UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10/A

(Amendment No. 1)

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

CHECKPOINT THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-2568632**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2 Gansevoort Street, 9th Floor New York, New York	**10014**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(781) 652-4500**

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

(Title of Class)	(Name of exchange on which registered)
n/a	**n/a**

Securities registered pursuant to section 12(g) of the Act:

(Title of Class)

Common Stock, par value $0.0001 per share

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

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

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this registration statement may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the "Securities Act") and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," and elsewhere in this registration statement. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- our use of clinical research centers and other contractors;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- acceptance of our products by doctors, patients or payors;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- the volatility of our stock price;
- expected losses; and
- expectations for future capital requirements.

The forward-looking statements contained in this registration statement reflect our views and assumptions as of the effective date of this registration statement. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements.

References in this registration statement to "Checkpoint Therapeutics," "Checkpoint," "our company," "we," "us" and "our" refer to Checkpoint Therapeutics, Inc., a Delaware company.

Item 1: Business

OVERVIEW

We are an immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. We aim to acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently we are developing a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute ("Dana-Farber"). The portfolio of antibodies we licensed from Dana-Farber includes antibodies targeting programmed death-ligand 1 ("PD-L1"), glucocorticoid-induced TNFR related protein ("GITR") and carbonic anhydrase IX ("CAIX") (together, the "Dana-Farber Antibodies"). We plan to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as published literature suggests that combinations of these targets may work synergistically together. We expect to submit investigational new drug ("IND") applications for our anti-PD-L1, anti-GITR and anti-CAIX antibodies in 2017. We have also licensed and are developing two oral targeted anti-cancer therapies, consisting of a small molecule inhibitor of poly (ADP-ribose) polymerase ("PARP") and a small molecule inhibitor of epidermal growth factor receptor ("EGFR") mutations. We plan to submit an IND application for our EGFR inhibitor, CK-101, in the first half of 2016, followed by the commencement of a Phase 1/2 clinical study. We are currently developing a clinical program for our PARP inhibitor, CK-102, which we expect to commence in the next six to twelve months. Additionally, we will seek to add additional immuno-oncology drugs as well as other targeted therapies to create wholly-owned proprietary combinations that leverage the immune system and other complimentary mechanisms. To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2015, we have an accumulated deficit of $10.9 million.

In December 2015, we closed on gross proceeds of $57.8 million, before commissions and expenses, in a series of private placement financings. Net proceeds from this offering were approximately $51.5 million. The financing involved the sale of Units, each consisting of 10,000 shares of common stock and a warrant exercisable for 2,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $50,000 per Unit. The warrants have a five year term and are only exercisable for cash. We expect to use the net proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at December 31, 2015, are sufficient to fund our anticipated operating cash requirements for at least the next 24 months.

We are a majority controlled subsidiary of Fortress Biotech, Inc. ("Fortress").

CORPORATE INFORMATION

Checkpoint Therapeutics, Inc. was incorporated in Delaware on November 10, 2014. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com.

We are currently filing for registration under this Form 10 under the Exchange Act and we are not subject to the reporting requirements of section 13(a) or 15(d) of the Exchange Act.

PRODUCTS UNDER DEVELOPMENT

Immuno-Oncology Agents

Anti-PD-L1 Research Program

Our anti-PD-L1 monoclonal antibody is a fully human antagonistic antibody designed to bind to PD-L1 and block its interaction with Programmed cell death protein 1 ("PD-1"). Scientific literature indicates that PD-1 and its ligand PD-L1 are checkpoints of immune activation and play a very important role in negative regulation of T-cell effector function and proliferation. Physiological interaction between these molecules inhibits immune activation to prevent autoimmunity and to induce self-tolerance. Many different cancers take advantage of this pathway by expressing PD-L1 and triggering negative signaling in PD-1 expressing tumor reactive T-cells thus blocking anti-tumor T-cell immune response.

Numerous preclinical and clinical studies of third party products have demonstrated that antibodies that block the interaction of PD-1 with its ligands, PD-L1 and PD-L2, or those that block only the interaction of PD-L1 with PD-1 can augment anti-tumor T-cell responses and lead to complete and lasting tumor eradication in a certain proportion of patients. Confirmed overall response rate ("ORR") in the U.S. Food and Drug Administration ("FDA") labels for the approved PD-1 blocking antibodies was cited in the 20-30% range based on clinical trials in patients with metastatic melanoma. Potent therapeutic anti-tumor responses due to blocking of PD-1/PD-L1 interaction has been demonstrated by these approved products in patients with melanoma, renal cell carcinoma ("RCC") and non-small cell lung cancer ("NSCLC").

We plan to develop an anti-PD-L1 antibody for oncology indications, including, but not limited to, the treatment of patients with NSCLC and RCC, indications where studies of other PD-1/PD-L1 antibodies have shown the potential to be effective. In March of 2015, we entered into a partnership agreement to co-develop an anti-PD-L1 antibody for hematological oncological indications with TG Therapeutics, Inc. ("TGTX"). We believe that an anti-PD-L1 antibody has the potential to be effective in many oncological indications as a monotherapy or in combination with other anti-tumor immune response potentiating compounds and other targeted therapies.

We licensed the exclusive worldwide rights to anti-PD-L1 antibodies from Dana-Farber in March 2015. Currently, we are in preclinical development for this program. In early 2016, we commenced chemistry, manufacturing and control ("CMC") development activities, which include the construction and testing of a production cell line, the development of a manufacturing process for production of the antibody, as well as the development of suitable analytical methods to characterize the antibody. We plan to develop control mechanisms to satisfy Good Manufacturing Practice ("GMP") requirements and scale-up manufacturing in order to conduct the required pharmacology and toxicology studies in the second half of 2016 to support a planned IND application filing in the first half of 2017.

Anti-GITR Research Program

Our anti-GITR monoclonal antibody is a fully human agonistic antibody that is designed to bind and trigger signaling in GITR expressing cells. Scientific literature indicates that GITR is a co-stimulatory molecule of the TNF receptor family and is expressed on activated T cells, B cells, natural killer ("NK") and regulatory T cells ("Treg"). As a co-stimulatory molecule, GITR engagement increases proliferation, activation, and cytokine production of CD4+ and CD8+ T cells**.** Our anti-GITR monoclonal antibody abrogates immunosuppressive activity of natural Treg on expansion of T-effector cells. GITR-specific agonistic monoclonal antibodies under development by third parties have been shown to induce tumor regression in vivo through the activation of CD4+ T cells, CD8+ T cells and NK cells in a number of tumor models.

We plan to develop an anti-GITR antibody for oncology indications, including, but not limited to, the treatment of patients with NSCLC and RCC, indications where scientific literature supports the potential for an anti-GITR to be effective. In March of 2015, we entered into a partnership agreement to co-develop an anti-GITR antibody for hematological oncological indications with TGTX. We believe that an anti-GITR antibody has the potential to be effective in many oncological indications as a monotherapy or in combination with anti-PD-L1 or anti-CAIX as well as other anti-tumor immune response potentiating compounds and other targeted therapies.

We licensed the exclusive worldwide rights to anti-GITR antibodies from Dana-Farber in March 2015. Currently, we are in preclinical development for this program and are in the process of identifying and optimizing a lead anti-GITR antibody to select as a clinical candidate. We plan to commence CMC development, pharmacology and toxicology activities on a lead anti-GITR antibody in the second half of 2016 in order to submit an IND application to the FDA in 2017.

Targeted Anti-Cancer Agents

CK-101 (formerly RX-518) EGFR Inhibitor Program

We are developing CK-101 as an oral, third generation covalent inhibitor against selective mutations of EGFR. Activating mutations in the tyrosine kinase domain of EGFR are found in approximately 20% of patients with advanced NSCLC. Compared to chemotherapy, first generation EGFR inhibitors significantly improved ORR and progression free survival in previously untreated NSCLC patients carrying EGFR mutations. However, tumor progression could develop due to resistance mutations, often within months of treatment with first generation EGFR inhibitors.

The EGFR T790M "gatekeeper" mutation is the most common resistant mutation found in patients treated with first generation EGFR inhibitors. The mutation decreases the affinity of first generation inhibitors to EGFR kinase domain, rendering the drugs ineffective. Second generation EGFR inhibitors have improved in vitro potency against the T790M mutation, but have not provided meaningful benefits in NSCLC patients due to toxicity from the wildtype EGFR activities.

Third generation EGFR inhibitors are designed to be highly selective against the T790M mutation while sparing wildtype EGFR, thereby improving tolerability and safety profiles. Recently, in November 2015, TAGRISSO(TM) (osimertinib), a third generation EGFR tyrosine kinase inhibitor ("TKI") developed by AstraZeneca that specifically targets the T790M mutation, received accelerated FDA approval for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR TKI therapy. The approval of TAGRISSO was based on an objective response rate of 59% in a pooled analysis of 411 patients in two single arm trials. In addition, third generation TKIs, including CK-101, have shown potential activity, pre-clinically, against activating EGFR mutations seen in first-line NSCLC patients such as L858R and del 19.

We plan to develop CK-101 for the treatment of various advanced and metastatic solid tumor cancers, including, but not limited to, the treatment of NSCLC patients carrying the susceptible EGFR mutations. These include the EGFR T790M mutation in second-line NSCLC patients as well as the EGFR L858R and del 19 mutations in first-line NSCLC patients. We believe that CK-101 has the potential to be effective in these oncological indications as a monotherapy or in combination with other anti-tumor immune response potentiating compounds and other targeted therapies. Existing preclinical data from other programs support the combination of third generation EGFR inhibitor with checkpoint inhibitors (PD-1 or PD-L1), cMET inhibitors, or MEK inhibitors.

In March 2015, we entered into an exclusive license agreement with NeuPharma, Inc. ("NeuPharma") to develop and commercialize novel covalent third generation EGFR inhibitors on a worldwide basis outside of certain Asian countries. We have substantially completed the CK-101 CMC development, and in-life portions of the pharmacology and toxicology programs required to file an IND application with the FDA, including the 28-day repeat dose toxicity studies in rats and dogs conducted under Good Laboratory Practices. In June 2016, following the manufacture of a GMP drug product batch, including one month stability data, we plan to submit an IND application to the FDA, to be followed by the initiation of a Phase 1/2 clinical study in advanced solid tumor cancers.

CK-102 (formerly CEP-9722) PARP Inhibitor Program

In December 2015, we obtained the exclusive worldwide rights to develop and commercialize CK-102 (formerly CEP-9722) from Teva Pharmaceutical Industries Ltd., through its subsidiary, Cephalon, Inc. CK-102 is an oral, small molecule selective inhibitor of PARP-1 and PARP-2 enzymes in early clinical development for solid tumors.

PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, and DNA repair. DNA repair enzymes such as PARP, whose activity and expression are up-regulated in tumor cells, are believed to contribute to resistance and dampen the effects of chemotherapy and radiation. By inhibiting PARP, certain cancer cells may be rendered unable to repair single strand DNA breaks, which in turn causes double strand DNA breaks and can lead to cancer cell death. Across multiple tumor types, including breast, ovarian and prostate cancer, PARP inhibitors have shown promising activity as a monotherapy against tumors with existing DNA repair defects, such as BRCA1 and BRCA2, and as a combination therapy when administered together with anti-cancer agents that induce DNA damage.

In November 2010, the licensor of CK-102 submitted an IND application to the FDA for CK-102 for the treatment of patients with advanced or metastatic solid tumors. Between 2009 and 2013, the licensor of CK-102 conducted three Phase 1 studies to evaluate the maximum tolerated dose, safety, pharmacokinetics, and pharmacodynamics of CK-102, as a single agent and in combination with chemotherapy in patients with advanced solid tumor cancers. Details of the studies are as follows:

- Study 1065, a first-in-human study of CK-102, was an open-label, non-randomized, dose-escalating Phase 1 study to identify the maximum tolerated dose of CK-102 and to evaluate the safety, pharmacokinetics, and pharmacodynamics of the combination treatment of CK-102 and temozolomide, administered at 150 mg/m^2/day, in patients with advanced solid tumors. The study enrolled and dosed 26 patients at two sites in France and the United Kingdom. In the study, the combination of oral CK-102 and oral temozolomide given on days 1 to 5 of 28-day cycles was determined to be adequately tolerated with no indication of potentiation of the known toxicities of temozolomide. One patient with melanoma treated with CK-102 at 1000 mg/day demonstrated a confirmed partial response that lasted up to 5.8 months. The patient did not progress on the study. In addition, four patients treated with CK-102 at 300 to 750 mg/day experienced stable disease for at least two months. A dose of CK-102 of 750 mg/day in combination with the standard dose of temozolomide of 150 mg/m^2/day was recommended as the regimen for further study.

- Study 1092 was a dose-escalation, open-label, phase 1 study to identify the maximum tolerated dose of CK-102 and to evaluate the safety, pharmacokinetics, and pharmacodynamics of CK-102 in combination with gemcitabine and cisplatin in patients with advanced solid tumors. In the study, conducted at three sites in France and Belgium, 18 patients were enrolled and received at least one dose of CK-102. Gemcitabine was administered at 1250 mg/m^2 intravenously on day 1 and day 8 of each 21-day cycle. Cisplatin was administered at 75 mg/m^2 intravenously on day 1 of each cycle, after the infusion of gemcitabine. The study was stopped before reaching its objective of determining the maximum tolerated dose of CK-102 when given in combination with cisplatin and gemcitabine due to the limited tolerability of the cisplatin and gemcitabine regimen and the variable exposure to the active moiety of CK-102 during the study.

- Study 2051 was a Phase 1, multicenter, open-label study to determine the maximum tolerated dose of CK-102 when administered as a single-agent in patients with advanced or metastatic solid tumors. In the study, conducted at four sites in the United States, 44 patients were enrolled and received at least one dose of CK-102. Though twelve patients had stable disease in the study, the variable systemic exposure to the active moiety of CK-102 within each cohort precluded any definitive efficacy conclusions. A dose of 750 mg administered twice daily was determined to be the maximum tolerated dose for CK-102 administered as a single agent.

We plan to develop CK-102 as both a monotherapy and in combination with other anti-cancer agents, including our novel immuno-oncology and checkpoint inhibitor antibodies currently in development. Due to the variable systemic exposure of the active moiety of CK-102 in the prior Phase 1 studies, we plan to evaluate a reformulation of the CK-102 drug product to improve its bioavailability, following which, we plan to commence a Phase 1b clinical study in advanced or metastatic solid tumors with existing DNA repair defects, such as BRCA1 and BRCA2.

Anti-CAIX Research Program

Our Anti-CAIX is a fully human pre-clinical antibody designed to recognize CAIX expressing cells and kill them via antibody-dependent cell-mediated cytotoxicity ("ADCC") and complement-dependent cytotoxicity ("CDC"). Scientific literature indicates that CAIX is a well characterized tumor associated antigen ("TAA") with expression almost exclusively limited to the cells of RCC. More than 85% of RCC cases have been demonstrated to express high levels of CAIX expression. There is a very limited expression of this antigen on healthy tissue which limits reactivity of this antibody against healthy tissues.

In 2015, pre-clinical data were published in the peer-reviewed journal, Molecular Cancer, that demonstrated that our anti-CAIX antibodies are able to trigger killing of CAIX-positive human RCC cell lines in tissue culture via ADCC and CDC. The killing activity correlated positively with the level of CAIX expression on RCC tumor cell lines. In addition, the study demonstrated that our anti-CAIX antibodies inhibited growth of CAIX-positive tumors in a mouse xenograft model as well as led to the activation of T-cells and NK cells.

We plan to develop an anti-CAIX antibody for the treatment of patients with RCC in combination with an anti-PD-L1 and/or anti-GITR antibody as well as other anti-tumor immune response potentiating compounds and/or targeted therapies.

We licensed the exclusive worldwide rights to anti-CAIX antibodies from Dana-Farber in March 2015. Currently, we are in preclinical development for this program and are in the process of identifying and optimizing a lead anti-CAIX antibody to select as a clinical candidate. We plan to commence CMC development, pharmacology and toxicology activities in the second half of 2016 in order to submit an IND application to the FDA in 2017.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for our product candidates. For a description of the risk factors that could significantly affect our ability to meet these cost and time estimates, see Item 1A of this registration statement.

Product Candidate	Target Indication	Development Status	Completion of Phase	Estimated Cost to Complete Phase
Immuno-Oncology Agents				
Anti-PD-L1	Multiple Forms of Cancer	Preclinical	1H 2017	$4 to $6 million
Anti-GITR	Multiple Forms of Cancer	Preclinical	2017	$4 to $6 million
Targeted Anti-Cancer Agents				
CK-101	Lung Cancer	Preclinical	1H 2016	$1 to $3 million
CK-102	Multiple Forms of Cancer	Phase 1b	2017	$2 to $4 million
Anti-CAIX	Renal Cell Carcinoma	Preclinical	2017	$4 to $6 million

Completion dates and costs in the above table are estimates due to the uncertainties associated with pre-clinical testing and clinical trials and the related requirements of development. In the cases where the requirements for pre-clinical testing and clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on funding.

INTELLECTUAL PROPERTY AND PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broad intellectual property protection for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors ("know-how"). To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We have a few patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability be extended through the patent restoration program, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

We in-licensed in March 2015 intellectual property related to certain antibodies from Dana-Farber. The intellectual property includes issued patents in a number of countries, including the United States and Europe, as well as pending patent applications in several countries elsewhere. The issued patents and pending patent applications relate generally to compositions and methods of treatment involving antibodies against CAIX, PD-L1 and GITR. In particular, we have exclusive rights under U.S. Patent No. 8,466,263, directed to CAIX antibodies, which is scheduled to expire no earlier than July 2029. Its European counterpart is in force in Switzerland, Liechtenstein, Germany, France and the United Kingdom. A Canadian counterpart patent has also issued. Both the European and Canadian counterpart patents, as well as any pending applications outside the United States, are scheduled to expire no sooner than December 2026. The PD-L1 segment of the portfolio includes patent applications pending in the United States, Australia, Canada, Europe, Israel and Korea. Any patents maturing from these pending applications will expire no sooner than October 2033. The GITR segment of the portfolio includes one U.S. provisional application filed in October 2014. Convention date filings, including an international (PCT) application, came due in October 2015.

In March 2015, we in-licensed intellectual property from NeuPharma, which is directed to technology involving small molecules that are inhibitors of EGFR and kinase mutants. EGFR is a receptor tyrosine kinase of the ErbB family and is also known as “Her1” and “ErbB1.” The in-licensed patent estate includes an international application and a pending U.S. non-provisional application. In February 2016, we filed separate national stage applications in the relevant territories worldwide. Any patents maturing from this patent estate are expected to expire no sooner than August 2034.

In December 2015, we in-licensed intellectual property from Teva Pharmaceutical Industries Ltd., through its subsidiary, Cephalon. Under the terms of the license agreement, Cephalon granted us exclusive, worldwide rights under Cephalon’s patents and know-how covering small molecule inhibitors of PARP, an enzyme important to a cell’s ability to repair DNA. Cephalon’s patents include four patent families covering certain compounds and pharmaceutical compositions, including claims to the compound, certain salts, and crystalline polymorphs of the pro-drug, CK-102, processes for preparing same, pharmaceutical compositions of same and certain methods of inhibition or prevention associated with certain indications. Cephalon’s patents include three granted United States patents, which are scheduled to expire as early as January 2023 and as late as September 2030. Foreign counterparts included in each patent family exist in numerous jurisdictions around the world having expected expiration dates ranging from May 2021 to June 2027 (November 2027 for certain methods of sensitizing tumors), August 2030 for claims directed to novel polymorphs and November 2035 for certain salts of CK-102.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, to provide market exclusivity for certain of our product candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan-drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product.

LICENSING AGREEMENTS AND COLLABORATIONS

Dana-Farber Cancer Institute, Inc.

On March 2, 2015, we entered into a License Agreement with Dana-Farber Cancer Institute, Inc., and on October 5, 2015, we entered into a First Amendment to the License Agreement, whereby we obtained an exclusive, worldwide license to Dana-Farber's patents for the Dana-Farber Antibodies. The field of use license includes all prophylactic, therapeutic or diagnostic uses in humans or animals excluding use in chimeric antigen receptor technology. The Dana- Farber Antibodies were generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a Professor in the Department of Cancer Immunology and AIDS at Dana-Farber. Under the terms of the agreement, we paid Dana-Farber an up-front licensing fee of $1.0 million and granted Dana-Farber five percent of our common stock on a fully-diluted basis, equal to 500,000 shares valued at $32,500. The agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that we raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, we granted to Dana-Farber an additional 136,830 shares of common stock valued at approximately $0.6 million and the anti-dilution clause thereafter expired. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon our successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon our successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, Dana-Farber will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due Dana-Farber. The license will terminate on a product-by-product and country-by-country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. To date, we have incurred $1.0 million of upfront licensing and milestone payments under the License Agreement.

NeuPharma, Inc.

On March 17, 2015, Fortress entered into a License Agreement with NeuPharma, which agreement was assigned to us by Fortress on the same date, whereby we obtained an exclusive, worldwide license, other than certain Asian countries, to NeuPharma's patents to a library of EGFR inhibitors. Under the terms of the agreement, we paid NeuPharma an up-front licensing fee of $1.0 million, and NeuPharma is eligible to receive payments of up to an aggregate of approximately $40.0 million per licensed product upon our successful achievement of certain clinical development and regulatory milestones in up to three indications, of which $22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of $40.0 million upon our successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales. The license will terminate on a product-by-product and country-by-country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. To date, we have incurred $1.0 million of upfront licensing and milestone payments under the License Agreement.

Teva Pharmaceutical Industries Ltd. (through its subsidiary, Cephalon, Inc.)

On December 18, 2015, Fortress entered into a License Agreement with Teva Pharmaceutical Industries Ltd. through its subsidiary, Cephalon, Inc. ("Cephalon"), which agreement was assigned to us by Fortress on the same date, whereby we obtained an exclusive, worldwide license to Cephalon's patents relating to CEP-8983 and its small molecule prodrug, CEP-9722, which we now refer to as CK-102. Under the terms of the agreement, we paid Cephalon an up-front licensing fee of $0.5 million, and Cephalon is eligible to receive milestone payments of up to an aggregate of approximately $220.0 million upon our successful achievement of certain clinical development, regulatory approval and product sales milestones, of which approximately $206.5 million are due on or following regulatory approvals to commercialize the product. In addition, Cephalon is eligible to receive royalty payments based on a tiered low double digit percentage of net sales. The license will terminate on a product-by-product and country-by-country basis upon the later of (i) expiration of the last licensed patent right, (ii) the end of any regulatory exclusivity period, or (iii) a specified number of years after first commercial sale of a product; in each case unless the agreement is earlier terminated. To date, we have incurred $0.5 million of upfront licensing and milestone payments under the License Agreement.

Collaboration Agreement and Option Agreement with TGTX

In connection with the License Agreement with Dana-Farber, on March 3, 2015, we entered into a Global Collaboration Agreement with TGTX to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies. We retain the right to develop and commercialize these antibodies in solid tumors. Both programs are currently in pre-clinical development. Under the terms of the Global Collaboration Agreement, TGTX paid us $500,000, representing a reimbursement for their share of the licensing fee, and we are eligible to receive up to an aggregate of approximately $21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, we are eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, we will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to us. The Global Collaboration Agreement will terminate on a product-by-product and country-by-country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated.

In connection with the License Agreement with NeuPharma, Inc., on March 17, 2015, Fortress entered into an Option Agreement with TGTX, which was assigned to us on the same date, granting TGTX the right, but not the obligation to enter into a global collaboration to develop and commercialize NeuPharma's patents to a library of EGFR inhibitors in the field of hematological malignancies. We would retain the right to develop and commercialize the EGFR inhibitors in solid tumors. Under the terms of the Option Agreement, TGTX paid us $25,000, representing consideration for granting the option. If the option is exercised, we are eligible to receive up to an aggregate of approximately $14.5 million upon TGTX's successful achievement of certain clinical development and regulatory milestones under a collaboration agreement. In addition, we are eligible to receive up to an aggregate of $40.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales by TGTX. The Option Agreement will expire on July 17, 2016, unless both parties agree to extend the option period.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. Other companies have products or product candidates in various stages of pre-clinical or clinical

development, or with marketing approvals, to treat conditions for which we are also seeking to discover and develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier.

In the Immuno-Oncology area, almost every major pharmaceutical company has a PD-1 and/or PD-L1 in clinical development or on the market, including, without limitation, Merck & Co. (approved drug PD-1 with the brand name Keytruda®), Bristol-Myers Squibb (approved PD-1 with the brand name (Opdivo®), Astra-Zeneca/Celgene and Pfizer/Merck KGA. We are aware of several anti-GITR antibody development programs in pre-clinical or early clinical studies, including by Merck & Co. and GITR, Inc., and an anti-CAIX antibody in past clinical studies by Wilex AG.

In the targeted anti-cancer agent area, there are several companies with marketing approvals or in late stage development with EGFR and PARP inhibitors that are targeting mutations similar to our programs. Tarceva®, Iressa® and Gilotrif® are currently approved drugs for the treatment of first-line EGFR-mutant NSCLC. In November 2015, AstraZeneca's Tagrisso ™ (formerly AZD9291) was approved by the FDA for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR tyrosine kinase inhibitor therapy. In addition, we are aware of a number of products in development targeting cancer-causing mutant forms of EGFR for the treatment of NSCLC patients, including Clovis Oncology's rociletinib (formerly CO-1686) which has a new drug application under review by the FDA, Pfizer's PF-299804 (dacomitinib), Astellas Pharma's ASP8273, Novartis' EGF816, Hanmi Pharmaceutical's HM61713 and HM781-36B (Poziotinib), and Acea Bio (Hangzhou)'s avitinib.

In the PARP inhibitor space, in late 2014, AstraZeneca's Lynparza™ (olaparib) was approved in the U.S. as monotherapy in patients with germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy and in the EU for the maintenance treatment of BRCA mutated platinum-sensitive relapsed serous ovarian cancer. There are a number of other PARP inhibitors in late-stage clinical development including Clovis Oncology's rucaparib, AbbVie's ABT-888 (veliparib), Tesaro, Inc's niraparib, Eisai's E-7016, and Biomarin's BMN-673 (talazoparib).

Additional information can be found under Item 1A - Risk Factors – Other Risks Related to Our Business.

EMPLOYEES

As of the date of this registration statement, we have two full-time employees, including our Chief Executive Officer, and two part-time employees.

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities. We have established, or intend to establish, contract manufacturing relationships for the preliminary supplies of our product candidates, in each case with a single manufacturer. As with any supply program, obtaining raw materials of the correct quality cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

At the time of commercial sale, to the extent possible and commercially practicable, we would seek to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current Good Manufacturing Practice ("cGMP") regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. Our contractors, if any, in Europe face similar challenges from the numerous European Union and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATIONS

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our product candidates, as well as our ongoing research and development activities. None of our product candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a product candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application ("NDA"). To receive fast track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;
- that the drug is intended to treat a serious aspect of the condition; and
- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of an NDA to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1*: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion and clinical pharmacology.
- *Phase 2*: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- *Phase 3*: Studies establish safety and efficacy in an expanded patient population.
- *Phase 4*: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;

- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the product candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the product candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a product candidate, known as toxicological studies, or clinical trials of product candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for a special protocol assessment ("SPA") from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of a NDA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments.

Pharmaceutical Coverage, Pricing and Reimbursement

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, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our products to enable us realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the health care reform legislation enacted in 2010, known as the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework could have a material adverse effect on our business.

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this registration statement and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this registration statement, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business and Industry

We currently have no drug products for sale. We are heavily dependent on the success of our product candidates, and we cannot give any assurances that any of our product candidates will receive regulatory approval or be successfully commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and 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. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers as required to meet clinical trial needs and commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms; and
- conducting sales and marketing activities including hiring, training, deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote our product candidates that we may later establish; and
- maintaining patent protection and regulatory exclusivity for our product candidates.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. 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.

Pre-clinical development is highly speculative and has a high risk of failure.

All but one of our current product candidates are in pre-clinical development, and, thus, have never been used in humans. Pre-clinical development is highly speculative and carries a high risk of failure. We can provide no assurances that pre-clinical toxicology and/or pre-clinical activity of our product candidates will support moving any of these product candidates into clinical development. If we are unsuccessful in our pre-clinical development efforts for any of these product candidates and they fail to reach clinical development, it would have a material adverse effect on our business and financial condition**.**

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to our product candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

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. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, however, we will have limited influence over their actual performance.

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

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. 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.

We may not receive regulatory approval for our product candidates, or their approval may be further delayed, which would have a material adverse effect on our business and financial condition.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. One or more of our product candidates or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of one or more of our product candidates or any future product candidate, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, 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. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

If any of our product candidates are approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of our product candidates or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We intend to enter into development and supply agreements with contract manufacturers for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies for each of our product candidates. Any termination or disruption of our relationships with our contract manufacturers may materially harm our business and financial condition, and frustrate any commercialization efforts for each respective product candidate.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture one or more of our product candidates, and any future product candidate we may in-license, fails to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

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

Our products candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable drugs to treat human patients with cancer or other diseases.

If serious adverse or unacceptable side effects are identified during the development of one or more of our product candidates or any future product candidate, we may need to abandon or limit our development of some of our product candidates.

If one or more of our product candidates or any future product candidate are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound. In the event that our clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of one or more of our product candidates or any future product candidate for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by one or more of our product candidates or any future product candidate could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of that product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally if one or more of our product candidates or any future product candidate receives marketing approval and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any of our product candidates or any future product candidate or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if one or more of our product candidates receives regulatory approval, it and any other products we may market will remain subject to substantial regulatory scrutiny.

One or more of our product candidates that we may license or acquire will also be subject to ongoing requirements and review of the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, operations, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if we believe the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will 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, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which 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, or in return for, 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;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, 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; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of one or more of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any of our product candidates, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any of our product candidates, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

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

We may not be able to initiate or continue clinical trials for one or more of 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 similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Available therapies for the indications we are pursuing can also affect enrollment in our clinical trials. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;

- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Our product candidates are in scientific areas of intense competition from many large pharmaceutical and biotechnology companies, many of which are significantly further along in development or are already on the market with competing products. We expect competition for our product candidates will intensify, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render one or more of our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render one or more of our product candidates obsolete or noncompetitive.

Our product candidates will compete with other product candidates with similar indications. Please refer to Item 1. “Business — Competition”.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for one or more of our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;

- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

If approved, our product candidates will face competition from less expensive generic products of competitors and, if we are unable to differentiate the benefits of our product candidates over these less expensive alternatives, we may never generate meaningful product revenues.

Generic therapies are typically sold at lower prices than branded therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, our product candidates will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form when the patents covering it begin to expire, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of our product candidates translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We intend to seek approval to market our product candidates in the U.S., Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidate that receives marketing approval, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of one or more of our product candidates or any future product candidate, we expect to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third-party contract research organizations and site management organizations to conduct some of our preclinical studies and all of our clinical trials for our product candidates and for any future product candidate. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice ("GLP") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third-party contract research organizations or site management organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our pre-clinical and clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our pre-clinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing pre-clinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our pre-clinical or clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw 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.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations for manufacture of our product candidates. Third-party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

One or more of the product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The U.S. Drug Enforcement Administration, or DEA, restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for one or more of our product candidates.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidates or any future product candidate. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised.

If we breach any of the agreements under which we license rights to one or more of product candidates from others, we could lose the ability to continue to develop and commercialize this product candidate.

Because we have in-licensed the rights to all of our product candidates from third parties, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or 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. 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 and results of operations, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We will obtain limited product liability insurance coverage for any and all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on novel combinations of immuno-oncology antibodies and small molecule kinase inhibitors. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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 harm 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. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental 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 for failure to comply with such laws and regulations.

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. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of one or more of our product candidates may be delayed.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our product candidates or any future product candidate that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output, and, if we do, an opportunity to obtain patent protection may have passed. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more of product candidates or any future product candidate we may license or acquire, third parties may be able to access our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, if at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first place for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a third-party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We depend on our licensors for the maintenance and enforcement of intellectual property covering certain of our product candidates and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting certain of our product candidates.

We depend on our licensors to protect the proprietary rights covering our antibody product candidates and our EGFR inhibitor and we have limited, if any, control over the amount or timing of resources that they devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage.

Our licensors, depending on the patent or application, are responsible for maintaining issued patents and prosecuting patent applications. We cannot be sure that they will perform as required. Should they decide they no longer want to maintain any of the patents licensed to us, they are required to afford us the opportunity to do so at our expense. If our licensors do not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, our licensors may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement alleged by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file one or more actions for patent infringement, which can be expensive and time consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell one or more of our product candidates or any future product candidate that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of fully human immuno-oncology targeted antibodies and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims asserted by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications that are unknown to us, which may later result in issued patents that one or more of our product candidates may infringe. There could also be existing patents of which we are not aware that one or more of our product candidates may infringe, even if only inadvertently.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently a party to license agreements with Dana-Farber, NeuPharma and Teva, through its subsidiary, Cephalon, Inc. In the future, we may become party to licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates or any future product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing our product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in November 2014, and have an accumulated deficit of $10.9 million as of December 31, 2015. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- there variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;

- there are any regulatory developments affecting product candidates of our competitors; and

- one or more of our product candidate receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire;

- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and

- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in November 2014 and have only been conducting operations with respect to our product candidates since March 2, 2015. Our operations to date have been limited to preclinical operations and the in-licensing of our product candidates. We have not yet demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. In December 2015, we closed on gross proceeds of $57.8 million, before commissions and expenses, in a series of private placement financings. Net proceeds from this offering were approximately $51.5 million. We expect to use the net proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at December 31, 2015, are sufficient to fund our anticipated operating cash requirements for at least the next 24 months.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, design and conduct of, and results from, pre-clinical and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and
- the success of the commercialization of one or more of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity 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 marketing, distribution 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.

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

We intend to become a public company. As a public company, we will incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

A target business may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding the adequacy of internal controls. The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such acquisition. Furthermore, any failure to implement required new or improved controls, or difficulties encountered in the implementation of adequate controls over our financial processes and reporting in the future, could harm our operating results or cause us to fail to meet our reporting obligations. 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 securities.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an "emerging growth company" for up to five years. However, if our non-convertible debt issued within a three-year period or revenues exceeds $1 billion, or the market value of our ordinary shares that are held by non-affiliates exceeds $700 million on the last day of the second fiscal quarter of any given fiscal year, we would cease to be an emerging growth company as of the following fiscal year. As an emerging growth company, we are not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, we have reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and we are exempt from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will not adopt the new or revised standard until the time private companies are required to adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Risks Relating to Securities Markets and Investment in Our Stock

There is not now and there may not ever be an active market for our common stock. There are restrictions on the transferability of these securities.

There currently is no market for our common stock and, except as otherwise described herein, we have no plans to file any registration statement or otherwise attempt to create a market for the shares. Even if an active market develops for the shares, Rule 144, which provides for an exemption from the registration requirements under the Securities Act under certain conditions, requires, among other conditions, a holding period prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. There can be no assurance that we will fulfill any reporting requirements in the future under the Exchange Act or disseminate to the public any current financial or other information concerning us, as is required by Rule 144 as part of the conditions of its availability.

If we desire, we may require that any request for transfer of our securities is accompanied by an opinion of counsel reasonably satisfactory to us and our counsel that neither the sale nor the proposed transfer results in a violation of the Securities Act or any applicable state securities or “blue sky” laws.

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize our product candidates or any future product candidate, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching these product candidates, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of one or more of our product candidates or any future product candidate, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

Fortress controls a voting majority of our common stock.

Pursuant to the terms of the Class A common stock held by Fortress, Fortress is entitled to cast, for each share of Class A common stock held by Fortress, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of outstanding Class A common stock. Accordingly, as long as Fortress owns any shares of Class A common stock, they will be able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of Fortress may not always coincide with the interests of other stockholders, and Fortress may take actions that advance its own interests and are contrary to the desires of our other stockholders. Moreover, this concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of Checkpoint or our assets, and might affect the prevailing market price of our common stock.

Fortress has the right to receive a significant grant of shares of our common stock annually which will result in the dilution of your holdings of common stock upon each grant, which could reduce their value.

Under the terms of the Founders Agreement (See Item 7. Certain Relationships and Related Transactions, and Director Independence), Fortress has the right to receive an annual grant of shares of our common stock equal to 2.5% of the fully-diluted outstanding equity at the time of issuance, on the anniversary of the date of the Founders Agreement, which became effective as of March 17, 2015. This annual issuance of shares to Fortress will dilute your holdings in our common stock and, if the value of Checkpoint has not grown over the prior year, would result in a reduction in the value of your shares.

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress.

The agreements we entered into with Fortress in connection with the separation include an MSA and the Founders Agreement. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales and the provision of employment and transition services. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business.

Our Executive Chairman is also the Executive Chairman, Interim President and Chief Executive Officer of TG Therapeutics, Inc. ("TGTX"), with whom we have a Collaboration Agreement, and as a result during the term of that agreement certain conflicts of interest may arise which will require the attention of our officers and independent directors who are unaffiliated with TGTX.

In connection with our license agreement with Dana-Farber, we entered into a collaboration agreement with TGTX to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies. Michael S. Weiss, our Executive Chairman, is also the Executive Chairman, Interim President and Chief Executive Officer of TGTX. As such, as the collaboration agreement proceeds, certain conflicts of interest may arise between us and TGTX. Those conflicts will have to be resolved by our officers and directors who are unaffiliated with TGTX, and also by officers and directors of TGTX who are unaffiliated with us. This may lead to less than desirable complications and costs to both companies, which could harm our results of operations.

The dual roles of our officers and directors who also serve in similar roles with Fortress could create a conflict of interest and will require careful monitoring by our independent directors.

We share some directors with Fortress, and in addition, under the Management Services Agreement, we will also share some officers with Fortress. This could create conflicts of interest between the two companies in the future. While we believe that the Founders Agreement and the Management Services Agreement were negotiated by independent parties on both sides on arm's length terms, and the fiduciary duties of both parties were thereby satisfied, in the future situations may arise under the operation of

both agreements that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, under the Management Services Agreement, Fortress and its affiliates are free to pursue opportunities which could potentially be of interest to Checkpoint, and they are not required to notify Checkpoint prior to pursuing the opportunity. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Checkpoint could expose us to claims by our investors and creditors, and could harm our results of operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Statements in the following discussion and throughout this registration statement that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this registration statement because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this registration statement or to reflect actual outcomes. Please see "Forward Looking Statements" at the beginning of this Form 10.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10.

Overview

We are an immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. We aim to acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently we are developing a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at Dana-Farber. The portfolio of antibodies we licensed from Dana-Farber includes antibodies targeting PD-L1, GITR and CAIX (together, the "Dana-Farber Antibodies"). We plan to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as published literature suggests that combinations of these targets may work synergistically together. We expect to submit IND applications for our anti-PD-L1, anti-GITR and anti-CAIX antibodies in 2017. We have also licensed and are developing two oral targeted anti-cancer therapies, consisting of a small molecule inhibitor of PARP and a small molecule inhibitor of EGFR mutations. We plan to submit an IND application to the FDA for our EGFR inhibitor in the first half of 2016, followed by the commencement of a Phase 1/2 clinical study. We are currently developing a clinical program for our PARP inhibitor, which we expect to commence in the next six to twelve months. Additionally, we will seek to add additional immuno-oncology drugs as well as other targeted therapies to create wholly-owned proprietary combinations that leverage the immune system and other complimentary mechanisms.

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2015, we have an accumulated deficit of $10.9 million.

We are a majority controlled subsidiary of Fortress.

Checkpoint Therapeutics, Inc. was incorporated in Delaware on November 10, 2014 and commenced principal operations in March 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in the notes to our consolidated financial statements appearing elsewhere in this Form 10.

Results of Operations

Revenue

For the year ended December 31, 2015, we generated $0.6 million of revenues in connection with our collaboration agreement with TGTX. Revenues consisted of $0.5 million representing a reimbursement for TGTX's share of the licensing fee under the Dana Farber license agreement and $0.1 million related to the reimbursement of patent fees in connection with this agreement.

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the year ended December 31, 2015, research and development expenses were $8.3 million, of which $3.2 million was related to the acquisition of the licenses and rights to the Dana Farber antibodies, the EGFR inhibitor, CK-101, and the PARP inhibitor, CK-102. An additional $2.1 million relates to pre-clinical development activities for our product candidates and $3.0 million relates to stock compensation expense.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executives and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities, and facilities-related expenses.

For the year ended December 31, 2015, general and administrative expenses were $2.5 million, which primarily consisted of stock compensation expense of $1.5 million, of which $1.3 million related to fees paid to Fortress in connection with the Founders' Agreement. In addition, of the remaining $0.7 million, $0.5 million relates to legal fees, primarily in connection with the acquisition and maintenance of our licenses.

For the period from November 10, 2014 (inception) to December 31, 2014, there was nominal general and administrative expenses.

We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- stock compensation granted to key employees and non-employees;
- support of business development activities; and
- increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a public reporting company.

Change in Fair Value of Warrant Liabilities

For the year ended December 31, 2015, the change in fair value of warrant liabilities were $0.4 million, which expense was a result of the change in probability from 25% to 100% related to contingently issuable warrants.

Liquidity and Capital Resources

In February 2015, Fortress closed a private placement of a promissory note for $10 million through National Securities Corporation (the "NSC Note"). Fortress used the proceeds from the NSC Note to acquire medical technologies and products. The NSC Note matures 36 months after issuance, provided that during the first 24 months, Fortress can extend the maturity date by six months. No principal amount will be due for the first 24 months after issuance (or the first 30 months after issuance if the maturity date is extended). Thereafter, the NSC Note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the NSC Note is 8% payable quarterly during the first 24 months after issuance (or the first 30 months after issuance if the NSC Note is extended) and monthly during the last 12 months. National Securities Corporation ("NSC"), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note.

The NSC Note allowed Fortress to transfer a portion of the proceeds from the NSC Note to us pursuant to which we executed an identical NSC Note in favor of NSC. Accordingly, we assumed $2,791,831 under the NSC Note and issued NSC 139,592 warrants to purchase our common stock, which was equal to twenty-five percent (25%) of the amount of NSC Note proceeds we received from Fortress divided by the lowest price at which we next sold common stock. The warrant issued has a term of 10 years and an exercise price equal to the par value of our common stock. In February 2016, we paid NSC $2,811,412, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment.

In September 2015, we launched a private placement of common stock and warrants for common stock the principal purpose of which was to provide us with working capital to continue our development and testing of our product candidates. As of December 31, 2015, we closed on gross proceeds of $57.8 million before offering expenses. Net proceeds from this offering were approximately $51.5 million. We expect to use the net proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. Together with our available working capital, we expect these funds are sufficient to fund our anticipated operating cash requirements for at least the next 24 months.

Operating Activities

Cash provided from our third party offering and the NSC note was $51.5 million and $2.6 million, net of fees, respectively, for the year ended December 31, 2015. We incurred $3.2 million for up-front payments to acquire the Dana-Farber antibodies, the EGFR inhibitors and the PARP inhibitor, and the remainder to fund operating activities related to our formation as well as preliminary research and development activities related to our licenses.

Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. We are currently evaluating the method of adoption and the impact of adopting ASU 2016-02 on our financial statements. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We are currently evaluating the impact that ASU 2016-01 will have on our balance sheet or financial statement disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We are currently evaluating the impact that ASU 2015-17 will have on our balance sheet or financial statement disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*("ASU 2015-03"), which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. ASU 2015-03 is effective for the interim and annual periods ending after December 15, 2015, with early adoption permitted. We adopted ASU 2015-03 and such adoption resulted in debt issuance costs presented as an offset against notes payable, long-term, in the accompanying balance sheet.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern* ("ASU 2014-15"), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2014-15 and its related disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In July 2015, the FASB voted to approve a one-year deferral of the effective date of ASU 2014-09, which will now be effective for us in the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. We are evaluating the impact of implementation and transition approach of this standard on our financial statements. When adopted, we do not expect this guidance to have a material impact on our financial statements.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Properties.

Our corporate and executive office is located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. We are not currently under a lease agreement at 2 Gansevoort Street. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth certain information with respect to the beneficial ownership of our common stock, and, as indicated, our Class A common stock and vested warrants, as of April 26, 2016, for:

- each of our named executive officers;
- each of our directors;
- all of our current executive officers and directors as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock.

As of April 26, 2016, there were 16,957,876 shares of our common stock outstanding and 7,000,000 shares of our Class A Common Stock outstanding. In order to calculate a stockholder's percentage of beneficial ownership, we include in the calculation those shares underlying options or warrants beneficially owned by that stockholder

that are vested or that will vest within 60 days of April 26, 2016. Shares of restricted stock are deemed to be outstanding. Options or warrants held by other stockholders that are not attributed to the named beneficial owner are disregarded in this calculation. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of our common stock. Except as indicated in footnotes to this table, we believe that the stockholders named in this table will have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Checkpoint Therapeutics, Inc., 2 Gansevoort Street, 9th Floor, New York, NY 10014.

The following table shows the ownership of the above mentioned group of our Common Stock only, and thus does not represent their percentage ownership of our total common equity as it excludes the Class A Common Stock which is shown separately below.

	Common Stock Beneficially Owned	
Name and Address of Beneficial Owner	**Number of Shares and Nature of Beneficial Ownership**	**Percentage of Total Common Stock**
Michael S. Weiss	500,000(1)	2.9%(1)
James F. Oliviero	1,000,000	5.9%
David J. Horin	0	0.0%
Lindsay A. Rosenwald, M.D.	500,000(1)	2.9%(1)
Neil Herskowitz	0	0.0%
Barry Salzman	50,000	0.3%
Scott Boilen	79,999(2)	0.5%
All executive officers and directors as a group	1,129,999(3)	6.7%(3)
5% or Greater Stockholders:		
Fortress Biotech, Inc.	1,981,006(4)	11.7%
Dr. Wayne Marasco, MD, PhD	1,500,000	8.8%

* Less than 1% of outstanding common stock.

(1) Includes 500,000 warrants issued by Fortress to each of Mr. Weiss and Dr. Rosenwald that cover shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.

(2) Includes 7,777 vested warrants exercisable at $7.00 per share.

(3) Includes 7,777 vested warrants held by Mr. Boilen exercisable at $7.00 per share. The total calculation for all executive officers and directors as a group does not include Mr. Weiss' and Dr. Rosenwald's warrants, which have not yet been exercised. The shares underlying the warrants are currently held by Fortress and are included in the 1,981,006 shares of common stock shown as held by Fortress.

(4) Includes 1,000,000 shares of common stock underlying the warrants granted by Fortress to Mr. Weiss and Dr. Rosenwald.

	Class A Common Stock Beneficially Owned	
Name and Address of Beneficial Owner	**Number of Shares and Nature of Beneficial Ownership**	**Percentage of Total Class A Common Stock**
Fortress Biotech, Inc.	7,000,000	100.0%

Item 5. Directors and Executive Officers.

The following table sets forth certain information about our directors and executive officers as of the date of this registration statement.

Name	Age	Position
Michael S. Weiss	50	Executive Chairman of the Board of Directors
James F. Oliviero, III	40	Chief Executive Officer and President
David J. Horin	47	Interim Chief Financial Officer
Lindsay A. Rosenwald, M.D.	60	Director
Neil Herskowitz	59	Director
Barry Salzman	53	Director
Scott Boilen	49	Director

None of the events listed in Item 401(f) of Regulation S-K has occurred during the past ten years and that is material to the evaluation of the ability or integrity of any of our directors, director nominees or executive officers.

The following is a brief account of the business experience during the past five years (and, in some instances, for prior years) of each executive officer and non-executive director of our company.

Executive Officers

Michael S. Weiss – Executive Chairman of the Board of Directors

Mr. Weiss has served as Executive Chairman of our Board of Directors since March 2015. He also served as Interim Chief Executive Officer and President from August 2015 until October 2015. Mr. Weiss has served in several capacities at Fortress, most recently as Executive Vice Chairman since February 2014. He has also been Co-Chairman of the Board of Directors of CB Pharma Acquisition Corp. since 2014. Mr. Weiss is currently Co-Portfolio Manager and Partner of Opus Point Partners, LLC, which he co-founded in 2009. He has also served as Executive Chairman, Interim Chief Executive Officer and President of TG Therapeutics, Inc., a company he founded in 2011. From 2002 to 2009, Mr. Weiss was the Chairman and Chief Executive Officer of Keryx Biopharmaceuticals, Inc., where he helped the company acquire and develop its lead drug, Auryxia, as well as executed a strategic alliance for Auryxia with Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd. worth more than $100 million. Mr. Weiss served as Chairman of the board of directors of National Holdings Corporation from 2011 to 2012. Mr. Weiss began his professional career as a lawyer with Cravath, Swaine & Moore LLP. He earned his J.D. from Columbia Law School and his B.S. in Finance from The University at Albany.

James F. Oliviero, III – Chief Executive Officer and President

James F. Oliviero, III, CFA, has been our Chief Executive Officer and President since October 13, 2015. Mr. Oliviero has over fifteen years of operational experience in the biotechnology industry. From May 2003 to September 2015, Mr. Oliviero served in a variety of leadership capacities at Keryx Biopharmaceuticals, Inc., a publicly-traded biotechnology company, most recently as its Chief Financial Officer since April 2009, where he was instrumental in the growth of the company to a market capitalization over $1 billion. During his tenure at Keryx, Mr. Oliviero oversaw all finance, accounting, investor relations, corporate governance, business development and legal matters, as well as a leading member of the design of several clinical studies and the regulatory oversight of Keryx's new drug application for Auryxia™, which successfully obtained FDA marketing approval in 2014 and recently gained EMA marketing approval. Also while at Keryx, Mr. Oliviero completed over $500 million in various public financings for the company. Prior to Keryx, from August 1999 to May 2003, Mr. Oliviero was Director of Finance for ACCESS Oncology, Inc., a privately-held biotechnology company. Mr. Oliviero began his professional career as an investment banker at ING Barings Furman Selz in New York City. Mr. Oliviero is a CFA charterholder and holds a B.B.A. in Finance with Highest Distinction from Emory University's Goizueta Business School.

David J. Horin – Interim Chief Financial Officer

Mr. Horin has served, on a part-time basis, as our Interim Chief Financial Officer under our agreement with Chord Advisors, LLC ("Chord") since August 31, 2015. Pursuant to such agreement, we pay Chord $7,500 per month for its back office accounting support and accounting policy and financial reporting services that it provides to us, including the services of Mr. Horin. We do not have information, nor any influence over Mr. Horin's direct compensation from Chord. Mr. Horin has been a Managing Partner of Chord since June 2012. Chord provides accounting advisory services, SEC reporting advisory services, and IPO-readiness services. While at Chord, Mr. Horin has gained extensive experience in financial accounting and SEC reporting for complex business transactions and issues arising from the application of existing or proposed financial accounting guidance. Mr. Horin also serves as interim Chief Financial Officer for our affiliate, Avenue Therapeutics, Inc. From March 2008 to June 2012, Mr. Horin was the Chief Financial Officer of Rodman & Renshaw Capital Group, Inc., a full-service investment bank dedicated to providing corporate finance, strategic advisory, sales and trading and related services to public and private companies across multiple sectors and regions. From March 2003 through March 2008, Mr. Horin was the Chief Accounting Officer at Jefferies Group, Inc., a full-service global investment bank and institutional securities firm focused on growth and middle-market companies and their investors. Prior to his employment at Jefferies Group, Inc., from 2000 to 2003, Mr. Horin was a Senior Manager in KPMG's Department of Professional Practice in New York, where he advised firm members and clients on technical accounting and risk management matters for a variety of public, international and early growth stage entities. Mr. Horin has a Bachelor of Science degree in Accounting from Baruch College, City University of New York. Mr. Horin is also a Certified Public Accountant.

Non-Executive Directors

Lindsay A. Rosenwald, M.D.

Dr. Rosenwald has served as a member of our Board of Directors since inception. From November 2014 to August 2015, he also was our Chief Executive Officer and President. Dr. Rosenwald has been a member of the Board of Directors of Fortress since October 2009 and has served as its Chairman, President and Chief Executive Officer since December 2013. Dr. Rosenwald is also Co-Chairman of the Board of Directors and Chief Executive Officer of CB Pharma Acquisition Corp., which he joined in 2014. Dr. Rosenwald also is Co-Portfolio Manager and Partner of Opus Point Partners Management, LLC, an asset management firm in the life sciences industry, which he co-founded in 2009. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 23 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine. Based on Dr. Rosenwald's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, the Board of Directors believes that Dr. Rosenwald has the appropriate set of skills to serve as a member of the Board in light of our business and structure.

Neil Herskowitz

Mr. Herskowitz joined our Board of Directors in August 2015. Mr. Herskowitz has served as the managing member of the ReGen Group of companies, located in New York, since 1998, which include ReGen Capital Investments LLC and Riverside Claims Investments LLC. He has also served as the President of its affiliate, Riverside Claims LLC, since June 2004. Mr. Herskowitz currently serves as director of CB Pharma Acquisition Corp, along with being the Chairman of its Audit Committee. He also serves as Chairman of the board of directors of Starting Point Services for Children, a not-for-profit corporation. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978.

Barry Salzman

Mr. Salzman joined our Board of Directors in January 2016. Mr. Salzman is currently a Managing Director for Compass Partners LLC, a merchant banking and financial advisory firm that specializes in middle market companies and corporate restructuring. Mr. Salzman joined Compass Partners LLC in July 2007, the same time at which he became a Board Member and Principal owner of BP Gamma Medical Supply Company, a regional Mid-Atlantic durable medical equipment and respiratory therapy distribution company based in Frederick, Maryland. Prior to July 2007, Mr. Salzman served as Board Chairman, President and Principal owner of Becker-Parkin Dental Supply Company. After 20 years at Becker-Parkin, Mr. Salzman sold the company, then recognized as one of the largest dental supply and equipment distribution companies in the United States, to Henry Schein Inc. (NASDAQ: HSIC). Five months after selling Becker-Parkin, Mr. Salzman served as President of Surgery Works, LLC, formed by Compass Partners LLC to provide financial management services for two of the largest Ambulatory Surgery Centers in the United States, for five years until the centers sold a controlling interest to Amsurg (NASDAQ: AMSG). Mr. Salzman has maintained a Board seat at both Surgery Works, LLC centers and continues to work in a consulting and advisory role to Amsurg. In 2014, Mr. Salzman founded and became President of Practice Management Works LLC, a financial management service provider for large dental group practices in the Northeast United States. During that same year, Mr. Salzman also accepted a board seat at Vivex Corporation, a private research driven Biologicals Company dedicated to new standards in patient care through technologies and diverse product offerings. Mr. Salzman is a 1987 graduate of Brooklyn Law School and is a member in good standing of the New York Bar Association.

Scott Boilen

Scott Boilen joined our Board of Directors in April 2016. Mr. Boilen has served as the Chief Executive Officer of Allstar Products Group since 1999. He also served on the Board of Directors for the Electronic Retailing Association from 2010 to 2012 and the Board of Directors for the Food Bank for Westchester (New York) since 2009. Boilen holds a degree in Business Administration from the State University of New York at Albany and a Master's Degree in Business Administration from Fordham University.

Family Relationships

There is no family relationship between any director, executive officer or person nominated to become a director or executive officer.

Composition of our Board of Directors

Our bylaws provide that our Board shall consist of between one and nine directors, and such number of directors within this range may be determined from time to time by resolution of our board of directors or our stockholders. Currently, we have four directors.

Our bylaws also provide that our directors may be removed with or without cause by the affirmative vote of the holders of at least a majority of the votes that all our stockholders would be entitled to cast in an annual election of directors. An election of our directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

Our current and future executive officers and significant employees serve at the discretion of our board of directors. Our board of directors may also choose to form certain committees, such as a compensation and an audit committee.

Communicating with the Board of Directors

Our Board has established a process by which stockholders can send communications to the Board. You may communicate with the Board as a group, or to specific directors, by writing to Robyn Hunter, our Corporate Secretary, at our offices located at 2 Gansevoort Street, 9 th Floor, New York, NY 10014. The Corporate Secretary will review all such correspondence and regularly forward to our Board a summary of all correspondence and copies of all correspondence that, in the opinion of the Corporate Secretary, deals with the functions of the Board or committees thereof or that he otherwise determines requires their attention. Directors may at any time review a log of all correspondence we receive that is addressed to members of our Board and request copies of any such correspondence. Concerns relating to accounting, internal controls, or auditing matters may be communicated in this manner, or may be submitted on an anonymous basis via e-mail at BOD@checkpointtx.com. These concerns will be immediately brought to the attention of our Board and handled in accordance with procedures established by our Board.

Code of Ethics

We adopted a Code of Ethics that applies to all directors, officers and employees. Our Code of Ethics is available on our website at www.checkpointtx.com. A copy of our Code of Ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 2 Gansevoort Street, 9th Floor, New York, NY 10014.

Item 6. Executive Compensation.

As an emerging growth company, we are required to disclose the compensation earned by or paid to our named executive officers during 2014 and 2015. During the fiscal years ended December 31, 2014 and 2015, Mr. Weiss and Dr. Rosenwald did not earn or receive any compensation for their respective services to us either from us or Fortress. During the fiscal year ended December 31, 2015, we received the services of Mr. Horin pursuant to the terms of our agreement with Chord for accounting support and accounting policy and financial reporting, as described below.

The following table sets forth the compensation earned by our Chief Executive Officer and President, our sole executive officer that received compensation from us since inception and our Interim Chief Financial Officer, provided to us under our agreement with Chord.

Name and Principal Position	Year	Salary ($)	Non-Equity Incentive Plan Compensation ($)	Stock Awards ($)(1)	Total ($)
James F. Oliviero III(2) Chief Executive Officer and President	2015	86,986	43,288	264,809	395,083
David J. Horin Interim Chief Financial Officer	2015	22,500(3)	—	—	22,500

(1) Reflects the aggregate grant date fair value of restricted stock granted during the fiscal year calculated in accordance with FASB ASC Topic 718. See Note 7 to our audited financial statements for the year ended December 31, 2015, included elsewhere in this Form 10 for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards.

(2) Mr. Oliviero's employment with us commenced on October 13, 2015. The amount reported represents the pro rata portion of Mr. Oliviero's annual salary from commencement of employment through December 31, 2015.

(3) This represents the amount paid to Chord during 2015, for services rendered, including those of Mr. Horin. We do not have information, nor any influence over Mr. Horin's direct compensation from Chord.

Compensation Arrangements for Executive Officers

There is currently only an employment agreement in place with Mr. Oliviero, our Chief Executive Officer and President. Mr. Weiss serves as Executive Chairman, but was not compensated through December 31, 2015. Beginning in January 2016, Mr. Weiss will be compensated $5,000 per month pursuant to the terms of a consulting agreement. Mr. Horin serves as Interim Chief Financial Officer, pursuant to the terms of our agreement with Chord. Pursuant to such agreement, we pay Chord $7,500 per month for its back office accounting support and accounting policy and financial reporting services that it provides to us, including the services of Mr. Horin.

Employment Agreement, CEO

On October 13, 2015, we entered into an at-will employment agreement with our newly appointed CEO, James Oliviero (the "Employment Agreement"). Pursuant to the Employment Agreement, Mr. Oliviero receives an annualized salary of $395,000, paid in equal installments in accordance with our normal payroll practices. The Employment Agreement further provides for an incentive bonus linked to the realization of certain corporate milestones, to be established annually by agreement between Mr. Oliviero and our Executive Chairman. The achievement of these milestones (as determined by the Executive Chairman) may result in a target annual award of up to fifty percent (50%) of Mr. Oliviero's annual salary, with a maximum annual award of up to seventy-five percent (75%). Mr. Oliviero will also receive a cash bonus of $100,000 upon the completion of the first public offering of our company's stock resulting in our receipt of gross proceeds of at least $20,000,000.

Upon the execution of the Employment Agreement, Mr. Oliviero received 1,000,000 restricted shares of our common stock (the "Shares"), subject to a repurchase right in favor of us. The Shares are subject to the vesting schedule described in the Employment Agreement.

Employee Benefit and Incentive Plans

We do not maintain any deferred compensation, retirement, pension or profit sharing plans. Our board of directors has adopted an incentive plan, the material terms of which are described below, allowing for the grant of equity and cash-based awards to our employees and directors.

2014 and 2015 Director Compensation

None of our directors received any compensation for their services as a director for the years ended December 31, 2014 and 2015.

2016 Director Compensation Program

In January 2016, our directors adopted a Non-Employee Directors Compensation Plan for our non-employee directors pursuant to our 2015 Incentive Plan. Our non-employee directors will receive the following compensation:

Cash Compensation:

- $50,000 annual retainer; and
- $10,000 additional annual retainer for the Audit Committee Chair.

Equity Compensation:

- Initial Equity Grant: 50,000 shares of restricted stock, which shares shall vest and become non-forfeitable in equal annual installments over three years, beginning on the third (3rd) anniversary of the grant date, subject to the director's continued service on the board of directors on such date.
- Re-Election Equity Grant: The greater of (i) a number of shares of restricted stock having a fair market value on the grant date of $50,000, or (ii) 10,000 shares of restricted stock, which shares shall vest and become non-forfeitable on the third (3rd) anniversary of the grant date, subject to the director's continued service on the board of directors on such date.

In addition, each non-employee director receives reimbursement for reasonable travel expenses incurred in attending meetings of our board of directors and meetings of committees of our board of directors.

Compensation Committee Interlocks and Insider Participation

We do not currently have a compensation committee and, for the year ended December 31, 2015, the compensation, if any, of our executive officers was recommended by our Chief Executive Officer and Chairman and such recommendations were approved by our board of directors. None of our executive officers currently serves as a member of the compensation committee or as a director with compensation duties of any entity that has executive officers serving on our board of directors. None of our executive officers has served in such capacity in the past 12 months.

Equity Incentive Plan

2015 Incentive Plan

Our board of directors adopted the Checkpoint Therapeutics, Inc. 2015 Incentive Plan (the "2015 Plan"). The material terms of the 2015 Plan are described below.

Purpose. The purpose of the 2015 Plan is to promote our success by linking the personal interests of our employees, officers, directors and consultants to those of our stockholders, and by providing participants with an incentive for outstanding performance.

Permissible Awards. The 2015 Plan authorizes the board of directors (or the Compensation Committee upon establishment by the board of directors) to grant awards in any of the following forms:

- options to purchase shares of our common stock, which may be nonstatutory stock options or incentive stock options under the Internal Revenue Code. The exercise price of an option granted under the 2015 Plan may not be less than the fair market value of our common stock on the date of grant. Stock options granted under the 2015 Plan may not have a term longer than ten (10) years;
- stock appreciation rights, or SARs, which give the holder the right to receive the excess, if any, of the fair market value of one (1) share of our common stock on the date of exercise, over the base price of the stock appreciation right. The base price of a SAR may not be less than the fair market value of our common stock on the date of grant. SARs granted under the 2015 Plan may not have a term longer than ten years;
- restricted stock, which is subject to restrictions on transferability and subject to forfeiture on terms set by the Compensation Committee;
- restricted stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, based upon the attainment of stated vesting or performance goals set by the Compensation Committee;
- deferred stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, generally without any vesting or performance restrictions;
- other stock-based awards in the discretion of the Compensation Committee, including unrestricted stock grants; and
- cash-based awards in the discretion of the Compensation Committee, including cash-based performance awards.

All awards will be evidenced by a written award certificate between us and the participant, which will include such provisions as may be specified by the Compensation Committee, or, if not yet established, all of the independent members of our board of directors (the "Compensation Committee"). Dividend equivalent rights, which entitle the participant to payments in cash or property calculated by reference to the amount of dividends paid on the shares of stock underlying an award, may be granted with respect to awards other than options or SARs.

Awards to Non-Employee Directors. Awards granted under the 2015 Plan to our non-employee directors will be made only in accordance with the terms, conditions and parameters of a plan, program or policy for the compensation of non-employee directors as in effect from time to time. The Compensation Committee may not make discretionary grants under the 2015 Plan to non-employee directors. The maximum aggregate number of shares associated with any award granted under the 2015 Plan in any calendar year to any one non-employee director is 100,000.

Shares Available for Awards; Adjustments. Subject to adjustment as provided in the 2015 Plan, the aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 2,000,000. Shares subject to awards that are canceled, terminated, forfeited, settled in cash, withheld to satisfy exercise prices or tax withholding obligations or otherwise not issued for any reason, including by reason of failure to achieve maximum performance goals, will again be available for awards under the 2015 Plan. In the event of a nonreciprocal transaction between us and our stockholders that causes the per share value of our common stock to change (including, without limitation, any stock dividend, stock split, spin-off, rights offering, or large nonrecurring cash dividend), the share authorization limits under the 2015 Plan will be adjusted proportionately, and the Compensation Committee must make such adjustments to the 2015 Plan and awards as it deems necessary, in its sole discretion, to prevent dilution or enlargement of rights immediately resulting from such transaction.

Administration. The 2015 Plan will be administered by the Compensation Committee. The Compensation Committee will have the authority to grant awards; designate participants; determine the type or types of awards to be granted to each participant and the number of awards to be granted and the number of shares or dollar amount to which an award will relate and the terms and conditions thereof; prescribe the form of award; establish, adopt or revise any rules and regulations as it may deem advisable to administer the 2015 Plan; make all other decisions and determinations that may be required under the 2015 Plan and amend the 2015 Plan. Our Board of Directors may at any time administer the 2015 Plan. If it does so, it will have all the powers of the Compensation Committee under the 2015 Plan. In addition, our Board of Directors or Compensation Committee may expressly delegate to a special committee some or all of the Compensation Committee's authority, within specified parameters, to grant awards to eligible participants who, at the time of grant, are not executive officers or directors.

Limitations on Transfer; Beneficiaries. No award will be assignable or transferable by a participant other than by will or the laws of descent and distribution; provided, however, that nonstatutory stock options may be transferred without consideration to members of a participant's immediate family, to trusts in which such immediate family members have more than fifty percent (50%) of the beneficial interest, to foundations in which such immediate family members (or the participant) control the management of assets, and to any other entity (including limited partnerships and limited liability companies) in which the immediate family members (or the participant) own more than fifty percent (50%) of the voting interest; and provided, further, that the Compensation Committee may permit other transfers (other than transfers for value) where the Compensation Committee concludes that such transferability does not result in accelerated taxation, does not cause any option intended to be an incentive stock option to fail to qualify as such, and is otherwise appropriate and desirable, taking into account any factors deemed relevant, including without limitation, any state or federal tax or securities laws or regulations applicable to transferable awards. A participant may, in the manner determined by the Compensation Committee, designate a beneficiary to exercise the rights of the participant and to receive any distribution with respect to any award upon the participant's death.

Treatment of Awards upon a Change in Control. Unless otherwise provided in an award certificate or any special plan document governing an award, upon the occurrence of a change in control of our company, (i) all outstanding options, SARs and other awards in the nature of rights that may be exercised will become fully exercisable, (ii) all time-based vesting restrictions on outstanding awards will lapse; and (iii) the payout opportunities attainable under all outstanding performance-based awards will vest based on target performance and the awards will pay out on a pro rata basis, based on the time elapsed prior to the change in control.

Discretionary Acceleration. The Compensation Committee may, in its discretion, accelerate the vesting and/or payment of any awards for any reason, subject to certain limitations under Section 409A of the Internal Revenue Code. The Compensation Committee may discriminate among participants or among awards in exercising such discretion.

Certain Transactions. Upon the occurrence or in anticipation of certain corporate events or extraordinary transactions, the Compensation Committee may also make discretionary adjustments to awards, including settling awards for cash, providing that awards will become fully vested and exercisable, providing for awards to be assumed or substituted, or modifying performance targets or periods for awards.

Termination and Amendment. The 2015 Plan will terminate on the tenth (10^{th}) anniversary of its adoption, or, if the stockholders approve an amendment to the 2015 Plan that increases the number of shares subject to the 2015 Plan, the tenth (10^{th}) anniversary of the date of such approval, unless earlier terminated by our Board of Directors or Compensation Committee. Our Board or Compensation Committee may, at any time and from time to time, terminate or amend the 2015 Plan, but if an amendment to the 2015 Plan would constitute a material amendment requiring stockholder approval under applicable listing requirements, laws, policies or regulations, then such amendment will be subject to stockholder approval. No termination or amendment of the 2015 Plan may adversely affect any award previously granted under the 2015 Plan without the written consent of the participant. Without the prior approval of our stockholders, and except as otherwise permitted by the anti-dilution provisions of the 2015 Plan, the 2015 Plan may not be amended to permit us to directly or indirectly reprice, replace or repurchase "underwater" options or SARs.

The Compensation Committee may amend or terminate outstanding awards. However, such amendments may require the consent of the participant and, unless approved by the stockholders or otherwise permitted by the anti-dilution provisions of the 2015 Plan, (i) the exercise price or base price of an option or SAR may not be reduced, directly or indirectly, (ii) an option or SAR may not be cancelled in exchange for cash, other awards, or options or SARS with an exercise price or base price that is less than the exercise price or base price of the original option or SAR, or otherwise, (iii) we may not repurchase an option or SAR for value (in cash or otherwise) from a participant if the current fair market value of the shares of our common stock underlying the option or SAR is lower than the exercise price or base price per share of the option or SAR, and (iv) the original term of an option or SAR may not be extended.

Prohibition on Repricing. As indicated above under "Termination and Amendment," outstanding stock options and SARs cannot be repriced, directly or indirectly, without the prior consent of our stockholders. The exchange of an "underwater" option or stock appreciation right (i.e., an option or stock appreciation right having an exercise price or base price in excess of the current market value of the underlying stock) for cash or for another award would be considered an indirect repricing and would, therefore, require the prior consent of our stockholders.

Certain Federal Tax Effects

The following discussion is limited to a summary of the U.S. federal income tax provisions relating to the grant, exercise and vesting of awards under the 2015 Plan and the subsequent sale of common stock acquired under the 2015 Plan. The tax consequences of awards may vary depending upon the particular circumstances, and it should be noted that the income tax laws, regulations and interpretations thereof change frequently. Participants should rely upon their own tax advisors for advice concerning the specific tax consequences applicable to them, including the applicability and effect of state, local, and foreign tax laws.

Nonstatutory Stock Options. There typically will be no federal income tax consequences to the optionee or to us upon the grant of a nonstatutory stock option under the 2015 Plan. When the optionee exercises a nonstatutory option, however, he or she will recognize ordinary income in an amount equal to the excess of the fair market value of our common stock received upon exercise of the option at the time of exercise over the exercise price, and we will typically be allowed a corresponding deduction. Any gain that the optionee realizes when he or she later sells or disposes of the option shares will be short-term or long-term capital gain, depending on how long the shares were held.

Incentive Stock Options. There typically will be no federal income tax consequences to the optionee or to us upon the grant or exercise of an incentive stock option. If the optionee holds the option shares for the required holding period of at least two (2) years after the date the option was granted or one (1) year after exercise, the difference between the exercise price and the amount realized upon sale or disposition of the option shares will be long-term capital gain or loss, and we will not be entitled to a federal income tax deduction. If the optionee disposes of the option shares in a sale, exchange, or other disqualifying disposition before the required holding period ends, he or she will recognize taxable ordinary income in an amount equal to the excess of the fair market value of the option shares at the time of exercise (or, if less, the amount realized on the disposition of the shares) over the exercise price, and we would typically be allowed a federal income tax deduction equal to such amount. While the exercise of an incentive stock option does not result in current taxable income, the excess of the fair market value of the option shares at the time of exercise over the exercise price will be an item of adjustment for purposes of determining the optionee's alternative minimum taxable income.

Stock Appreciation Rights. A participant receiving a stock appreciation right typically will not recognize income, and we will not be allowed a tax deduction, at the time the award is granted. When the participant exercises the stock appreciation right, the amount of cash and the fair market value of any shares of our common stock received will be ordinary income to the participant and we will typically be allowed as a corresponding federal income tax deduction at that time.

Restricted Stock. Unless a participant makes an election to accelerate recognition of income to the date of grant as described below, the participant will not recognize income, and we will not be allowed a tax deduction, at the time a restricted stock award is granted, provided that the award is subject to restrictions on transfer and is subject to a substantial risk of forfeiture. When the restrictions lapse, the participant will recognize ordinary income equal to the fair market value of our common stock as of that date (less any amount he or she paid for the stock), and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances. If the participant files an election under Code Section 83(b) within thirty (30) days after the date of grant of the restricted stock, he or she will recognize ordinary income as of the date of grant equal to the fair market value of the stock as of that date (less any amount paid for the stock), and we will typically be allowed a corresponding federal income tax deduction, subject to limitations in certain circumstances at that time. Any future appreciation in the stock will be taxable to the participant at capital gains rates. However, if the stock is later forfeited, the participant will not be able to recover the tax previously paid pursuant to the Section 83(b) election. To the extent unrestricted dividends are paid during the restricted period under the applicable award agreement, any such dividends will be taxable to the participant at ordinary income tax rates and will be deductible by us unless the participant has made a Section 83(b) election, in which case the dividends will thereafter be taxable to the participant as dividends and will not be deductible by us.

Stock Units. A participant typically will not recognize income, and we will not be allowed a tax deduction, at the time a stock unit award is granted. Upon receipt of shares of our common stock (or the equivalent value in cash) in settlement of a stock unit award, a participant will recognize ordinary income equal to the fair market value of our common stock or other property as of that date, and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances.

Cash-Based Performance Awards. A participant will not recognize income, and we will not be allowed a tax deduction, at the time a cash-based performance award is granted (for example, when the performance goals are established). Upon receipt of cash in settlement of the award, the participant will recognize ordinary income equal to the cash received, and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

The following is a summary of each transaction or series of similar transactions since the inception of Checkpoint to which it was or is a party and that:

- the amount involved exceeded or exceeds $120,000 or is greater than 1% of our total assets; and
- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

Effective March 17, 2015, we entered into a Founders Agreement with Fortress pursuant to which Fortress assigned to Checkpoint all of its right and interest (i) under Fortress' license agreement for the EGFR inhibitors and (ii) under Fortress' license agreement under negotiation for the PARP inhibitor that was subsequently executed and assigned to us. As consideration for the Founders Agreement, we assumed $2.8 million in debt that Fortress accumulated under the NSC Note for expenses and costs of forming Checkpoint and obtaining the Dana-Farber Antibodies and the EGFR inhibitors. As additional consideration for the transfer of rights under the Founders Agreement, we shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to 2.5% of the fully-diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Checkpoint's voting equity, equal to 2.5% of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to 4.5% of our annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), we will pay a one-time change in control fee equal to five (5x) times the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective March 17, 2015, we entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to us. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of our Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). We are obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, we are not obligated to take or act upon any advice rendered to us from Fortress and Fortress shall not be liable for any of our actions or inactions based upon their advice. Fortress and its affiliates, including all members of our Board of Directors, have been contractually exempt from their fiduciary duties to our Company relating to corporate opportunities. In consideration for the Services, we will pay Fortress an annual consulting fee of five hundred thousand dollars ($500,000) (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to one million dollars ($1,000,000) for each calendar year in which we have net assets in excess of one hundred million dollars ($100,000,000) at the beginning of the calendar year.

Michael S. Weiss, our Executive Chairman of the Board of Directors, is currently Executive Vice Chairman of Fortress. The MSA and Founders Agreements were negotiated with Fortress.

On August 17, 2015, we entered into a full service consulting agreement with Chord to provide advisory accounting services to us. Under the terms of the agreement, we pay Chord $7,500 per month to perform back office accounting functions, accounting analysis and financial reporting. Either party upon 30-days written notice can terminate the agreement. In addition to these services, Mr. Horin, a Managing Partner of Chord, will serve as our Interim Chief Financial Officer. Chord also provides advisory accounting services to Fortress under a separate agreement.

In connection with the license agreement with Dana-Farber, we entered into a collaboration agreement with TGTX to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies. Michael Weiss, our Executive Chairman of the Board of Directors and Fortress' Executive Vice Chairman, Strategic Development, is also Co-Portfolio Manager and a Partner of Opus Point Partners Management, LLC ("OPPM") with Dr. Rosenwald, Fortress's Chairman and Chief Executive Officer. Further, Michael Weiss is the Executive Chairman, Interim President and Chief Executive Officer and a stockholder of TGTX. Checkpoint retains the right to develop and commercialize these antibodies in the field of solid tumors. Both programs are currently in pre-clinical development. Under the terms of the Global Collaboration Agreement, TGTX paid us $500,000, representing a reimbursement for their share of the licensing fee, and will make additional development and sales-based milestone payments and royalties on net sales. For the year ended December 31, 2015, we recognized $590,000 in revenue from our collaboration agreement with TGTX in our Statements of Operations.

On February 23, 2016, we closed on gross proceeds of $0.6 million, before expenses, in a private placement of shares and warrants to Opus Point Healthcare Fund GP, LLC, a fund managed by OPPM, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $45,000 per unit. The warrants have a five year term and are only exercisable for cash. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, us were consistent with terms of the December 2015 third-party financing which included the payment of fees and issuance of warrants to a placement agent.

Fortress Financing Arrangements Affecting our Company

On February 27, 2015, Fortress executed a Note Purchase Agreement (the "Fortress Note Purchase Agreement") with NSC Biotech Venture Fund I LLC ("Investor") and issued the NSC Note in favor of the Investor. See "Liquidity and Capital Resources" for a description of the NSC Note. In connection with the Founders Agreement, we assumed $2,791,831 under the NSC Note and issued 139,592 warrants to purchase our common stock, which was equal to twenty-five percent (25%) of the amount of NSC Note proceeds we received from Fortress divided by the lowest price at which we next sold common stock. In February 2016, we paid NSC $2,811,412, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment.

Further, until June 18, 2017, upon any proposed issuance by us of capital stock or debt, including common stock or similar forms of capital stock, as well as securities that may be convertible into or exercisable or exchangeable for such capital stock (including convertible and non-convertible debt), in a private financing, other than equity or convertible debt securities, units or other combinations or securities that include equity or convertible debt securities issued in connection with a strategic partnership, acquisition of another company or a merger and/or acquisition of substantially all of our or Fortress's assets (a "Subsequent Financing"), NSC shall have the right, but not the obligation, to participate for twenty percent (20%) of the Subsequent Fortress Financing on the same terms, conditions and price provided for in the Subsequent Financing. We must provide NSC reasonable written notice of our intention to affect a Subsequent Financing which must include the terms and conditions of such Subsequent Financing. NSC then has five (5) business days to respond to our written notice with NSC's election to participate in the Subsequent Financing.

Director Independence

Though not a listed company, we intend to adhere to the corporate governance standards adopted by NASDAQ. NASDAQ rules require our Board to make an affirmative determination as to the independence of each director. Consistent with these rules, our Board conducted its annual review of director independence. During the review, our Board considered relationships and transactions since incorporation between each director or any member of his immediate family, on the one hand, and us and our subsidiaries and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our Board determined that of the current members of our Board, three directors, Neil Herskowitz, Barry Salzman and Scott Boilen are independent directors under the criteria established by NASDAQ and by our Board.

Our board of directors has a chairman, Michael S. Weiss, who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors.

Item 8. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our company or our officers or directors in their capacities as such.

Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.

Market information

There is no established public trading market in our common stock. Our securities are not listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

Equity Compensation Plans

We expect that in the future we will file a registration statement on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our 2015 Plan. That registration statement will become effective immediately upon filing, and shares covered by that registration statement will thereupon be eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 limitations applicable to our affiliates.

Holders

As of December 31, 2015, there were approximately 16.0 million shares of common stock outstanding held by 563 record stockholders and 7.0 million shares of Class A common stock outstanding held by one record stockholder.

Dividends

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

Stock Not Registered Under the Securities Act; Rule 144 Eligibility

Our common stock has not been registered under the Securities Act. Accordingly, the shares of common stock issued and outstanding may not be resold absent registration under the Securities Act and applicable state securities laws or an available exemption thereunder.

Rule 144

Shares of our common stock that are restricted securities will be eligible for resale in compliance with Rule 144 ("Rule 144") or Rule 701 ("Rule 701") of the Securities Act, subject to the requirements described below. "Restricted Securities," as defined under Rule 144, were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or if they qualify for an exemption from registration, such as Rule 144 or Rule 701. Below is a summary of the requirements for sales of our common stock pursuant to Rule 144, as in effect on the date of this Form 10, after the effectiveness of this Form 10.

Affiliates

Affiliates will be able to sell their shares under Rule 144 beginning 90 days after the effectiveness of this Form 10, subject to all other requirements of Rule 144. In general, under Rule 144, an affiliate would be entitled to sell within any three-month period a number of shares that does not exceed one percent of the number of shares of our common stock then outstanding. Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Persons who may be deemed to be our affiliates generally include individuals or entities that control, or are controlled by, or are under common control with, us and may include our directors and officers, as well as our significant stockholders.

Non-Affiliates

For a person who has not been deemed to have been one of our affiliates at any time during the 90 days preceding a sale, sales of our shares of common stock held longer than six months, but less than one year, will be subject only to the current public information requirement and can be sold under Rule 144 beginning 90 days after the effectiveness of this Form 10. A person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144 upon the effectiveness of this Form 10.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this Form 10, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effective date of this Form 10 before selling their shares under Rule 701.

Securities Authorized for Issuance under Equity Compensation Plans

Subject to adjustment as provided in the 2015 Plan, the aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 2,000,000.

Item 10. Recent Sales of Unregistered Securities.

In December 2015, we closed on gross proceeds of $57.8 million, before commissions and expenses, in a series of private placement financings. Net proceeds from this offering were approximately $51.5 million. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 2,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $50,000 per unit. The warrants have a five year term and are only exercisable for cash.

In February 2016, we closed on gross proceeds of $0.6 million, before expenses, in a private placement of shares and warrants to Opus Point Healthcare Fund GP, LLC, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $45,000 per unit. The warrants have a five year term and are only exercisable for cash. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, us were consistent with terms of the December 2015 third-party financing, noted above, which included the payment of fees and issuance of warrants to a placement agent.

We expect to use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at December 31, 2015, are sufficient to fund our anticipated operating cash requirements for at least the next 24 months.

All of the above transactions were conducted pursuant to the exemption provided by Regulation D under the Securities Act.

Item 11. Description of Registrant's Securities to be Registered.

The following description summarizes the material terms of Checkpoint capital stock as of the date of this registration statement. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of our capital stock, you should refer to our certificate of incorporation, our bylaws and to the provisions of applicable Delaware law.

The authorized capital stock of Checkpoint consists of 50,000,000 shares of common stock, of which 7,000,000 shares have been designated as Class A common stock. Only our 43,000,000 shares of common stock are being registered hereby. The description of our Class A Common Stock in this item is for information purposes only. All of the Class A common stock has been issued to Fortress. Class A common stock is identical to common stock other than as to voting rights, the election of directors for a definite period, and conversion rights. On any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A common stock will be entitled to cast for each share of Class A common stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of outstanding Class A common stock. Thus, the Class A common stock will at all times constitute a voting majority. For a period of ten (10) years from the date of the first issuance of shares of Class A common stock (the "Class A Director Period"), the holders of record of the shares of Class A common stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A common stock), exclusively and as a separate class, will be entitled to appoint or elect the majority of the directors of Checkpoint (the "Class A Directors"). Finally, each share of Class A common stock is convertible, at the option of the holder, into one fully paid and nonassessable share of common stock (the "Conversion Ratio"), subject to certain adjustments.

If Checkpoint at any time effects a subdivision of the outstanding common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) by any stock split, stock dividend, recapitalization or otherwise, the applicable Conversion Ratio in effect immediately before that subdivision will be proportionately decreased so that the number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) issuable on conversion of each share of Class A common stock will be increased in proportion to such increase in the aggregate number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) outstanding. If Checkpoint at any time combines the outstanding shares of common stock, the applicable Conversion Ratio in effect immediately before the combination will be proportionately increased so that the number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) issuable on conversion of each share of Class A common stock will be decreased in proportion to such decrease in the aggregate number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) outstanding. Additionally, if any reorganization, recapitalization, reclassification, consolidation or merger involving Checkpoint occurs in which the common stock (but not the Class A common stock) is converted into or exchanged for securities, cash or other property (other than a transaction involving the subdivision or combination of the common stock), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Class A common stock becomes convertible into the kind and amount of securities, cash or other property which such Class A Stockholder would have been entitled to receive had he or she converted the Class A Shares immediately before said transaction. In such case, appropriate adjustment (as determined in good faith by the Board of Directors of Checkpoint) will be made in the application of the provisions of Checkpoint's Amended and Restated Certificate of Incorporation relating the subdivision or combination of the common stock with respect to the rights and interests thereafter of the holders of the Class A common stock, such that the provisions set forth in of Checkpoint's Amended and Restated Certificate of Incorporation relating to the subdivision or combination of the common stock (including the provisions with respect to changes in and other adjustments of the applicable Conversion Ratio) will thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Class A common stock. Checkpoint is not authorized to issue preferred stock.

Other features of our common stock include:

- *Dividend Rights*. The holders of outstanding shares of our common stock, including Class A common stock, are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine. All dividends are non-cumulative.

- *Voting Rights*. The holders of our common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors, except as to the Class A Directors during the Class A Director Period. Our certificate of incorporation and bylaws do not provide for cumulative voting rights.

- *No Preemptive or Similar Rights.* The holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock.

- *Right to Receive Liquidation Distributions.* Upon our liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock, including Class A common stock, outstanding at that time after payment of other claims of creditors, if any.

— *Fully Paid and Non-Assessable.* All of the outstanding shares of our common stock, including Class A common stock, are, and the shares of our common stock to be issued pursuant to this offering will be, duly issued, fully paid and non-assessable.

Item 12. Indemnification of Directors and Officers.

We have adopted provisions in our certificate of incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the Delaware General Corporation Law ("DGCL"). Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to the corporation or the stockholder;

- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or

- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our certificate of incorporation and our bylaws also provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our bylaws would permit indemnification. We have secured such insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our charter documents. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by each of these persons in any action or proceeding arising out of his or her services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

Item 13. Financial Statements and Supplementary Data.

The information required by this item may be found beginning on page F-1 of this Form 10.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

We engaged EisnerAmper LLP to audit our initial financial statements on August 17, 2015. There have been no changes since or any disagreements with EisnerAmper regarding any accounting or financial disclosure matter.

Item 15. Financial Statements and Exhibits

(a) Financial Statements.

The following financial statements are filed as part of this registration statement:

(b) Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc.
3.2	Certificate of Amendment to Certificate of Incorporation of Checkpoint Therapeutics, Inc.
3.3	Bylaws of Checkpoint Therapeutics, Inc.
4.1	Specimen certificate evidencing shares of common stock.
4.2	Form of warrant agreement.
10.1	Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015.
10.2	Management Services Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015.
10.3	Promissory Note to NSC Biotech Venture Fund I, LLC dated February 27, 2015.
10.4	Common Stock Warrant issued by Checkpoint Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC dated July 30, 2015.
10.5	License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc. dated March 2, 2015.*
10.6	Amendment 1 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 5, 2015.*
10.7	License Agreement by and between NeuPharma Inc. and Coronado Biosciences, Inc. (Fortress' predecessor) dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Founders Agreement).*
10.8	Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated March 3, 2015.*
10.9	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan.
10.10	Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated October 13, 2015.
10.11	License Agreement by and between Cephalon, Inc. and Fortress Biotech, Inc. dated December 18, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Founders Agreement).*
10.12	Non-Employee Directors Compensation Plan

* Subject to a request for confidential treatment.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Checkpoint Therapeutics, Inc.

We have audited the accompanying balance sheets of Checkpoint Therapeutics, Inc. (the "Company") as of December 31, 2015 and 2014 and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2015 and for the period from November 10, 2014 (inception) to December 31, 2014. The 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. The Company is not required to have, nor were we engaged to perform, an audit of its 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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 Checkpoint Therapeutics, Inc. as of December 31, 2015, and the results of its operations and its cash flows for the year ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
March 23, 2016, except for Note 6 as to which the date is April 26, 2016

Checkpoint Therapeutics, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	As of December 31,	
	2015	**2014**
ASSETS		
Current Assets:		
Cash	$ 50,418	$ -
Prepaid expenses	171	-
Other receivables	65	-
Total current assets	50,654	-
Total Assets	**$ 50,654**	**$ -**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,288	$ -
Accrued expenses - related party	502	-
Total current liabilities	1,790	-
Note payable, long-term (net of debt discount of $324)	2,468	-
Total Liabilities	**4,258**	**-**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	1	1
Common shares, 15,989,315 shares and 1,000,000 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	1	-
Additional paid-in capital	57,262	(1)
Accumulated deficit	(10,868)	-
Total Stockholders' Equity	46,396	-
Total Liabilities and Stockholders' Equity	**$ 50,654**	**$ -**

The accompanying notes are an integral part of these financial statements.

Checkpoint Therapeutics, Inc.
Statements of Operations
(in thousands, except share and per share amounts)

	For the year ended December 31, 2015	For the period from November 10, 2014 (inception) to December 31, 2014
Revenue - related party	$ 590	$ -
Operating expenses:		
Research and development	8,299	-
General and administrative	2,488	-
Total operating expenses	10,787	-
Loss from operations	(10,197)	-
Change in fair value of warrant liabilities	438	-
Interest expense and amortization of debt discount	233	-
Net Loss	**$ (10,868)**	**$ -**
Loss per Share:		
Net loss per common share outstanding, basic and diluted	**$ (0.96)**	**$ -**
Weighted average number of common shares outstanding, basic and diluted	**11,324,506**	**8,000,000**

The accompanying notes are an integral part of these financial statements.

Checkpoint Therapeutics, Inc.
Statements of Stockholders' Equity
(in thousands, except share amounts)

	Class A Common Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Issuance of Class A common shares to Fortress on November 10, 2014	7,000,000	$ 1	-	$ -	$ (1)	$ -	$ -
Issuance of common shares to Fortress on November 10, 2014	-	-	1,000,000	-	-	-	-
Balances at December 31, 2014	**7,000,000**	**1**	**1,000,000**	**-**	**(1)**	**-**	**-**
Cash received for issuance of founder shares	-	-	-	-	1	-	1
Issuance of common shares for cash	-	-	11,563,400	1	57,816	-	57,817
Offering costs	-	-	-	-	(6,321)	-	(6,321)
Stock-based compensation expenses	-	-	1,000,000	-	265	-	265
Issuance of common shares - Founders Agreement (see Note 4)	-	-	289,085	-	1,269	-	1,269
Issuance of restricted stock and warrants for services	-	-	1,500,000	-	2,987	-	2,987
Issuance of common shares for license expenses	-	-	636,830	-	633	-	633
Issuance of warrants in conjunction with NSC debt	-	-	-	-	613	-	613
Net loss	-	-	-	-	-	(10,868)	(10,868)
Balances at December 31, 2015	7,000,000	$ 1	**15,989,315**	**$ 1**	**$ 57,262**	**$ (10,868)**	**$ 46,396**

The accompanying notes are an integral part of these financial statements.

Checkpoint Therapeutics, Inc.
Statements of Cash Flows
(in thousands)

	For the year ended December 31, 2015	For the period from November 10, 2014 (inception) to December 31, 2014
Cash flows from operating activities:		
Net loss	$ (10,868)	$ -
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expenses	265	-
Change in fair value of warrant liabilities	438	-
Issuance of common shares - Founders Agreement	1,269	-
Issuance of restricted stock and warrants for services	2,987	-
Research and development-licenses acquired, expensed	2,525	-
Issuance of common shares for license expenses	633	-
Amortization of debt discount	89	-
Changes in operating assets and liabilities:		
Prepaid expenses	(171)	-
Other receivables	(65)	-
Accounts payable and accrued expenses	1,790	-
Net cash used in operating activities	(1,108)	-
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(2,525)	-
Net cash used in investing activities	(2,525)	-
Cash flows from financing activities:		
Proceeds from note payable, net of debt discount	2,554	-
Proceeds from issuance of common stock	57,817	-
Payment of costs related to offering	(6,321)	-
Cash received for issuance of founder shares	1	-
Net cash provided by financing activities	54,051	-
Net change in cash	50,418	-
Cash, beginning of year	-	-
Cash, end of year	**$ 50,418**	**$ -**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 56	$ -
Supplemental disclosure of noncash investing and financing activities:		
Debt discount associated with derivative warrant liabilities	$ 175	$ -
Issuance of founder shares to Fortress on November 10, 2014	$ -	$ 1

The accompanying notes are an integral part of these financial statements.

Note 1 — Organization and Description of Business Operations

Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") was incorporated in Delaware on November 10, 2014, as a wholly owned subsidiary of Fortress Biotech, Inc. ("Fortress" or "Parent") and commenced its principal operations in March 2015. Checkpoint was formed as an immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. The Company may acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Portfolio of Immuno-Oncology and Anti-Cancer Agents

In March 2015, Checkpoint entered into a license agreement with Dana-Farber Cancer Institute ("Dana-Farber") for an exclusive, worldwide license to a portfolio of antibodies targeting programmed-death ligand 1 ("PD-L1"), glucocorticoid-induced TNFR-related protein ("GITR") and carbonic anhydrase IX ("CAIX"). These antibodies are currently in pre-clinical development. Checkpoint plans to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as published literature suggests that combinations of these targets can work synergistically together. The Company expects to submit investigational new drug ("IND") applications for its anti-PD-L1, anti-GITR and anti-CAIX antibodies in 2017 (see Note 3).

In connection with the license agreement with Dana-Farber dated March 3, 2015, Checkpoint entered into a Global Collaboration Agreement with TG Therapeutics, Inc. ("TGTX"), a related party, to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies, while Checkpoint retains the right to develop and commercialize these antibodies in the field of solid tumors (see Note 3).

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma, Inc. ("NeuPharma") to develop and commercialize novel irreversible, 3rd generation EGFR inhibitors, including CK-101, on a worldwide basis other than certain Asian countries. This license was assigned by Fortress to the Company effective March 17, 2015 pursuant to the terms of an Assignment and Assumption Agreement. The program is currently in pre-clinical development and the Company plans to submit an IND application to the FDA during the first half of 2016 (see Note 3 and Note 4).

In December 2015, Fortress licensed the exclusive worldwide rights to develop and commercialize CK-102 (formerly CEP-9722), a poly (ADP-ribose) polymerase ("PARP") inhibitor, from Teva Pharmaceutical Industries Ltd., through its subsidiary, Cephalon, Inc. CK-102 is an oral, small molecule selective inhibitor of PARP-1 and PARP-2 enzymes in early clinical development for solid tumors. This license was assigned by Fortress to the Company effective December 18, 2015 pursuant to the terms of an Assignment and Assumption Agreement. The Company plans to develop CK-102 as both a monotherapy and in combination with other anti-cancer agents, including the Company's novel immuno-oncology and Checkpoint inhibitor antibodies currently in development (see Note 3 and Note 4).

Liquidity and Capital Resources

The Company has incurred substantial operating losses since its inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2015, the Company had an accumulated deficit of $10.9 million.

On September 18, 2015, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with National Securities Corporation (the "Placement Agent") relating to the Company's offering, issuance and sale (the "Offering") to select institutional investors (the "Investors") of units consisting of 10,000 shares of the Company's common stock, $0.0001 par value per share (the "Common Stock"), and warrants (the "Warrants") exercisable for 2,500 shares of Common Stock at an exercise price of $7.00 per share, for a purchase price of $50,000 per unit. The warrants have a five year term and are only exercisable for cash. The Offering closed on December 18, 2015 (see Note 7). The net proceeds to the Company from the Offering, after deducting Placement Agent fees and the Company's offering expenses, were approximately $51.5 million.

On February 23, 2016, the Company closed on gross proceeds of $0.6 million, before expenses, in a private placement of shares and warrants to Opus Point Healthcare Fund GP, LLC, a fund managed by Opus Point Partners Management, LLC, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $45,000 per unit. The warrants have a five year term and are only exercisable for cash. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, the Company were consistent with terms of the December 2015 third-party financing, noted above, which included the payment of fees and issuance of warrants to a placement agent.

The Company expects to use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash balances at December 31, 2015, are sufficient to fund its anticipated operating cash requirements for at least the next 24 months.

Note 2 — Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company has no subsidiaries.

The financial statements may not be indicative of future performance and may not reflect what the Company's results of operations, financial position, and cash flows would have been had Checkpoint operated as an independent entity. Certain estimates, including allocations from Fortress, have been made to provide financial statements for stand-alone reporting purposes. All inter-company transactions between Fortress and Checkpoint are classified as accrued expenses – related party in the financial statements. The Company believes that the assumptions underlying the financial statements are reasonable.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. There were no cash equivalents at December 31, 2015.

Research and Development Costs

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings, laboratory costs and other supplies.

Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired during the period was reflected as research and development expenses in the Company's Statements of Operations for the year ended December 31, 2015.

Stock-Based Compensation Expenses

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as stock-based compensation expense in the period of change.

Fair Value Measurement

The Company follows the accounting guidance in ASC 820 for its fair value measurements of financial assets and liabilities measured at fair value on a recurring basis. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Revenue Recognition

Reimbursement Arrangements and Collaborative Arrangements

The Company is reimbursed by TGTX, a related party, for their share of the cost of the license and future milestone payments that are payable to Dana-Farber pursuant to the license agreement (see Note 1). The gross amount of these reimbursed costs are reported as revenue in the accompanying Statements of Operations. The Company acts as a principal (as the Company is responsible for designing the future clinical development pathway), bears credit risk and may perform part of the services required in the transactions. Consistent with ASC 605-45-15 these reimbursements are treated as revenue to the Company. The actual expenses creating the reimbursements are reflected as research and development expenses.

The Company recognizes revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or as services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

The Company follows ASC 605-25, *Revenue Recognition - Multiple-Element Arrangements* and ASC 808, *Collaborative Arrangements*, if applicable, to determine the recognition of revenue under the Company's collaborative research, options to enter into collaborative research agreements and development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) grants of licenses, or options to obtain licenses, to the Company's intellectual property, (ii) research and development services, (iii) drug product manufacturing, and/or (iv) participation on joint research and/or joint development committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the Balance Sheet and recognized as revenue in the Statements of Operations when the related revenue recognition criteria are met. See Note 3 for a description of the collaborative arrangement.

Income Taxes

For purposes of these financial statements, the Company's income tax expense and deferred tax balances have been recorded as if it filed tax returns on a stand-alone basis separate from Fortress.

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities measured at the enacted tax rates in effect for the year in which these items are expected to reverse. Deferred tax assets are reduced by valuation allowances if, based on the consideration of all available evidence, it is more likely than not that some portion or all of the deferred tax asset will not be realized.

Valuation of Warrant Related to NSC Note

In accordance with ASC 815, the Company classified the fair value of the warrant ("Contingently Issuable Warrants") that may have be granted in connection with the NSC Note transferred to the Company in various traches from March 19, 2015 to August 31, 2015 as a derivative liability as there was a potential that the Company would not have a sufficient number of authorized common shares available to settle this instrument. The Company valued these Contingently Issuable Warrants using an option pricing model (which approximates intrinsic value) with estimates for an expected dividend yield, a risk-free interest rate, and expected volatility together with management's estimate of the probability of issuance of the Contingently Issuable Warrants. At each reporting period, as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants, the Contingently Issuable Warrants should be revalued and any difference from the previous valuation date would be recognized as a change in fair value in the Company's Statement of Operations.

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants, as their inclusion would be anti-dilutive. There are 4,286,782 warrants outstanding as of December 31, 2015, which are not included in the computation of net loss per share.

Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2016-02 on its financial statements. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2016-01 will have on its balance sheet or financial statement disclosures. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2015-17 will have on its balance sheet or financial statement disclosures. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*("ASU 2015-03"), which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. ASU 2015-03 is effective for the interim and annual periods ending after December 15, 2015, with early adoption permitted. The Company adopted ASU 2015-03 and such adoption resulted in debt issuance costs presented as an offset against notes payable, long-term, in the accompanying balance sheet.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern* ("ASU 2014-15"), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2014-15 and its related disclosures. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In July 2015, the FASB voted to approve a one-year deferral of the effective date of ASU 2014-09, which will now be effective for the Company in the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. The Company is evaluating the impact of implementation and transition approach of this standard on its financial statements. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

Note 3 – License Agreements

Dana-Farber Cancer Institute

In March 2015, Checkpoint entered into an exclusive license agreement with Dana-Farber to develop a portfolio of fully human immuno-oncology targeted antibodies. Under the terms of the agreement, Checkpoint paid Dana-Farber an up-front licensing fee of $1.0 million and, on May 11, 2015, Checkpoint granted Dana-Farber 500,000 shares, valued at $32,500 or $0.065 per share, both of which have been included in research and development expenses on the Company's Statements of Operations. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the license agreement, Dana-Farber will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due Dana-Farber. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX.

In connection with the license agreement with Dana-Farber, Checkpoint entered into a collaboration agreement with TGTX, a related party, to develop and commercialize the Anti-PD-L1 and Anti-GITR antibody research programs in the field of hematological malignancies, while Checkpoint retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Executive Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also Co-Portfolio Manager and a Partner of Opus Point Partners Management, LLC ("OPPM") with Dr. Rosenwald, Director of Checkpoint, Fortress's Chairman and Chief Executive Officer. Further, Michael Weiss is the Executive Chairman, Interim President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Global Collaboration Agreement, TGTX paid the Company $0.5 million, representing a reimbursement for their share of the licensing fee, and the Company is eligible to receive up to an aggregate of approximately $21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, the Company is eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, the Company will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to the Company. For the year ended December 31, 2015, the Company recognized $0.5 million in revenue in connection with this collaboration agreement with TGTX in the Statements of Operations.

NeuPharma, Inc.

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma to develop and commercialize novel irreversible, 3rd generation EGFR inhibitors, including CK-101, on a worldwide basis other than certain Asian countries. On the same date, Fortress and the Company entered into a Founders Agreement pursuant to which Fortress assigned all of its right and interest in the EGFR inhibitors to the Company in exchange for certain consideration (see Note 4). Under the terms of the agreement, the Company paid NeuPharma an up-front licensing fee of $1.0 million, included in research and development expenses on the Company's Statement of Operations, and NeuPharma is eligible to receive payments of up to an aggregate of approximately $40.0 million per licensed product upon the Company's successful achievement of certain clinical development and regulatory milestones in up to three indications, of which $22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of $40.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales.

Teva Pharmaceutical Industries Ltd. (through its subsidiary, Cephalon, Inc.)

In December 2015, Fortress entered into a license agreement with Teva Pharmaceutical Industries Ltd. through its subsidiary, Cephalon, Inc. ("Cephalon"), which agreement was assigned to the Company by Fortress on the same date pursuant to the Founders Agreement (see Note 4). Under the terms of the license agreement, Checkpoint obtained an exclusive, worldwide license to Cephalon's patents relating to CEP-8983 and its small molecule prodrug, CEP-9722, a PARP inhibitor, which the Company now refers to as CK-102. The Company paid Cephalon an up-front licensing fee of $0.5 million, included in research and development expenses on the Statement of Operations. Cephalon is eligible to receive milestone payments of up to an aggregate of approximately $220.0 million upon the Company's successful achievement of certain clinical development, regulatory approval and product sales milestones, of which approximately $206.5 million are due on or following regulatory approvals to commercialize the product. In addition, Cephalon is eligible to receive royalty payments based on a tiered low double digit percentage of net sales.

Note 4 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, Fortress and the Company entered into a Founders Agreement pursuant to which Fortress assigned to Checkpoint all of its right and interest (i) under Fortress' license agreement for the EGFR inhibitors and (ii) to a license agreement for a PARP inhibitor that was under negotiation, as set forth in the Founders Agreement. As consideration for the Founders Agreement, the Company assumed $2.8 million in debt that Fortress accumulated under the NSC Note (see Note 5) for expenses and costs of forming Checkpoint and obtaining the Dana-Farber antibodies and the EGFR inhibitors. As additional consideration for the transfer of rights under the Founders Agreement, the Company will also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to 2.5% of the fully-diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Checkpoint's voting equity, equal to two and one-half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Checkpoint's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Checkpoint will pay a one-time change in control fee equal to five (5x) times the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective March 17, 2015, the Company entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Checkpoint's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of the Company's actions or inactions based upon their advice. Fortress and its affiliates, including all members of the Company's Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. For the year ended December 31, 2015, the Company recognized approximately $0.4 million in expense in its Statements of Operations related to the MSA.

Note 5 – NSC Note

In March 2015, Fortress closed the private placement of a promissory note for $10 million through National Securities Corporation (the "NSC Note"). Fortress used the proceeds from the NSC Note to acquire medical technologies and products. The NSC Note matures in 36 months, provided that during the first 24 months Fortress can extend the maturity date by six months. No principal amount will be due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the NSC Note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the note is 8% payable quarterly during the first 24 months (or the first 30 months if the note is extended) and payable monthly during the last 12 months. National Securities Corporation ("NSC"), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note.

The NSC Note, was amended and restated on July 29, 2015, to provide that any time a Fortress subsidiary receives from Fortress any proceeds from the NSC Note, Fortress may, in its sole discretion, cause the Fortress subsidiary to issue to NSC Biotech Venture Fund I LLC a new promissory note (the "Amended NSC Note") on identical terms as the NSC Note (giving effect to the passage of time with respect to maturity). The Amended NSC Note will equal the dollar amount of the Fortress subsidiary's share of the NSC Note and reduce Fortress' obligations under the NSC Note by such amount. Fortress will guarantee the Amended NSC Note until the company either completes an initial public offering of its securities or raises sufficient equity capital so that it has cash equal to five times the Amended NSC Note.

If the Fortress subsidiary has an initial public offering or raises sufficient equity capital so that it has cash equal to five times the amount of the portion of the proceeds of the NSC Note transferred to it, then NSC will receive a warrant to purchase the company's stock equal to 25% of the amount of NSC Note proceeds the company receives from Fortress divided by the lowest price at which the company next sells common stock. The warrants issued will have a term of 10 years and an exercise price equal to the par value of the company's common stock. On October 30, 2015, Checkpoint granted 139,592 warrants to NSC after an initial closing of the Offering on September 30, 2015. The warrant was valued at approximately $0.6 million by using an option pricing model (see Note 9).

As of December 31, 2015, the Company's Amended NSC Note totaled $2.8 million, including a debt discount related to the Company's pro rata share of Fortress' debt issuance costs of approximately $0.2 million. For the year ended December 31, 2015, the Company recorded costs of approximately $89,000 related to the amortization of the debt discount and $0.1 million of interest expense at 8%, both recorded in interest expense in the Statements of Operations. The effective interest rate of the NSC Note approximates 14.09%. The following table summarizes the Company's Amended NSC Note activities as of December 31, 2015 (in thousands).

	NSC Note Payable	Discount	NSC Note Payable, Net
January 1, 2015 balance	$ -	$ -	$ -
Proceeds from issuance of Amended NSC Note	2,792	(238)	2,554
Derivative warrant liabilities	-	(175)	(175)
Amortization of debt discount	-	89	89
December 31, 2015 balance	$ 2,792	$ (324)	$ 2,468

In February 2016, the Company paid NSC $2.8 million, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment.

Note 6 – Commitments and Contingencies

Leases

The Company is not a party to any leases for office space or equipment.

NeuPharma Sponsored Research Agreement

In connection with a Sponsored Research Agreement, the Company entered into a work order approximating $1.6 million, which shall be expensed over the next 12 months as work is incurred, unless earlier terminated by the Company.

Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and reimbursed the Company for all amounts paid previously by the Company.

License Agreements

The Company has undertaken to make contingent milestone payments to the licensors of its portfolio of drug candidates. In addition, the Company shall pay royalties to such licensors based on a percentage of net sales of each drug candidate following regulatory marketing approval (See Note 3).

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company accrues the most likely amount of such loss, and if such amount is not determinable, then the Company accrues the minimum of the range of probable loss. As of December 31, 2015, there was no litigation against the Company.

Note 7 — Stockholders' Equity

Common Stock

The Company is authorized to issue 50,000,000 common shares with a par value of $0.0001 per share, of which 7,000,000 shares were designated as "Class A common stock". On November 10, 2014, Fortress subscribed for 7,000,000 shares of the Class A common stock and 1 million shares of the Company's common stock. Fortress paid the par value in November 2015. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. Dividends are to be distributed pro-rata to the Class A and common stock holders. The holders of common stock are entitled to one vote per share of common stock held. The Class A common stock holders are entitled to a number of votes per share equal to 1.1 times a fraction the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of Class A common stock. Each share of Class A common stock shall be convertible, at the option of the holder thereof, into one (1) fully paid and non-assessable share of common stock subject to adjustment for stock splits and combinations.

Offerings of Common Stock and Warrants

On September 18, 2015, the Company entered into a Placement Agency Agreement with the Placement Agent relating to the Company's Offering. Pursuant to the Placement Agency Agreement, the Company agreed to pay the Placement Agent a cash fee of 10.0% of the gross proceeds from the Offering and granted a warrant exercisable for shares of Common Stock equal to 10% of the aggregate number of shares of Common Stock sold in the Offering (the "Placement Agent Warrants"). In addition, the Company and the Investors entered into a unit purchase agreement (the "Unit Purchase Agreement") relating to the issuance and sale of the Common Stock and the Warrants in five separate closings during the third and fourth quarter of 2015. The Common Stock and Warrants were sold in units, with each unit consisting of 10,000 shares of the Company's Common Stock, and Warrants exercisable for 2,500 shares of Common Stock at an exercise price of $7.00 per share. The purchase price was $50,000 per Unit. The warrants have a five year term and are only exercisable for cash. The Offering's final closing was held on December 18, 2015. The Company issued 11,563,400 unregistered shares of Common Stock and 2,890,850 Warrants in this Offering. The Placement Agent received 1,156,340 Placement Agent Warrants. For the year ended December 2015, the Company closed on gross proceeds of $57.8 million, before commissions and expenses of $6.3 million, in the Offering.

On February 23, 2016, the Company closed on gross proceeds of $0.6 million, before expenses, in a private placement of shares and warrants to Opus Point Healthcare Fund GP, LLC, a fund managed by Opus Point Partners Management, LLC, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of $7.00 per share, for a purchase price of $45,000 per unit. The warrants have a five year term and are only exercisable for cash. The Company issued 126,640 unregistered shares of common stock and 44,324 warrants in connection with this transaction. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, the Company were consistent with terms of the December 2015 third-party financing, noted above, which included the payment of fees and issuance of warrants to a placement agent.

Pursuant to the Founders Agreement, the Company issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the offerings noted above. Accordingly, for the year ended December 31, 2015, the Company issued 289,085 shares to Fortress and recorded expense of approximately $1.3 million related to this stock grant, which is included in general and administrative expenses in the Company's Statements of Operations. Subsequent to December 31, 2015, the Company issued an additional 3,166 shares to Fortress associated with the February 2016 offering.

Restricted Stock

On March 3, 2015, the Company granted Dr. Marasco 1,500,000 shares of restricted stock for his services. The Company valued the restricted stock granted to Dr. Marasco utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8% and a weighted average cost of capital of 30%, resulting in a value of $0.065 per share. Under the terms of the stock grant, the shares vest 25% on the first anniversary of the grant date and monthly thereafter for 48 months. The Company re-measured this non-employee restricted stock based upon a fair value of $4.39 per share at December 31, 2015, and recorded non-cash expenses of approximately $3.0 million, which is included in research and development expenses in the Statements of Operations.

The 500,000 shares Checkpoint granted to Dana-Farber in May 2015 vested immediately and included an anti-dilution clause that maintained Dana-Farber's ownership of the Company at 5%, until such time that the Company raised $10 million in cash in exchange for common shares. The shares were valued by the Company utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8% and a weighted average cost of capital of 30%, net of debt utilized resulting in a value of $0.065 per share for which the Company recorded non-cash expense of $32,500. Additionally, pursuant to the license agreement, on September 30, 2015, Checkpoint granted to Dana-Farber an additional 136,830 shares of common stock that vested immediately. The Company recorded non-cash expense of approximately $0.6 million related to this stock grant based upon a value of $4.39 per share, which is included in research and development expenses in the Company's Statements of Operations.

On October 13, 2015, pursuant to his employment agreement, the Company granted Mr. Oliviero, President and Chief Executive Officer, 1,000,000 shares of restricted stock under the Company's 2015 Incentive Plan. One-third of the shares will vest in four equal annual installments beginning on October 13, 2016. The shares were valued by the Company utilizing traditional techniques including market income and cost valuation approaches. This yielded a price per share of $4.39 utilizing a risk free rate of return of 1.5% and expected volatility of 83%. One-third of the shares will vest in three equal annual installments based on the Company's achievement of fully-diluted market capitalizations of $250 million, $500 million and $750 million, respectively. The Company estimated the date of achievement and implied values per common share utilizing Monte Carlo model, which yielded implied values per restricted share of $4.26, $3.89 and $3.64, and the achievement dates of November 28, 2017, March 3, 2019 and November 2, 2019. The final third vests upon the achievement of certain milestones. For the year ended December 31, 2015, the Company recorded stock-based compensation expense of approximately $265,000 related to this stock grant, which is included in general and administrative expenses in the Company's Statements of Operations.

The following table summarizes restricted stock award activity for the year ended December 31, 2015.

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2015	-	$ -
Granted	3,136,830	1.58
Vested	(636,830)	0.99
Nonvested at December 31, 2015	2,500,000	$ 1.73

The remaining weighted-average life of unvested restricted stock was 1.73 years.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 1,000,000 shares at December 31, 2015.

Warrants

On August 31, 2015, the Company granted warrants on 100,000 shares of common stock to a Fortress employee for consulting services provided to the Company. The Company valued the warrants utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.3% and a weighted average cost of capital of 30%, resulting in a value of $0.129 per warrant. The warrants are immediately vested, and are exercisable at $0.129 per share. The Company recorded stock-based compensation expense of approximately $13,000 related to this warrant, which is included in research and development expenses in the Statements of Operations.

On October 30, 2015, the Company granted 139,592 warrants to NSC after an initial closing of the Offering on September 30, 2015. The warrants are immediately vested with a ten-year term, and are exercisable at $0.0001 per share. The Company valued these warrants using an option pricing model and estimates for an expected dividend yield, a risk-free interest rate, and expected volatility (see Note 9).

A summary of warrant activities for year ended December 31, 2015 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2015	-	$ -	-
Granted	4,286,782	6.61	5.68
Outstanding as of December 31, 2015	4,286,782	$ 6.61	5.68

Upon the exercise of warrants, the Company will issue new shares of its common stock.

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the year ended December 31, 2015 (in thousands).

	Research and Development	General and Administrative	Total
Employee awards	$ -	$ 265	$ 265
Non-employee awards	2,987	-	2,987
Fortress - Founders Agreement (see Note 4)	-	1,269	1,269
Total stock-based compensation expense	$ 2,987	$ 1,534	$ 4,521

Note 8 – Income Taxes

For financial reporting purposes, the Company calculated income tax provision and deferred income tax balances as if it was a separate entity and had filed its own separate tax return under Sub-chapter C of the Internal Revenue Code.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	As of December 31, 2015
Statutory federal income tax rate	35%
State taxes, net of federal tax benefit	5%
Credits	1%
Change in valuation allowance	(41)%
Income tax provision (benefit)	0.0%

The components of the net deferred tax asset as of December 31, 2015 are the following (in thousands):

	As of December 31, 2015
Deferred tax assets:	
Net operating loss carryovers	$ 1,657
Stock based compensation and other	1,299
Change in fair value of warrant liabilities	175
In process research and development	1,210
Tax credits	115
Total deferred tax assets	4,456
Valuation allowance	(4,456)
Deferred tax asset, net of allowance	-

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against it. The Company recorded a valuation allowance of approximately $4.5 million for the year ended December 31, 2015.

As of December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately $4.1 million and $3.9 million, respectively. The federal and state net operating loss carryforwards will expire, if not utilized, by 2035 and 2025, respectively. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986. In December 2015, the company experienced on ownership change as a result of an issuance of its common stock. Utilization of the company's net operating loss may be subject to substantial limitation.

There are no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with 740 "Income Taxes" ("ASC 740"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the year ended December 31, 2015. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the year ended December 31, 2015.

The federal and state tax returns for the year ended December 31, 2015 are currently openfor examination under the applicable federal and state income tax statues of limitations.

Note 9 – Fair Value Measurement

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The following table sets forth the changes in the estimated fair value for Level 3 classified derivative contingently issuable warrant liability (in thousands):

	Contingently Issuable Warrants
Fair value at the beginning of period:	$ -
Additions	175
Change in fair value	438
Issuance of Warrants (October 30, 2015)	(613)
Fair value at end of period:	$ -

The fair value of the Contingently Issuable Warrants was determined at various issuance dates from March 19, 2015 to August 31, 2015 ("Issuance Dates") for $0.2 million and on October 30, 2015 for $0.6 million by applying management's estimate of the probability of issuance of the Contingently Issuable Warrants together with an option pricing model with the following key assumptions:

	Issuance Dates	October 30, 2015
Risk-free interest rate	2.26%	2.16%

Expected dividend yield	-	-
Expected term in years	10.00	10.00
Expected volatility	83%	100.86%
Probability of issuance of the warrant	25%	100%

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Checkpoint Therapeutics, Inc.

By: /s/ James F. Oliviero
Name: James F. Oliviero
Title: Chief Executive Officer and President

April 27, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this registration statement has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael S. Weiss* Michael S. Weiss	Executive Chairman of the Board	April 27, 2016
/s/ James F. Oliviero* James F. Oliviero	Chief Executive Officer and President	April 27, 2016
/s/ David J. Horin* David J. Horin	Interim Chief Financial Officer	April 27, 2016
/s/ Lindsay A. Rosenwald* Lindsay A. Rosenwald, M.D.	Director	April 27, 2016
/s/ Neil Herskowitz* Neil Herskowitz	Director	April 27, 2016
/s/ Barry Salzman* Barry Salzman	Director	April 27, 2016
Scott Boilen	Director	April 27, 2016
* /s/ James F. Oliviero Attorney in Fact		