and re-examinations) and maintaining the CanBas Patents listed in Exhibit A as of the Effective Date in the Territory; and (b) have the sole right (but not the obligation) to obtain, prosecute and maintain any Patents that become CanBas Patents in the Territory after the Effective Date. CanBas shall update Exhibit A from time to time upon Licensee's reasonable request. Licensee shall have the sole right to prepare, file, prosecute and maintain Patent applications in the Territory to seek Patent rights for any patentable CanBas Know-How as far as such prosecution would not adversely affect the intellectual property rights of CanBas including the right to make similar filings outside the Territory. CanBas shall at the request and cost of Licensee do all such acts and execute all such documents as may be necessary to (i) authorize Licensee to prosecute the relevant CanBas Patent(s) in the Territory and (ii) assist Licensee with the prosecution and maintenance of the CanBas Patent(s) in the Territory.

8.2.2. Licensee shall not become an assignee of any such Patent application or any such Patent as a result of its continuing the prosecution of a Patent application or paying any fees according to this Section 8.2.1, and such Patent shall remain a CanBas Patent hereunder.

8.2.3. Cooperation. CanBas shall assist and cooperate with Licensee as Licensee may reasonably request from time to time in connection with its activities set forth in Section 8.2.1. Licensee shall keep CanBas currently informed of all steps to be taken in the preparation and prosecution of all applications filed by it according to this Section 8.2 and shall furnish CanBas with copies of such applications for Patents, amendments thereto and other related correspondence to and from patent offices and, to the extent reasonably practicable, permit CanBas an opportunity to offer its comments thereon before making a submission to a patent office which could materially affect the scope or validity of the patent coverage that may result. CanBas shall offer its comments, if any, promptly, and Licensee shall consider such comments in good faith and shall use reasonable efforts to accommodate such other Party's comments.

8.3 Extensions and Regulatory Exclusivity Periods. The Parties shall cooperate with each other in obtaining any patent term restoration or supplemental protection certificates or their equivalent for the CanBas Patents for Licensed Product, and in listing any such Patents as required by Applicable Law with respect to Regulatory Exclusivity Periods. In the event that elections with respect to patent term restoration for Licensed Product are to be made for any CanBas Patent in the Territory, Licensee shall have the right, upon consultation, and reasonably considering input from, CanBas, to make the election. With respect to filings relevant to any Regulatory Exclusivity Periods or for any CanBas Patent in the Territory, Licensee shall have the right to determine which such Patents to list in the Territory. Each Party shall provide prompt reasonable assistance to the other Party in such activities, including executing such documents as may be required of the Patent owner thereof.

8.4 Enforcement of Patents and Trademarks.

8.4.1. Enforcement Rights and Procedures. In the event that either Party reasonably believes that a Third Party may be infringing any of the CanBas Patents Developing or Commercializing Licensed Product (but no other activities), such Party shall promptly notify the other Party in writing, identifying the alleged infringer and the alleged infringement complained of and furnishing the information upon which such determination is based. CanBas shall have the first right, but not the obligation, through counsel of its choosing, to take any measures it deems appropriate to stop such infringing activities by such Third Party occurring in any part outside the Territory and Licensee shall have the first right, but not the obligation, through counsel of its choosing, to take any measures it deems appropriate to stop such infringing activities by such Third Party occurring in any part in the Territory. With respect to the Stemline Trademarks and CanBas Trademarks licensed to Licensee hereunder and used in Commercializing the Licensed Product in the Territory, Licensee shall have the first right, but not the obligation, through counsel of its choosing, to take any measures it deems appropriate to stop infringing activities by a Third Party in the Territory. With respect to CanBas Trademarks and Stemline Trademarks licensed to CanBas hereunder and used in Commercializing the Licensed Product outside the Territory, CanBas shall have the first right, but not the obligation, through counsel of its choosing, to take any measures it deems appropriate to stop such

infringing activities by such Third Party occurring in any part in the Territory. Upon reasonable request by the enforcing Party, the other Party shall give the enforcing Party all reasonable information and assistance, including allowing the enforcing Party access to the other Party's files and documents and to the other Party's personnel who may have possession of relevant information and, if necessary for the enforcing Party to prosecute any legal action, joining in the legal action as a party at the enforcing Party's sole cost and expense. The other Party shall have the right to participate and be represented in any such action by its own counsel at its sole cost and expense and without reimbursement hereunder. If the other Party elects to so participate or be involved, the enforcing Party shall provide the other Party and its counsel with an opportunity to consult with the enforcing Party and its counsel regarding the prosecution of such action (including reviewing the contents of any non-privileged correspondence, legal papers or other documents related thereto). In the event Licensee fails to exercise its first right to enforce within ninety (90) days following notice of such infringement, or earlier notifies CanBas in writing of its intent not to take commercially appropriate steps to remove any such infringement, then CanBas shall have the right, but not the obligation to do so (at CanBas's sole cost and expense), unless Licensee provides CanBas with a commercially reasonable basis in writing for not taking such steps; provided, however, that if Licensee has commenced negotiations with an alleged infringer for discontinuance of such infringement within such ninety (90) day period, Licensee shall have an additional ninety (90) days to conclude its negotiations before CanBas may bring a legal action against such infringement. Upon reasonable request by CanBas, Licensee shall give CanBas all reasonable information and assistance in connection with such action for infringement.

8.4.2. Defense Rights and Procedures. Licensee shall have the first right, but shall not be obligated, to defend any action or proceeding alleging invalidity or unenforceability of any CanBas Patents in the Territory, at Licensee's sole cost and expense and in a manner intended not to adversely affect the scope or validity of such CanBas Patents. Upon reasonable request by the Licensee, CanBas shall give Licensee all reasonable information and assistance, including allowing Licensee access to CanBas's files and documents and personnel who may have possession of relevant information and, if necessary for Licensee to defend any such action or proceeding, joining in such action or proceeding as a party at its sole cost and expense. CanBas shall have the right to participate and be represented in any such action or proceeding by its own counsel at its sole cost and expense. If CanBas elects to so participate or be involved, Licensee shall provide CanBas and its counsel with an opportunity to consult with Licensee and its counsel regarding the prosecution of such action (including reviewing the contents of any non-privileged correspondence, legal papers or other documents related thereto). In the event Licensee fails to take reasonably diligent action at least ten (10) days before any deadline, or earlier notifies CanBas in writing of its intent not to do so, then CanBas may defend such action or proceeding at its sole cost and expense, with reasonable assistance and information from the non-defending Party as provided above.

8.4.3. Withdrawal. If either Party brings an action under this Section 8.4 and subsequently ceases to pursue or withdraws from such action, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 8.4.

8.4.4. Settlement. No settlement of any action under this Section 8.4 that restricts the scope, or adversely affects the validity or enforceability, of any CanBas Patent or Trademark in the Territory may be entered into by CanBas without the prior written consent of Licensee, such consent not to be unreasonably withheld or delayed; no settlement of any action under this Section 8.4 that restricts the scope, or adversely affects the validity or enforceability, of any CanBas Patent outside of the Territory may be entered into by Licensee without the prior written consent of CanBas, such consent not to be unreasonably withheld or delayed; provided that a sublicense by a Party of a Patent licensed or sublicensed by the other Party hereunder, which sublicense is consistent with the terms hereof, shall not require the prior written consent of such other Party.

8.4.5. Costs and Expenses. Each Party shall bear its own costs and expenses relating to any enforcement or defensive action or proceeding pursuant to Section 8.4.1. Any damages or other amounts collected shall be used to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses and shall not be applied to any costs or expenses which are expressly made not reimbursable hereunder), with any remainder being retained by the Party that pursued such enforcement action; *provided*, *however*, with respect to any amount received by Licensee that is attributable (i) to lost profits in the Territory, Licensee shall pay a royalty to CanBas pursuant to Section 7.1 with respect to the imputed loss in Net Sales, or (ii) to reasonable royalties in the Territory, Licensee shall pay to CanBas a percentage thereof that reasonably reflects CanBas's average share of profits (as between CanBas and Licensee) with respect to Net Sales.

8.5 Potential Third Party Rights.

8.5.1. Third Party Licenses. As between the Parties, and subject to Section 7.2.1, Licensee shall be solely responsible for securing any Third Party licenses that it deems necessary or desirable in connection with the Exploitation of the Licensed Product in the Territory by Licensee or any of its Affiliates or Sublicensees or Distributors, and for any associated license fees, milestones, royalties or other payments due to such Third Party.

8.5.2. Third Party Litigation. In the event of any actual or threatened suit against Licensee or its Affiliates, Sublicensees, Distributors or customers alleging that the Development, Manufacture, marketing, sale, offering for sale, importation, use or other Commercialization of the Licensed Compound or the Licensed Product in the Territory infringes the Patent or Intellectual Property Rights of any Person, Licensee shall at its sole cost and expense (including any damages, royalties or other payments resulting therefrom), assume direction and control of the defense of claims arising therefrom (including the right to settle such claims); provided, however, that no settlement of any action under this Section 8.5.2 that restricts the scope or adversely affects the validity or enforceability of any CanBas Patent or any Intellectual Property Rights of CanBas, any of its Affiliates or CanBas Licensees, may be entered into without the prior written consent of CanBas, such consent not to be unreasonably withheld or delayed (provided that a sublicense by Licensee of a Patent licensed or sublicensed by CanBas hereunder, which sublicense is consistent with the terms hereof, shall not require the prior written consent of CanBas except to the extent required by Section 6.3.1).

8.5.3. Cooperation. In the event that a Third Party institutes a Patent, trade secret or other infringement suit, concerning the Development, Manufacture, marketing, sale, offering for sale, importation, use or other Commercialization of the Licensed Compound or the Licensed Product, against CanBas, Licensee or their respective Affiliates or, in the case of Licensee, Sublicensees, Distributors or Licensee's customers, or, in the case of CanBas, CanBas Licensees, CanBas Distributors or CanBas's customers, during the term of this Agreement, each Party shall, at its own cost and expense, use all reasonable efforts to assist and cooperate with the other Party in connection with the defense of such suit.

ARTICLE IX
COMPLAINTS AND ADVERSE EVENT REPORTING

9.1 Adverse Event Reporting. Each Party shall provide the other Party with all information available to such Party that such other Party may reasonably require to comply with its pharmacovigilance responsibilities under Applicable Law, including notice of any Adverse Drug Experiences from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical trials and commercial experiences with the Licensed Compound or the Licensed Product, whether by such Party, its Affiliates or, in the case of CanBas, CanBas Licensees or CanBas Distributors, or, in the case of Licensee, Sublicensees or Distributors. "**Adverse Drug Experience**" shall mean (a) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity and (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use, or occurring following administration, of the Licensed Compound or the Licensed Product in humans, occurring at any dose, whether expected or unexpected and whether considered related or unrelated to the Licensed Compound or the Licensed Product, including such an event or experience as occurs in the course of the use of the Licensed Compound or the Licensed Product in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected pharmacological or biological therapeutic action of the Licensed Compound or the Licensed Product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. Sections 312.32 or 314.80, or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States.

9.2 Pharmacovigilance. Subject to the terms and conditions of this Agreement, within nine (9) months of the Effective Date, CanBas and Licensee shall discuss and develop mutually acceptable guidelines and procedures for the investigation, exchange, receipt, recordation, communication (as between the Parties) and exchange of Adverse Drug Experience information and all other information regarding matters covered in this ARTICLE IX. Until such guidelines and procedures are set forth in an agreement between the Parties (the "**Data Exchange Agreement**"), the terms of Section 9.1 shall apply. Following the execution of the Data Exchange Agreement, such Section shall cease to apply unless expressly agreed otherwise by the Parties. Such Data Exchange Agreement shall include provisions for the direct and prompt reporting of adverse events to Licensee in the English language by CanBas employees or representatives and vice versa, the recording and maintenance by Licensee of records of all adverse events reported with respect to the Licensed Compound or the Licensed Product in the Field on a worldwide basis in an electronic database, and the establishment of appropriate mechanisms by which CanBas can access such database on a read only basis to comply with

Applicable Law and to perform its responsibilities and exercise its rights under this Agreement; provided, however, that Licensee shall not assume any regulatory compliance responsibilities of CanBas with respect to pharmacovigilance outside the Territory by virtue of its establishment and maintenance of such global database. *

ARTICLE X
PRODUCT RECALLS

10.1 Notification and Recall. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with the Licensed Product or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the Party notified of or desiring such recall or similar action shall, within twenty-four (24) hours, advise the other Party thereof by telephone (and confirmed by email or facsimile), email or facsimile. Licensee shall have the sole right to decide, in its discretion, whether to conduct a recall, at its expense, of the Licensed Product in the Territory, and the manner in which any such recall shall be conducted.

10.2 *.

ARTICLE XI
CONFIDENTIALITY AND NON-DISCLOSURE

11.1 Confidentiality Obligations. This Section 10 hereby supersedes the Confidential Disclosure Agreement entered into on June 10, 2014 by and between CanBas and Licensee. Commencing as of June 10, 2014, throughout the Term of this Agreement and for a period of * following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents to, keep completely confidential and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, before or after the Effective Date, by the other Party or its Affiliates, except to the extent such disclosure or use is expressly permitted by the terms and conditions of this Agreement. "**Confidential Information**" means any information provided by one Party to the other Party relating to the following: the terms of this Agreement; the Licensed Compound or the Licensed Product (including without limitation CanBas Know-How, Regulatory Documentation, Regulatory Approvals and Drug Master Files and any information or data contained therein); any Development or Commercialization of the Licensed Compound or the Licensed Product;

*Confidential material redacted and filed separately with the Commission.

information from any Third Party that a Party has obtained under any non-use or non-disclosure obligations; or the scientific, regulatory or business affairs or other activities of a Party. Notwithstanding the foregoing, Confidential Information shall not include any information that:

11.1.1. is, or hereafter becomes, part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of receiving Party;

11.1.2. can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to said information;

11.1.3. is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to said information;

11.1.4. can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

11.2 Permitted Disclosures. Each Party may disclose Confidential Information received from the other Party to the extent that such disclosure is:

11.2.1. Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by law; provided, however, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

11.2.2. Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information; or

11.2.3. Made by the receiving Party or its Affiliates or sublicensees to their respective directors, employees, contractors, agents, or to Third Parties as may be necessary or useful in connection with the Manufacture or other Exploitation of the Licensed Compound, the Licensed Product, or otherwise in connection with the performance of their obligations or exercise of their rights (including, with respect to CanBas, its rights under Sections 6.2, 6.3or disclosures to its Affiliates and potential or actual CanBas Licensees and CanBas Distributors, and, with respect to Licensee, its rights under Section 6.1, 6.3, or disclosures to its Affiliates and potential or actual Sublicensees and Distributors) as contemplated by this Agreement, including (i) subcontracting and sublicensing transactions with licensees and sublicensees in connection therewith, (ii) permitted acquirers or assignees under Section 15.3, and (iii) investment bankers, investors, lenders, and in each case (clauses (i) to (iii)) their respective directors, employees, contractors and agents; provided, however, that such disclosure may only be made to such Persons as are subject to written obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party set forth in this ARTICLE XI.

11.3 Use of Name. Except as expressly set forth in Sections 6.1.24 or 11.4, neither Party shall mention or otherwise use the name, insignia, symbol, Trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 11.3 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

11.4 Press Releases. Press releases or other similar public communications by either Party relating to this Agreement or the activities described herein shall be subject to a right of prior review and approval by the other Party; provided, however, that such right shall not apply to communications required by Applicable Law, disclosures of information for which consent has previously been obtained, or information that has been previously disclosed publicly, in such event the disclosing Party shall use best efforts to provide the other Party with reasonable advance notice notification.

11.5 Patient Information. The Parties agree to abide (and, in the case of Licensee, to cause its Affiliates, Sublicensees and Distributors to abide, and in the case of CanBas, to cause its Affiliates, CanBas Distributors and CanBas Licensees to abide) and to take (and, in the case of Licensee, to cause its Affiliates and Sublicensees and Distributors to take, and in the case of CanBas, to cause its Affiliates, CanBas Distributors and CanBas Licensees to take) all reasonable and appropriate actions to ensure that all Third Parties conducting or assisting with any clinical development activities hereunder in accordance with, and subject to the terms of, this Agreement, shall abide, to the extent applicable, by all Applicable Law concerning the confidentiality or protection of patient identifiable information and/or patient's protected health information, including the regulations at 45 C.F.R. Parts 160 and 164 and where relevant, the applicable national laws implementing the European Union Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data of 24 October 1995 and any other Applicable Law, in the course of their performance under this Agreement.

11.6 Publications. Each Party shall have the right to review and approve any paper proposed for publication by the other Party, including any oral presentation or abstract: (a) which pertains to results of Clinical Studies, Post Approval Studies or other studies with respect to the Licensed Compound or the Licensed Product; (b) which includes other data generated by either Party or any of its Affiliates or licensees or sublicensees relating to the Licensed Compound or the Licensed Product during the term of this Agreement; or (c) which includes Confidential Information of either Party. Before any such paper is submitted for publication or an oral presentation is made, the submitting Party shall deliver a complete copy of the paper or materials for oral presentation to the other Party ("recipient party") at least thirty (30) days prior to submitting the paper to a publisher or making the presentation. The recipient Party shall review any such paper and give its comments to the submitting Party within fifteen (15) days of the delivery of such paper to recipient Party. With respect to oral presentation materials and abstracts, the recipient Party shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the submitting Party with appropriate comments, if any, but in no event later than fifteen (15) days from the date of delivery to recipient Party. Failure to respond within such fifteen (15) days shall be deemed approval to publish or present. Notwithstanding the foregoing, each Party shall comply with the other Party's request to delete references to Confidential Information in any such paper, and if recipient Party deems it necessary, the submitting Party will withhold publication of any such paper or any presentation of same for an additional sixty (60) days in order to permit recipient Party to obtain patent protection. Any publication shall include recognition of the contributions of recipient Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Both Parties shall use commercially reasonable efforts to cause investigators and institutions participating in Clinical Studies and Post Approval Studies for the Licensed Compound or the Licensed Product with which it contracts to agree to terms substantially similar to those set forth in this Section 11.6, which efforts shall satisfy the Parties' obligations under this Section 11.6 with respect to such investigators and institutions.

ARTICLE XII
REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Execution Date as follows:

12.1.1. Corporate Authority. Such Party (i) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

12.1.2. Litigation. Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities

related to this Agreement have violated or that by conducting the activities as contemplated herein such Party would violate, any Patent or Intellectual Property Rights of any other Person.

12.1.3. Consents and Approvals. All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

12.1.4. Conflicts. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation or bylaws or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

12.2 Additional Representations, Warranties and Covenants of Licensee. Licensee represents, warrants and covenants to CanBas that:

12.2.1. Organization. As of the Execution Date, Licensee is a corporation duly organized under the laws of the State of Delaware and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement. Exhibit D (in the form initially attached hereto) lists all Affiliates of Licensee as of the Execution Date. Licensee shall provide written notice to CanBas in the case of new Affiliates or changes to existing Affiliates, and Exhibit D shall be amended accordingly.

12.2.2. No Debarment. As of the Execution Date, neither Licensee nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA. Neither Licensee nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. Licensee shall inform CanBas in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Licensee's Knowledge, is threatened, relating to the debarment or conviction of Licensee or any Person performing services hereunder.

12.3 Additional Representations, Warranties and Covenants of CanBas. CanBas represents, warrants and covenants to Licensee that:

12.3.1. Organization. As of the Execution Date, CanBas is a corporation duly organized under the laws of Japan and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement. Exhibit B (in the form initially attached hereto) lists all Affiliates of CanBas as of the Execution Date.

12.3.2. No Debarment. As of the Execution Date, neither CanBas nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA.

Neither CanBas nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the Federal Food, Drug, and Cosmetic Act or who is the subject of a conviction described in such section. CanBas shall inform Licensee in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to CanBas's Knowledge, is threatened, relating to the debarment or conviction of CanBas or any Person performing services hereunder.

12.3.3. No Misappropriation or Infringement. As of the Execution Date, to CanBas's Knowledge, except as previously and expressly disclosed to Licensee, (i) the issued Valid Claims included in the CanBas Patents are not invalid or unenforceable, (ii) there is no pending litigation which alleges, and CanBas has not received any written communication alleging, that CanBas's or its Affiliates' activities with respect to the CanBas Patents, the Licensed Compound or the Licensed Product have infringed or misappropriated any Patents or any Intellectual Property Rights of any Third Party, (iii) the conception and reduction to practice of the CanBas Patents have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party, (iv) no Third Party has infringed any CanBas Patents, and (v) all fees required to be paid by CanBas in order to maintain the CanBas Patents have been paid to date, and none of such CanBas Patents have been abandoned or cancelled for failure to prosecute or maintain them. As of the Execution Date, CanBas has disclosed to Licensee all Patents known to CanBas that the Exploitation of the Licensed Compound or the Licensed Product would infringe.

12.3.4. Owned Patents; No Encumbrance. As of the Execution Date, (i) CanBas has not, nor has any of its Affiliates, previously assigned, transferred, licensed, conveyed or otherwise encumbered any of its, or its Affiliates', right, title or interest in or to the CanBas Patents or CanBas Know-How, (ii) none of the CanBas Patents or CanBas Know-How is subject to any security interest, lien or other encumbrance, and (iii) there are no CanBas Licensees or CanBas Distributors. As of the Execution Date, Exhibit A is a complete and accurate list of all Patents owned or otherwise Controlled by CanBas and its Affiliates that would be infringed by Licensee's (or its Affiliates') Development, Commercialization, manufacture, use, sale, offer for sale or importation of the Licensed Compound or the Licensed Product, absent the licenses granted herein. As of the Execution Date, CanBas is the sole and exclusive owner of all right, title and interest in and to the CanBas Patents, including that CanBas has obtained any and all Patent assignments and inventor signatures relating thereto, none of the CanBas Patents, CanBas Know-How or Regulatory Documentation subject to the license grants in Section 6.1 is in- licensed by CanBas or any of its Affiliates, and the grant, use or practice of the licenses granted in Section 6.1 will not trigger any payment obligations of CanBas or any of its Affiliates. None of the CanBas Patents are the subject of any interference, opposition, re-examination or re-issue proceeding as of the Execution Date.

12.3.5. No Encumbrance or Inconsistent Grants. CanBas agrees not to, and agrees to cause its Affiliates and CanBas Licensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the CanBas Patents or CanBas Know-How or any Regulatory Documentation that is subject to the licenses granted in Section 6.1, (ii) grant any license or other right, title or interest in or to any of the foregoing in any manner, or (iii)

agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the foregoing, in each case (clauses (i) to (iii)) to the extent that such action would be inconsistent with the licenses and other rights granted to Licensee and its Affiliates under this Agreement.

12.3.6. Material Adverse Information. As of the Execution Date, there are no scientific or clinical facts known to CanBas or any of its Affiliates that would materially and adversely affect the safety or efficacy of the Licensed Compound or Licensed Product that have not been disclosed to Licensee by CanBas.

12.4 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 12.1, 12.2 AND 12.3, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

12.5 Performance by Affiliates. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates, provided that each Party shall remain responsible and liable for the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection therewith.

ARTICLE XIII
INDEMNITY

13.1 Indemnification of CanBas. Licensee shall indemnify CanBas, its Affiliates and their respective directors, officers, employees, licensors and agents, and their respective successors, heirs and assigns, and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (a) the material breach by Licensee of any term of this Agreement or any violation by Licensee or any of its Affiliates of Applicable Law; (b) any gross negligence or willful misconduct on the part of Licensee in performing its obligations under this Agreement; or (c) the Development, Manufacture, Commercialization or other Exploitation by Licensee or its Affiliates or any Sublicensees or Distributors of the Licensed Compound or the Licensed Product, including any such Third Party Claims relating to any alleged infringement or misappropriation of Patents or Intellectual Property Rights, except in each case (clauses (a) - (c)) for those Losses as to which CanBas has an obligation to indemnify Licensee pursuant to Section 13.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability; provided, however, that Licensee shall not be obligated to indemnify CanBas for any Losses to the extent that such Losses arise as a result of gross negligence or willful

misconduct on the part of CanBas or any of its Affiliates, CanBas Distributors or CanBas Licensees.

13.2 Indemnification of Licensee. CanBas shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns, and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the material breach by CanBas of any term of this Agreement or any violation by CanBas or any of its Affiliates of Applicable Law; (b) any gross negligence or willful misconduct on the part of CanBas in performing its obligations under this Agreement; or (c) the Development, Manufacture, Commercialization or other Exploitation by CanBas or its Affiliates, CanBas Distributors or CanBas Licensees of the Licensed Compound or the Licensed Product, including any such Third Party Claims relating to any alleged infringement or misappropriation of Patents or Intellectual Property Rights, except in each case (clauses (a) - (c)) for those Losses for which Licensee has an obligation to indemnify CanBas pursuant to Section 13.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses; provided, however, that CanBas shall not be obligated to indemnify Licensee for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of Licensee or any of its Affiliates, Sublicensees or Distributors.

13.3 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents, or their respective successors, heirs and assigns, shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Section 13.1 or 13.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

13.4 Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 13.4.1, the indemnifying Party shall not be

liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Third Party Claims incurred by the indemnifying Party in its defense of the Third Party Claim.

13.4.1. Right to Participate in Defense. Without limiting Section 13.4 above, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.4 (in which case the Indemnified Party shall control the defense) or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

13.4.2. Settlement. With respect to any Third Party Claims relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.4.1, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld or delayed.

13.4.3. Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other Indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified

Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

13.4.4. Expenses. Except as provided above in this Section 13.4, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.5 Limitation on Damages and Liability. EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE AND INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES (OR WITH RESPECT TO LICENSEE, ITS SUBLICENSEES OR DISTRIBUTORS, OR WITH RESPECT TO CANBAS, THE CANBAS DISTRIBUTORS OR CANBAS LICENSEES), OR WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTION 13.1 OR 13.2, NO PARTY OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR FOR LOST PROFITS OR ROYALTIES, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, INCLUDING WITH RESPECT TO ANY LIABILITY ARISING OUT OF (a) THE DEVELOPMENT, MANUFACTURE, USE OR SALE OF THE LICENSED PRODUCT OR LICENSED COMPOUND UNDER THIS AGREEMENT, (b) THE PRACTICE OF THE CANBAS PATENTS, CANBAS KNOW-HOW, (c) REFERENCE TO THE REGULATORY DOCUMENTATION OR THE DRUG MASTER FILE, OR (d) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT.

13.6 Insurance. Each Party shall have and maintain such types and amounts of liability insurance covering the Manufacture, development, use and sale of the Licensed Compound or the Licensed Product as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and shall upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

ARTICLE XIV
TERM AND TERMINATION

14.1 Term. This Agreement shall take effect upon the last date written below (the "**Effective Date**") and shall continue in each country in the Territory (on a country-by-country basis) until such time as Licensee no longer owes any royalty payments under this Agreement with respect to such country, unless earlier terminated by mutual agreement of the Parties, or otherwise in accordance with this ARTICLE XIV.

14.2 Termination for Material Breach. In the event that either Party (the "**Breaching Party**") shall be in material breach in the performance of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party

(the "**Complaining Party**") may have, the Complaining Party may terminate this Agreement in its entirety upon * prior written notice (the "**Notice Period**") to the Breaching Party, specifying the breach and its claim of right to terminate, provided, however, that the Notice Period shall be * in the case of a material breach by Licensee of its Diligence Obligations, subject to the condition that Licensee shall commence action to cure such breach within * after receipt of such notice and shall diligently continue such actions thereafter. Notwithstanding the foregoing, the Notice Period shall be * in the case of any payment breach by Licensee. Such termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach during the Notice Period; provided, however, that such termination shall not become effective at the end of the Notice Period (i) in the case of a payment breach, if the Breaching Party pays any undisputed portion of such payment and initiates the dispute resolution process under Section 15.6 with respect to the balance of such payment during the Notice Period, or (ii) in the case of any other breach (including of the Diligence Obligations), if the dispute resolution process set forth in Section 15.6 has been initiated, and in each case ((i) and (ii)) the Breaching Party shall have the right to cure any such material breach, if any, still outstanding at the end of such process for a period equal in duration to the cure period specified above, less the elapsed time between the receipt of notice of termination and the initiation of such dispute resolution process. For the avoidance of doubt, the dispute resolution process in this context refers only to the * period of time provided to the Chief Executive Officer of CanBas and the Chief Executive Officer of Licensee for resolution and not to arbitration proceedings. The Parties acknowledge and agree that the failure by Licensee to use Commercially Reasonable Efforts to Develop and Commercialize the Licensed Product pursuant to Sections 2.1.4 and 5.1.2 (collectively, the "**Diligence Obligations**"), respectively, for a period of more than *, and expressly including failure to meet any Reference Milestones for a period of more than * immediately following the relevant Reference Date, shall constitute a material breach of this Agreement. In the event of a Material Breach due to failure to meet a Reference Milestone and/or Reference Date where such References Date and/or Reference Milestone has not been amended pursuant to Section 2.1.3, Licensee may extend the relevant Reference Date once only by up to * by paying to CanBas a one-time upfront fee in cash calculated at $* USD per month (e.g., $* if the Reference Date is extended by * (*) months). Termination of this Agreement by CanBas under this Section 14.2 shall be on a country-by-country and Licensed Product-by-Licensed Product basis (and not for this Agreement as a whole) if the material breach giving rise to termination is reasonably specific to one or more countries or one or more Licensed Products (e.g., a royalty dispute for one Licensed Product in one or more countries).

Upon termination, the Breaching Party shall cease any activity under this Agreement and each Party shall return as soon as reasonably practicable all Confidential Information received from the other Party (provided that one archival copy may be retained solely for such Party to monitor its compliance with its obligations under this Agreement); provided, however, that such Confidential Information shall not include CanBas's return of information related to Development or use for Development inside and outside the Territory.

The licenses granted to CanBas under Section 6.1 shall survive such termination and shall stay in full force and effect. Licensee agrees to transfer any INDs, API, and supporting data at no cost to CanBas.

*Confidential material redacted and filed separately with the Commission.

In order to ensure the smooth transition of the development and/or commercialization of any Licensed Compound or Licensed Product from Licensee to CanBas or a Third Party designated by CanBas, promptly after receipt by either Party of written notice, representatives of Licensee and CanBas will meet to negotiate in good faith the terms of a transition plan with respect to all then-current as well as planned activities relating to Licensed Compounds and Licensed Products.

Notwithstanding the foregoing, if there will be any ongoing clinical trials in the Territory at the termination of this Agreement due to the reasons attributable to Licensee, Licensee shall, if so requested by CanBas, use Commercially Reasonable Efforts to complete such ongoing clinical trials notwithstanding the termination of this Agreement, provided that CanBas shall fund all activities and costs associated with such completion (expressly excluding any and all costs incurred by Licensee prior to the termination of this Agreement, which shall be borne by Licensee) and shall indemnify Licensee from any and all claims arising out of such activities, and further provided that Licensee shall have no obligation to complete such trials if (i) the termination of this Agreement was for reasons related to the safety of any Licensed Compound or Licensed Product or (ii) the protocol of the clinical trial clearly allows early termination, in which case Licensee shall have the obligation to complete such trials until the time of such early termination.

14.3 Termination by Licensee

14.3.1. Without Cause. Licensee may terminate the Agreement for any or no reason, upon sixty (60) days' prior written notice to CanBas. Upon such a termination, Licensee shall cease any activity under this Agreement and each Party shall return as soon as reasonably practicable all Confidential Information received from the other Party (provided that one archival copy may be retained solely for such Party to monitor its compliance with its obligations under this Agreement); provided, however, that such Confidential Information shall not include CanBas's return of information related to Development or use for Development inside and outside the Territory. Further, the licenses granted to CanBas under Section 6.1 shall survive such termination and shall stay in full force and effect. Licensee agrees to transfer any INDs, API, and supporting data at no cost to CanBas.

In order to ensure the smooth transition of the Development and/or Commercialization of any Licensed Compound or Licensed Product from Licensee to CanBas or a Third Party designated by CanBas, promptly after receipt by CanBas of such written notice, representatives of Licensee and CanBas will meet to negotiate in good faith the transition plan with respect to all then-current as well as planned activities relating to Licensed Compounds and Licensed Products.

Notwithstanding the foregoing, if there will be any ongoing clinical trials in the Territory at the termination of this Agreement due to the reasons attributable to Licensee (including termination by Licensee pursuant to Section 14.3.1), Licensee shall, if so requested by CanBas, use Commercially Reasonable Efforts to complete such ongoing clinical trials notwithstanding the termination of this Agreement, provided that CanBas shall fund all activities and costs associated with such completion (expressly excluding any and all costs incurred by Licensee prior to the

termination of this Agreement, which shall be borne by Licensee) and shall indemnify Licensee from any and all claims arising out of such activities, and further provided that Licensee shall have no obligation to complete such trials if (i) the termination of this Agreement was for reasons related to the safety of any Licensed Compound or Licensed Product or (ii) the protocol of the clinical trial clearly allows early termination, in which case Licensee shall have the obligation to complete such trials until the time of such early termination.

14.3.2 *.

14.4 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Licensee or CanBas or their Affiliates are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties and their respective Affiliates, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterparts thereto. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or such foreign counterpart, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non- subject Party's or its Affiliates' possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

14.5 Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may otherwise be available in law or equity.

14.6 Accrued Rights; Surviving Obligations.

14.6.1. Accrued Rights. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

*Confidential material redacted and filed separately with the Commission.

14.6.2. Survival. Sections 7.9, 7.10, 7.11, 14.6.2, 15.5, 15.6, 15.7, 15.10 and 15.11 and ARTICLES VIII, XI and XIII shall survive the termination or expiration of this Agreement for any reason in accordance with their terms. Except as otherwise expressly provided in this ARTICLE XIV or elsewhere hereunder, upon expiration or termination of this Agreement, all rights and obligations of the Parties shall cease.

ARTICLE XV
MISCELLANEOUS

15.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. In the event that such force majeure event lasts for more than ninety (90) days, such other Party shall have the right to terminate this Agreement upon sixty (60) days written notice to the non-performing Party.

15.2 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on related to the Parties from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

15.3 Assignment. Without the prior written consent of the other Party hereto, neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided*, *however*, that either Party may, without such consent, assign or transfer this Agreement and its rights and obligations hereunder to an Affiliate, or to a successor entity or acquirer in the event of a merger or consolidation (by operation of law or otherwise) or sale of all or substantially all of the assets of such Party to which this Agreement relates; *provided*, *further*, that in the event of an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. In the event that a Party assigns this Agreement, or this Agreement is transferred by operation of law, to a successor entity or acquirer in the event of a merger, consolidation or sale of all or substantially all of such Party's assets, the assignee or transferee shall assume all obligations of such Party hereunder. In

the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to another Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

15.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

15.5 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, however, that any dispute relating to the scope, validity, enforceability or infringement of any legal rights in any Patent or Intellectual Property Rights shall be governed by, and construed and enforced in accordance with, the laws of the jurisdiction in which such right(s) apply. The Parties agree to exclude the application to this Agreement of (i) the United Nations Convention on Contracts for the International Sale of Goods, (ii) the 1974 Convention on the Limitation Period in the International Sale of Goods, and (iii) the Protocol amending the 1974 Convention on the Limitation Period in the International Sale of Goods, done at Vienna April 11, 1980, each as amended or restated.

15.6 Dispute Resolution. If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a **"Dispute**"), other than for matters addressed by Sections 7.9 and 7.10, then either Party shall have the right to refer such Dispute to the Chief Executive Officer of CanBas and the Chief Executive Officer of Licensee who shall confer on the resolution of the issue. Any final decision mutually agreed to by such representatives shall be conclusive and binding on the Parties. If such officers are not able to agree on the resolution of an issue within thirty (30) days after such issue was first referred to them, then all disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with the said Rules. The place of arbitration shall be Tokyo, Japan in the case Licensee files the request for arbitration and New York, NY in the case CanBas files the request for arbitration. The language of the arbitration shall be English. Notwithstanding any of the foregoing in this Section 15.6, Licensee and its Affiliates and Sublicensees shall have the right to continue their Development and Commercialization of Licensed Compound and Licensed Product during the pendency of any Dispute resolution process described above.

15.7 Notices.

15.7.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 15.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 15.7. Such Notice shall be deemed to have been given as of the date delivered by hand or transmitted by electronic transmission (with transmission confirmed) or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by electronic transmission shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 15.7 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms and conditions of this Agreement.

15.7.2. Address for Notice.

If to Licensee, to:
Stemline Therapeutics, Inc.
750 Lexington Ave., 11th Floor
New York, NY 10022
Attention: Chief Executive Officer

with a required copy to:
Goodwin Procter, LLP
Exchange Place
Boston, MA 02109 USA
Attention: Christopher Denn, Esq.

If to CanBas, to:
CanBas Co., Ltd.
2-2-1 Otemachi, Numazu City
Shizuoka 410-0801 Japan
Attention:

with required copies to:
CanBas Co., Ltd.
Legal Department
2-2-1 Otemachi, Numazu City
Shizuoka 410-0801 Japan
Attention:

15.8 Entire Agreement. This Agreement, together with the Exhibits attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.9 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.10 Equitable Relief. The Parties acknowledge and agree that the restrictions set forth in ARTICLE XI are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of ARTICLE XI may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of ARTICLE XI, the non- breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non- breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 15.10 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

15.11 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

15.12 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

15.13 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further

acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.14 Relationship of the Parties. It is expressly agreed that CanBas, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither CanBas, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so, such consent not to be unreasonably withheld or delayed. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.15 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile signatures and such signatures shall be deemed to bind each party hereto as if they were original signature.

15.16 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Exhibit shall mean references to such Article, Section or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

15.17 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

CANBAS, CO. LTD		STEMLINE THERAPEUTICS, INC.	
By:	/s/	By:	/s/ Ivan Bergstein, M.D.
Name:		Name:	Ivan Bergstein, M.D.
Title:		Title:	Chairman, President and Chief Executive Officer

EXHIBIT A

CANBAS PATENTS

*

*Confidential material redacted and filed separately with the Commission.

CANBAS TRADEMARKS

NONE

EXHIBIT B
AFFILIATES OF CANBAS

NONE

EXHIBIT C
STEMLINE TRADEMARKS

NONE

EXHIBIT D
AFFILIATES OF STEMLINE

NONE

EXHIBIT E
*

*Confidential material redacted and filed separately with the Commission.

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Exhibit 10.31

AMENDMENT TO THE
STEMLINE THERAPEUTICS, INC.
2012 EQUITY INCENTIVE PLAN

This Amendment to the Stemline Therapeutics, Inc. 2012 Equity Incentive Plan (the "Plan"), is hereby adopted this 13th day of March, 2015, by the Board of Directors (the "Board") of Stemline Therapeutics, Inc. (the "Company").

W I T N E S S E T H:

WHEREAS, the Company adopted the Plan for the purposes set forth therein; and

WHEREAS, pursuant to Section 11(d) of the Plan, the Board has the authority to amend the Plan; and

WHEREAS, the Board has approved and authorized this Amendment to the Plan and has determined that this Amendment does not require approval of the stockholders of the Company and does not adversely affect the rights of participants under the Plan;

NOW, THEREFORE, BE IT RESOLVED, that the Plan is hereby amended, effective as of the date hereof, in the following particulars:

1.

Section 9 of the Plan is hereby amended by adding the following as a new subsection 9(c):

"(c) Change in Control.

(1) Definition. A "*Change in Control*" shall mean and include the occurrence of any one of the following events but shall specifically exclude a public offering of any class or series of the Company's equity securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended:

(i) during any consecutive 12-month period, individuals who, at the beginning of such period, constitute the Board of Directors of the Company (the "Incumbent Directors") cease for any reason to constitute at least a majority of such Board, provided that any person becoming a director after the beginning of such 12-month period and whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors then on the Board shall be an Incumbent Director; provided, however, that no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to the election or removal of directors ("*Election Contest*") or other actual or threatened solicitation of proxies or consents by or on behalf of any Person other than the Board ("*Proxy Contest*"), including by reason of any agreement intended to avoid or settle any Election Contest or Proxy Contest, shall be deemed an Incumbent Director; or

(ii) any person becomes a "*Beneficial Owner*" (using the meaning given such term in Rule 13d-3 of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended), directly or indirectly, of either (A) 51% or more

of the then-outstanding shares of Stock ("Company Common Stock") or (B) securities of the Company representing 51% or more of the combined voting power of the Company's then outstanding securities eligible to vote for the election of directors (the "Company Voting Securities"); provided, however, that for purposes of this subsection (ii), the following acquisitions of Company Common Stock or Company Voting Securities shall not constitute a Change in Control: (w) an acquisition directly from the Company, (x) an acquisition by the Company or any corporation, limited liability company, partnership or other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company (a "*Subsidiary*"), (y) an acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Subsidiary, or (z) an acquisition pursuant to a Non-Qualifying Event (as defined in subsection (iii) below); or

(iii) the consummation of a reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company or a Subsidiary (a "*Transaction*"), or the sale or other disposition of all or substantially all of the Company's assets (a "*Sale*") or the acquisition of assets or stock of another corporation or other entity (an "*Acquisition*"), unless immediately following such Transaction, Sale or Acquisition: (A) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the outstanding Company Common Stock and outstanding Company Voting Securities immediately prior to such Transaction, Sale or Acquisition beneficially own, directly or indirectly, more than 51% of, respectively, the then outstanding shares of common stock and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the entity resulting from such Transaction, Sale or Acquisition (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets or stock either directly or through one or more subsidiaries, the "*Surviving Entity*") in substantially the same proportions as their ownership, immediately prior to such Transaction, Sale or Acquisition, of the outstanding Company Common Stock and the outstanding Company Voting Securities, as the case may be, and (B) no person (other than (x) the Company or any Subsidiary, (y) the Surviving Entity or its ultimate parent entity, or (z) any employee benefit plan (or related trust) sponsored or maintained by any of the foregoing) is the Beneficial Owner, directly or indirectly, of 51% or more of the total common stock or 51% or more of the total voting power of the outstanding voting securities eligible to elect directors of the Surviving Entity, and (C) at least a majority of the members of the board of directors of the Surviving Entity were Incumbent Directors at the time of the Board's approval of the execution of the initial agreement providing for such Transaction, Sale or Acquisition (any Transaction, Sale or Acquisition which satisfies all of the criteria specified in (A), (B) and (C) above shall be deemed to be a "Non-Qualifying Event").

(2) Consequences of a Change in Control. The provisions of this Subsection 9(c) shall apply in the case of a Change in Control, unless otherwise provided in the Award agreement or any special Plan document or separate agreement with a Participant governing an Award.

(i) Awards Assumed or Substituted by Surviving Entity. With respect to Awards assumed by the Surviving Entity or otherwise equitably converted or

substituted in connection with a Change in Control: if within two years after the effective date of the Change in Control, a Participant's employment is terminated without Cause or the Participant resigns for Good Reason, then (i) all time-based vesting requirements on his or her outstanding Awards shall be deemed to have been satisfied and vested in full, and (ii) unless otherwise provided in the Award agreement, all performance-based vesting requirements on his or her outstanding Awards shall be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the date of termination of employment. Any Awards other than Options or SARs shall pay out within sixty (60) days following the Change in Control (unless a later date is required by Section 11(f) hereof), and any Options or SARs shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Award agreement. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Nonstatutory Stock Options.

(ii) Awards not Assumed or Substituted by Surviving Entity. Upon the occurrence of a Change in Control, and except with respect to any Awards assumed by the Surviving Entity or otherwise equitably converted or substituted in connection with the Change in Control in a manner approved by the Committee or the Board: (i) all time-based vesting requirements on his or her outstanding Awards shall be deemed to have been satisfied and vested in full, and (ii) unless otherwise provided in the Award agreement, all performance-based vesting requirements on his or her outstanding Awards shall be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the Change in Control. Any Awards other than Options or SARs shall pay out within sixty (60) days following the Change in Control (unless a later date is required by Section 11(f) hereof), and any Options or SARs shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Award agreement. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Nonstatutory Stock Options.

(3) Cause. If a Participant is party to an employment, consulting or severance agreement with the Company that contains a definition of "cause" for termination of employment or other relationship, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment or other relationship shall be considered to have been terminated for "Cause" if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(4) Good Reason. "*Good Reason"* as a reason for a Participant's termination of employment or service after a Change in Control shall have the meaning assigned such term in the written employment, severance or similar agreement, if any, between such Participant and the Company; provided, however, that if there is no such written employment, severance or similar agreement in which such term is defined, and unless

otherwise defined in the applicable Award agreement, "Good Reason" shall mean, without the Participant's prior written consent, (A) a material diminution in a Participant's title or duties, or the assignment to a Participant of duties materially inconsistent with his or her authority, responsibilities and reporting requirements, as compared to those in effect immediately prior to the Change in Control, or (B) a material breach by the Company or the Surviving Entity of its obligations to a Participant under any written employment, severance or similar agreement, or (C) the relocation of the Participant's primary work location to a location more than 50 miles from the Participant's primary work location immediately prior to the Change in Control. A Participant may not resign for Good Reason without providing the employer written notice of the grounds that the Participant believes constitute Good Reason and giving the employer at least 30 days after such notice to cure and remedy the claimed event of Good Reason.

2.

Except as specifically set forth herein, the terms of the Plan shall be and remain unchanged, and the Plan as amended shall remain in full force and effect.

The foregoing is hereby acknowledged as being the Amendment to the Stemline Therapeutics, Inc. 2012 Equity Incentive Plan as adopted by the Board on March 13, 2015.

STEMLINE THERAPEUTICS, INC.

By: /s/ Kenneth Hoberman

Its: Chief Operating Officer

Exhibit 10.32

AMENDMENT TO THE
STEMLINE THERAPEUTICS, INC.
AMENDED AND RESTATED 2004 EMPLOYEE, DIRECTOR
AND CONSULTANT STOCK PLAN

This Amendment to the Stemline Therapeutics, Inc. Amended and Restated 2004 Employee, Director and Consultant Stock Plan (the "Plan"), is hereby adopted this 13th day of March, 2015, by the Board of Directors (the "Board") of Stemline Therapeutics, Inc. (the "Company").

W I T N E S S E T H:

WHEREAS, the Company adopted the Plan for the purposes set forth therein; and

WHEREAS, pursuant to Section 30 of the Plan, the Board has the authority to amend the Plan; and

WHEREAS, the Board has approved and authorized this Amendment to the Plan and has determined that this Amendment does not require approval of the stockholders of the Company and does not adversely affect the rights of participants under the Plan;

NOW, THEREFORE, BE IT RESOLVED, that the Plan is hereby amended, effective as of the date hereof, in the following particulars:

1.

The Plan is hereby amended by adding the following as a new Section 33:

"33. CHANGE IN CONTROL.

(1) Definition. A "*Change in Control*" shall mean and include the occurrence of any one of the following events but shall specifically exclude a public offering of any class or series of the Company's equity securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended:

(i) during any consecutive 12-month period, individuals who, at the beginning of such period, constitute the Board of Directors of the Company (the "Incumbent Directors") cease for any reason to constitute at least a majority of such Board of Directors, provided that any person becoming a director after the beginning of such 12-month period and whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors then on the Board of Directors shall be an Incumbent Director; provided, however, that no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to the election or removal of directors ("*Election Contest*") or other actual or threatened solicitation of proxies or consents by or on behalf of any Person other than the Board of Directors ("*Proxy Contest*"), including by reason of any agreement intended to avoid or settle any Election Contest or Proxy Contest, shall be deemed an Incumbent Director; or

(ii) any person becomes a "*Beneficial Owner*" (using the meaning given such term in Rule 13d-3 of the General Rules and Regulations under the Securities

Exchange Act of 1934, as amended), directly or indirectly, of either (A) 51% or more of the then-outstanding shares of Stock ("Company Common Stock") or (B) securities of the Company representing 51% or more of the combined voting power of the Company's then outstanding securities eligible to vote for the election of directors (the "Company Voting Securities"); provided, however, that for purposes of this subsection (ii), the following acquisitions of Company Common Stock or Company Voting Securities shall not constitute a Change in Control: (w) an acquisition directly from the Company, (x) an acquisition by the Company or any corporation, limited liability company, partnership or other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company (a "*Subsidiary*"), (y) an acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Subsidiary, or (z) an acquisition pursuant to a Non-Qualifying Event (as defined in subsection (iii) below); or

(iii) the consummation of a reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company or a Subsidiary (a "*Transaction*"), or the sale or other disposition of all or substantially all of the Company's assets (a "*Sale*") or the acquisition of assets or stock of another corporation or other entity (an "*Acquisition*"), unless immediately following such Transaction, Sale or Acquisition: (A) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the outstanding Company Common Stock and outstanding Company Voting Securities immediately prior to such Transaction, Sale or Acquisition beneficially own, directly or indirectly, more than 51% of, respectively, the then outstanding shares of common stock and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the entity resulting from such Transaction, Sale or Acquisition (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets or stock either directly or through one or more subsidiaries, the "*Surviving Entity*") in substantially the same proportions as their ownership, immediately prior to such Transaction, Sale or Acquisition, of the outstanding Company Common Stock and the outstanding Company Voting Securities, as the case may be, and (B) no person (other than (x) the Company or any Subsidiary, (y) the Surviving Entity or its ultimate parent entity, or (z) any employee benefit plan (or related trust) sponsored or maintained by any of the foregoing) is the Beneficial Owner, directly or indirectly, of 51% or more of the total common stock or 51% or more of the total voting power of the outstanding voting securities eligible to elect directors of the Surviving Entity, and (C) at least a majority of the members of the board of directors of the Surviving Entity were Incumbent Directors at the time of the Board of Directors' approval of the execution of the initial agreement providing for such Transaction, Sale or Acquisition (any Transaction, Sale or Acquisition which satisfies all of the criteria specified in (A), (B) and (C) above shall be deemed to be a "Non-Qualifying Event").

(2) Consequences of a Change in Control. The provisions of this Section 32 shall apply in the case of a Change in Control, unless otherwise provided in the Option Agreement or Stock Grant Agreement or any special Plan document or separate agreement with a Participant governing an Option or Stock Grant.

(i) Awards Assumed or Substituted by Surviving Entity. With respect to any Options or Stock Grants assumed by the Surviving Entity or otherwise equitably converted or substituted in connection with a Change in Control: if within two years after the effective date of the Change in Control, a Participant's employment is terminated without Cause or the Participant resigns for Good Reason, then (i) all time-based vesting requirements for his or her outstanding Options and Stock Grants shall be deemed to have been satisfied and vested in full, and (ii) unless otherwise provided in the Option Agreement or Stock Grant Agreement, all performance-based vesting requirements on his or her outstanding Options and Stock Grants shall be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the date of termination of employment. Any Stock Grants shall pay out within sixty (60) days following the Change in Control, and any Options shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Option Agreement. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Non-Qualified Stock Options.

(ii) Awards not Assumed or Substituted by Surviving Entity. Upon the occurrence of a Change in Control, and except with respect to any Options or Stock Grants assumed by the Surviving Entity or otherwise equitably converted or substituted in connection with the Change in Control in a manner approved by the Committee or the Board of Directors: (i) all time-based vesting requirements for his or her outstanding Options and Stock Grants shall be deemed to have been satisfied and vested in full, and (ii) unless otherwise provided in the Option Agreement or Stock Grant Agreement, all performance-based vesting requirements on his or her outstanding Options and Stock Grants shall be deemed to have been satisfied at the "target" level and vested pro rata based upon the length of time within the performance period that has elapsed prior to the Change in Control. Any Stock Grants shall pay out within sixty (60) days following the Change in Control, and any Options shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Option Agreement. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Non-Qualified Stock Options.

(3) Cause. If a Participant is party to an employment, consulting or severance agreement with the Company that contains a definition of "cause" for termination of employment or other relationship, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant's employment or other relationship shall be considered to have been terminated for "Cause" if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(4) Good Reason. "*Good Reason"* as a reason for a Participant's termination of employment or service after a Change in Control shall have the meaning assigned such term in the written employment, severance or similar agreement, if any, between such

Participant and the Company; provided, however, that if there is no such written employment, severance or similar agreement in which such term is defined, and unless otherwise defined in the applicable Option Agreement or Stock Grant Agreement, "Good Reason" shall mean, without the Participant's prior written consent, (A) a material diminution in a Participant's title or duties, or the assignment to a Participant of duties materially inconsistent with his or her authority, responsibilities and reporting requirements, as compared to those in effect immediately prior to the Change in Control, or (B) a material breach by the Company or the Surviving Entity of its obligations to a Participant under any written employment, severance or similar agreement, or (C) the relocation of the Participant's primary work location to a location more than 50 miles from the Participant's primary work location immediately prior to the Change in Control. A Participant may not resign for Good Reason without providing the employer written notice of the grounds that the Participant believes constitute Good Reason and giving the employer at least 30 days after such notice to cure and remedy the claimed event of Good Reason.

2.

Except as specifically set forth herein, the terms of the Plan shall be and remain unchanged, and the Plan as amended shall remain in full force and effect.

The foregoing is hereby acknowledged as being the Amendment to the Stemline Therapeutics, Inc. Amended and Restated 2004 Employee, Director and Consultant Stock Plan as adopted by the Board of Directors on March 13, 2015.

STEMLINE THERAPEUTICS, INC.

By: /s/ Kenneth Hoberman

Its: Chief Operating Officer

Exhibit 21.1

Stemline Therapeutics, Inc.
List of Subsidiaries

Stemline Therapeutics, Inc. does not have any subsidiaries.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement on Form S-3 No. 333-193726 of Stemline Therapeutics, Inc., and,

(2) Registration Statements on Form S-8 No. 333-188115 of Stemline Therapeutics, Inc.;

of our report dated March 16, 2015, with respect to the financial statements of Stemline Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 16, 2015

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2015

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

Exhibit 31.2

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

I, David G. Gionco, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 16, 2015

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

Exhibit 32.1

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

In connection with the annual report of Stemline Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Ivan Bergstein, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: March 16, 2015

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

Exhibit 32.2

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

In connection with the annual report of Stemline Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, David G. Gionco, Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: March 16, 2015

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