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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2016

or

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

For the Transition Period from _____ to _____.

Commission File Number 000-55506

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	**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)**
Common Stock, par value $0.0001 per share	**None**

Securities registered pursuant to section 12(g) of the Act: None.

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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	☐

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock. The registrant's common stock began trading on the OTCQX market on December 19, 2016.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of March 6, 2017
Class A Common Stock, $0.0001 par value	7,000,000
Common Stock, $0.0001 par value	17,476,876

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2017 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

CHECKPOINT THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report 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 report. 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 product 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 report reflect our views and assumptions as of the effective date of this report. 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.

PART I

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 cell 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 antibody in 2017, and our anti-GITR and anti-CAIX antibodies in 2018. We have also licensed and are developing three oral targeted anti-cancer therapies consisting of an inhibitor of epidermal growth factor receptor ("EGFR") mutations, an inhibitor of the bromodomain and extra-terminal ("BET") protein, BRD4, and an inhibitor of poly (ADP-ribose) polymerase ("PARP"). We submitted an IND application to the U.S. Food and Drug Administration ("FDA") for our EGFR inhibitor, which was accepted in August 2016, and in September 2016 we dosed the first patient in a Phase 1/2 clinical trial. We plan to submit an IND application for our BET inhibitor in 2017. We are currently developing a clinical program for our PARP inhibitor, which we expect to commence in the next 12 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, 2016, we have an accumulated deficit of $36.4 million.

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

CORPORATE INFORMATION

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, 9 th Floor, New York, NY 10014. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com .

We maintain a website with the address www.checkpointtx.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any such reports and amendments thereto at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov .

PRODUCTS UNDER DEVELOPMENT

Immuno-Oncology Agents

CK-301 (Anti-PD-L1) Program

Our anti-PD-L1 monoclonal antibody, CK-301, 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 FDA labels for the approved PD-1 and PD-L1 blocking antibodies was cited in the 20-45% range based on clinical trials in patients with metastatic melanoma and non-small cell lung cancer ("NSCLC"). 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"), head and neck cancer, NSCLC, and urothelial carcinoma.

We are developing our anti-PD-L1 antibody for oncology indications, including, but not limited to, the treatment of patients with NSCLC, melanoma and RCC, indications where studies of other PD-1/PD-L1 antibodies have shown to be effective. We licensed the exclusive worldwide rights to certain anti-PD-L1 antibodies from Dana-Farber in March 2015. Also in March 2015, we entered into a Global Collaboration Agreement with TG Therapeutics, Inc. ("TGTX"), a related party, to develop and commercialize anti-PD-L1 antibodies in the field of hematological malignancies. We retain the right to develop and commercialize our anti-PD-L1 antibodies in solid tumors. We believe that CK-301 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.

Currently, we are in preclinical development for this program. In 2016, we substantially completed 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 developed control mechanisms to satisfy Good Manufacturing Practice ("GMP") requirements and scaled-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 2017.

CK-302 (Anti-GITR) Program

Our anti-GITR monoclonal antibody, CK-302, 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 **.** We believe 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 are developing CK-302 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. We licensed the exclusive worldwide rights to anti-GITR antibodies from Dana-Farber in March 2015. Also in March 2015, we entered into a Global Collaboration Agreement with TGTX to develop and commercialize anti-GITR antibodies in the field of hematological malignancies. We retain the right to develop and commercialize anti-GITR antibodies in solid tumors. We believe that an anti-GITR antibody has the potential to be effective in many oncological indications as a monotherapy or in combination with an anti-PD-L1 or anti-CAIX antibody as well as other anti-tumor immune response potentiating compounds and other targeted therapies.

Currently, we are in preclinical development for this program. In late 2016, we commenced 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 GMP requirements and scale-up manufacturing in order to conduct the required pharmacology and toxicology studies in 2017 to support a planned IND application filing in 2018.

Targeted Anti-Cancer Agents

CK-101 (also known as RX518) EGFR Inhibitor Program

We are developing CK-101 as an oral, third-generation, irreversible kinase 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 resistance 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 also inhibiting wild-type EGFR.

Third-generation EGFR inhibitors are designed to be highly selective against the EGFR T790M mutation while sparing wild-type EGFR, thereby improving tolerability and safety profiles. In November 2015, TAGRISSO ® (osimertinib), a third-generation EGFR tyrosine kinase inhibitor ("TKI") developed by AstraZeneca that specifically targets the EGFR 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 exon 19 deletion.

We are developing CK-101 for 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 exon 19 deletion 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 inhibitors with checkpoint inhibitors (PD-1 or PD-L1), cMET inhibitors, or MEK inhibitors.

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma, Inc. ("NeuPharma"), which agreement was assigned to us by Fortress on the same date, to develop and commercialize novel covalent third-generation EGFR inhibitors on a worldwide basis outside of certain Asian countries. In August 2016, the FDA accepted our IND application and we initiated a Phase 1/2 clinical study in September 2016.

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

In December 2015, Fortress obtained the exclusive worldwide rights to develop and commercialize CK-102 (formerly CEP-9722) from Teva Pharmaceutical Industries Ltd., through its subsidiary, Cephalon, Inc., which license was assigned to us by Fortress on the same date. 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 activity as a monotherapy against tumors with existing DNA repair defects, such as BRCA1 and BRCA2, and promising activity 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 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 prior to commencing a Phase 1b clinical study in advanced or metastatic solid tumors with existing DNA repair defects, such as BRCA1 and BRCA2.

CK-103 BET Inhibitor Program

We are developing CK-103, an oral, inhibitor of the BET protein, BRD4. A bromodomain is an amino acid protein domain that recognizes acetylated-lysine. The binding of the drug prevents interaction between BET proteins and both acetylated histones and transcription factors. Therefore, BET proteins, such as BRD4, are considered potential therapeutic targets in cancer, as they may play a pivotal role in regulating the transcription of key regulators of cancer cell growth and survival, including the c-Myc oncogene. BRD4 is often required for expression of c-Myc. Scientific literature has shown that small molecule inhibition of BET bromodomains may lead to selective killing of tumor cells across a broad range of hematologic malignancies and certain targeted solid tumors. We plan to develop CK-103 for the treatment of various advanced and metastatic solid tumor cancers, including, but not limited to, those associated with elevated c-Myc expression.

In May 2016, we entered into an exclusive license agreement with Jubilant Biosys Limited ("Jubilant") to develop and commercialize novel compounds that inhibit the BRD4 protein on a worldwide basis. Currently, we are in preclinical development for this program and plan to conclude the required CMC, pharmacology and toxicology activities to support an IND application to the FDA in 2017.

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 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 very limited expression of this antigen on healthy tissue which we believe will limit reactivity of this antibody against healthy tissues.

In 2015, preclinical 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 certain 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. Upon selection, we plan to commence CMC development, pharmacology and toxicology activities in order to submit an IND application to the FDA in 2018.

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 report.

Product Candidate	Target Indication	Development Status	Completion of Phase	Estimated Cost to Complete Phase
Immuno-Oncology Agents				
CK-301	Multiple Forms of Cancer	Preclinical	2017	$1 to $2 million
CK-302	Multiple Forms of Cancer	Preclinical	2018	$4 to $6 million
Targeted Anti-Cancer Agents				
CK-101	Lung Cancer	Phase 1/2 study	2018	$7 to $9 million
CK-102	Multiple Forms of Cancer	Phase 1b study planned	2018	$2 to $4 million
CK-103	Multiple Forms of Cancer	Preclinical	2017	$2 to $3 million
Anti-CAIX	Renal Cell Carcinoma	Preclinical	2018	$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 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 to be extended through the patent restoration program, although any such extension could still be minimal.

If a patent is issued, or has previously been 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.

In March 2015 we licensed 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 been 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 an International Application No. PCT/US2015/054010, filed in October 2015. Any national stage applications, which are pursued off of this international application (including one in the United States Patent and Trademark Office), would expire no earlier than October 2035.

In March 2015, Fortress in-licensed intellectual property from NeuPharma, assigned to us by Fortress on the same date, which is directed to technology involving small molecules that are inhibitors of EGFR and kinase mutants, including the compound CK-101. EGFR is a receptor tyrosine kinase of the ErbB family and is also known as "Her1" and "ErbB1." The in-licensed patent estate includes a recently granted US Patent No. 9,559,770 with claims directed to a generic formula of small molecules, as well as a specific claim directed to the compound, CK-101. The granted claims also cover pharmaceutically acceptable salts, pharmaceutical compositions, particular dosage forms and packaged goods. The term of the granted patent runs to August 22, 2034, not including any patent term restorations, which might become available under the provisions of US patent laws, based on regulatory delays associated with obtaining marketing approval. A continuation application remains pending before the US Patent and Trademark Office, and counterpart applications exist in selected jurisdictions around the world, including, but not limited to, Canada and Europe. Any patents maturing from these pending applications would be scheduled to expire no sooner than August 2034.

In December 2015, Fortress in-licensed intellectual property from Teva Pharmaceutical Industries Ltd., through its subsidiary, Cephalon, which Fortress assigned to us on the same date. 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.

In May 2016, we in-licensed intellectual property from Jubilant. Under the terms of the license agreement, Jubilant granted us exclusive, worldwide rights under Jubilant's patents and know-how covering small molecule inhibitors of BET, specifically targeting BRD4, a member of the BET family which is often required for the expression of c-Myc. The in-licensed patent estate includes two international (PCT) applications filed in March 2016 (WO 2016/157221) and September 2016, respectively, claiming the benefit of two earlier-filed Indian provisional applications. Any patents maturing from this patent estate are expected to expire no sooner than March 2036.

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., which license was amended effective on October 5, 2015, April 12, 2016, and October 24, 2016, 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 country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. The royalty term, on a product-by-product and country-by-country basis, is the later of (i) ten years after first commercial sale of a given product in such country, or (ii) the expiration of the last-to-expire Dana-Farber patent containing a valid claim to the product in such country. To date, we have incurred $1.2 million of upfront licensing and milestone payments under this license agreement.

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. Under the terms of the Global Collaboration Agreement, TGTX paid us $500,000, representing an upfront licensing fee, and we are eligible to receive substantive potential milestone payments 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. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. 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.

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, and amended on February 21, 2017, whereby we obtained an exclusive, worldwide license, other than certain Asian countries, to NeuPharma's patents to a library of EGFR inhibitors, including CK-101. 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 country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. Royalty term means, on a licensed product-by-licensed product and country-by-country basis, the period from the first commercial sale of a given licensed product in such country until the later of (a) expiry of the last-to-expire licensor patent containing a valid claim to the compound in such country; or (b) the 10 th anniversary of the first commercial sale of such licensed product in such country. In a country where no licensor patent containing a valid claim with respect to the compound has ever existed nor ever exists, the royalty term means on a product-by-product and country-by-country basis, the period from the first commercial sale of such product in such country until the 10 th anniversary of such first commercial sale of such product in such country. To date, we have incurred $2.0 million of upfront licensing and milestone payments under the license agreement.

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 December 31, 2017, unless both parties agree to extend the option period.

Also in connection with the license agreement with NeuPharma, we entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid us for all amounts we paid NeuPharma previously. For the year ended December 31, 2016, we recognized approximately $1.0 million in revenue related to the Sponsored Research Agreement in the Statements of Operations.

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.

Jubilant Biosys Limited

On May 26, 2016, we entered into a license agreement with Jubilant, whereby we obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, which we refer to as CK-103. Under the terms of the agreement, we paid Jubilant an up-front licensing fee of $2.0 million, and Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon our successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 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. The license will terminate on a country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this agreement shall expire in its entirety with respect to such licensed product in such country. The royalty term, on a product-by-product and country-by-country basis, begins on the first commercial sale of a product in a country and ends on the expiration of the last-to-expire Jubilant patent containing a valid claim to the product in such country.

In connection with the license agreement with Jubilant, we entered into a sublicense agreement with TGTX to develop and commercialize the compounds licensed in the field of hematological malignancies, while we retain the right to develop and commercialize these compounds in the field of solid tumors. Under the terms of the sublicense agreement, TGTX paid us $1.0 million, representing an upfront licensing fee, and we are eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.5 million upon TGTX's successful achievement of preclinical, clinical development, and regulatory milestones. This is comprised of up to approximately $0.3 million upon TGTX's successful achievement of one preclinical milestone, up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, we are eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of three sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays us for 50% of IND enabling costs and patent expenses. For the year ended December 31, 2016, we recognized approximately $1.5 million in revenue related to the sublicense agreement in the Statements of Operations. There was no related revenue recognized during 2015.

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.

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 antibody 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 ®), Roche (approved PD-L1 with the brand name Tecentriq ®), AstraZeneca/Celgene and Pfizer/Merck KGA. We are aware of several anti-GITR antibody development programs in pre-clinical or early clinical studies, including, without limitation, by Merck & Co. and Leap Therapeutics, 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. There are also a number of early stage programs developing BET inhibitors which could overlap with our upcoming programs.

In the EGFR inhibitor space, 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, 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. In late 2016, Clovis Oncology's Rubraca™ (rucaparib) was approved in the U.S. as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. There are a number of other PARP inhibitors in late-stage clinical development, or with a new drug application under review by the FDA, including AbbVie's ABT-888 (veliparib), Tesaro, Inc's niraparib, Eisai's E-7016, and Pfizer's talazoparib.

In the BET inhibitor space, there are a number of companies which have advanced to early stage clinical trials, including Merck & Co's MK-8628, Roche's TEN-010, Constellation Pharmaceuticals' CPI-0610, Bristol-Myers Squibb's BMS-986158, GlaxoSmithKline's GSK525762, Abbvie's ABBV-075, Incyte's INCB54329, Forma Therapeutics' FT-1101 and Gilead Sciences' GS-5829.

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

EMPLOYEES

As of December 31, 2016, we have five 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 GMP ("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 ("DEA") 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 preclinical 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 to 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 report 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 report, 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. 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;
- 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.

Preclinical development is highly speculative and has a high risk of failure.

All but two of our current product candidates are in preclinical development, and, thus, have never been used in humans. Preclinical development is highly speculative and carries a high risk of failure. We can provide no assurances that preclinical toxicology and/or preclinical activity of our product candidates will support moving any of these product candidates into clinical development. If we are unsuccessful in our preclinical 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, or comparable foreign regulatory authority, will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether current or 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 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 European Medicines Agency ("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 product candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to become 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 it believes 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, and any similar regulatory authorities outside the United States, 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 and any similar regulatory authorities outside the United States. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. If we are not able to obtain regulatory 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, or the similar regulatory authority outside the United States. 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, or any applicable foreign regulatory authority, rules and guidelines relating to promotion and advertising may cause the FDA, or such applicable foreign regulatory authority, 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. 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 preclinical 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 preclinical 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 preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical 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. 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 have obtained, and will continue to obtain, limited product liability insurance coverage for any and all of our current and future 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 targeted anti-cancer agents. 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 and certain of our small molecule product candidates 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 for our antibody and certain of our small molecule product candidates. 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 targeted anti-cancer agents 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, Teva, through its subsidiary, Cephalon, Inc., and Jubilant. In the future, we may become party to additional 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 $36.4 million as of December 31, 2016. 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 are variations in the level of expenses related to our current and 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 2015. Our operations to date have been limited to preclinical and clinical 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 increased clinical activities and future potential 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 continue 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 and cash equivalents balances at December 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 18 to 21 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.

As a public company, we will continue to 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 will be 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 we issue non-convertible debt within a three-year period in excess of $1 billion or have revenues in excess of $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 downturns.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. 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. could contribute to increased volatility and diminished expectations for the economy and the markets going forward. These factors, potentially combined with volatile oil prices, declining business and consumer confidence and increased unemployment, may precipitate an economic recession and fears of a possible depression. Domestic and international equity markets may experience heightened volatility and turmoil. These events and any market upheavals may have an adverse effect on us. In the event of a 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

The market price and trading volume of our common stock has been volatile. Our stock may continue to 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 and trading volume of our common stock has been highly volatile and 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, or comparable regulatory authorities outside the United States, for additional studies or data that result in delays in obtaining regulatory approval or launching these product candidates, if approved;
- the depth and liquidity of the market for our common stock;
- investor perceptions about us and our business;
- 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, 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 and was amended and restated on July 11, 2016. 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 a Management Services Agreement 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.

The Chairman of our Board of Directors is also the Executive Chairman, President and Chief Executive Officer of TG Therapeutics, Inc. ("TGTX"), with whom we have a collaboration agreement, an option agreement and a sublicense agreement, and as a result during the term of these agreements 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 Chairman of the Board of Directors, is also the Executive Chairman, 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.

In connection with our license agreement with NeuPharma, we entered into an option agreement with TGTX 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. As such, if the option agreement is exercised by TGTX, 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.

In connection with our license agreement with Jubilant, we entered into a sublicense agreement with TGTX to develop and commercialize the Jubilant family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment in the field of hematological malignancies. As such, as the sublicense 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 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 which 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 market price and trading volume of our common stock has been highly volatile and is likely to continue to be highly volatile. In addition, 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 1B. Unresolved Staff Comments

None.

Item 2. 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 3. 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 4. Mine Safety Disclosures

Not applicable

PART II

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

Market information

Our common stock has been quoted on the OTCQX market since December 19, 2016, under the symbol "CKPT." Prior to this, there was no public market for our common stock.

The following table sets forth the high and low closing sale prices of our common stock for the period indicated.

Fiscal Year Ended December 31, 2016	High	Low
Fourth Quarter (beginning 12/19)	$ 8.00	$ 5.00

Equity Compensation Plans

We expect that in the near 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 Amended and Restated 2015 Incentive Plan ("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 February 23, 2017, there were approximately 17.5 million shares of common stock outstanding held by 421 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.

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.

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 proceeds of $0.6 million 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 continue 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 and cash equivalents balances at December 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 18 to 21 months.

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

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 report. 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. 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 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 6. Selected Financial Data

The following Statements of Operations data for the years ended December 31, 2016, 2015 and for the period from November 10, 2014 (inception) to December 31, 2014, and Balance Sheet data as of December 31, 2016, 2015 and 2014, as set forth below are derived from our audited financial statements. This financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" contained elsewhere in this annual report on Form 10-K.

	Year Ended December 31,		For the period from November 10, 2014 (inception) to
	2016	2015	December 31, 2014
Income Statement:			
Revenue - related party	$ 2,570	$ 590	$ -
Operating expenses:			
Research and development	20,267	11,323	-
General and administrative	4,467	2,488	-
Total operating expenses	24,734	13,811	-
Loss from operations	(22,164)	(13,221)	-
Other income (expense)			
Interest income	47	2	-
Interest expense and debt amortization	(344)	(235)	-
Change in fair value of warrant liabilities	-	(438)	-
Total other expense	(297)	(671)	-
Net Loss	**$ (22,461)**	**$ (13,892)**	**$ -**
Loss per Share:			
Basic and diluted net loss per common share outstanding	$ (1.04)	$ (1.41)	$ -
Basic and diluted weighted average number of common shares outstanding	21,544,205	9,855,668	8,000,000
Financial Condition:			
Cash and cash equivalents	$ 35,086	$ 50,418	$ -
Total assets	$ 35,978	$ 50,654	$ -
Total liabilities	$ 3,673	$ 4,258	$ -
Stockholders' equity	$ 32,305	$ 46,396	$ -

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

Forward-Looking Statements

Statements in the following discussion and throughout this report 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 report 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 report or to reflect actual outcomes. Please see "Forward-Looking Statements" at the beginning of this Form 10-K.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K. We undertake no obligation to update any forward-looking statements in the discussion of our financial condition and results of operations to reflect events or circumstances after the date of this report or to reflect actual outcomes .

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 antibody in 2017, and our anti-GITR and anti-CAIX antibodies in 2018. We have also licensed and are developing three oral targeted anti-cancer therapies consisting of an inhibitor of EGFR mutations, an inhibitor of the BET protein, BRD4, and an inhibitor of PARP. We submitted an IND application to the FDA for our EGFR inhibitor, which was accepted in August 2016, and in September 2016 we dosed the first patient in a Phase 1/2 clinical trial. We plan to submit an IND application for our BET inhibitor in 2017. We are currently developing a clinical program for our PARP inhibitor, which we expect to commence in the next 12 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.

We have also entered into various collaboration agreements including a sponsored research agreement with TGTX to develop and commercialize certain assets in connection with our licenses in the field of hematological malignancies, while we retain the right to develop and commercialize these assets in solid tumors.

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, 2016, we have an accumulated deficit of 36.4 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, 9 th 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 financial statements appearing elsewhere in this Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

Revenue

For the year ended December 31, 2016, revenue was approximately $2.6 million compared to approximately $0.6 million for the year ended December 31, 2015, an increase of approximately $2.0 million. Revenue for the current period primarily consisted of $1.5 million from TGTX related to the sublicense agreement for CK-103 and approximately $1.0 million from TGTX in connection with the Sponsored Research Agreement with NeuPharma. A small portion of revenue was also generated in connection with the collaboration agreement with TGTX related to patent costs. Revenue for the year ended December 31, 2015 consisted of $0.5 million representing TGTX's upfront licensing fee for the collaboration agreement and $0.1 million related to patent costs.

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, 2016, research and development expenses were approximately $20.3 million, compared to approximately $11.3 million for the year ended December 31, 2015, an increase of $9.0 million. The current period research and development expenses primarily consisted of $8.7 million related to preclinical and product development activities for our product candidates, $3.9 million related to the non-cash annual equity fee in connection with the Founders' Agreement, $2.6 million related to stock compensation expense, $2.0 million paid to Jubilant upon the signing of the license agreement for CK-103, $1.0 million paid to NeuPharma upon first dosing of a patient in our Phase 1 trial for CK-101, and $0.8 million related to clinical costs for CK-101. The prior year research and development expenses primarily consisted of $3.2 million related to the acquisition of the licenses and rights to the Dana-Farber antibodies, CK-101, and CK-102, $2.1 million related to preclinical development activities for our product candidates, $3.0 million related to the non-cash annual equity fee in connection with the

Founders' Agreement and $3.0 million related 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 stock compensation;
- 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, regulatory submissions and 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, 2016, general and administrative expenses were $4.5 million, compared to approximately $2.5 million for the year ended December 31, 2015, an increase of $2.0 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $1.3 million, $1.3 million related to legal and accounting fees and $0.9 million related to salary expenses. The prior period general and administrative expenses primarily consisted of $1.3 million related to non-cash equity fees paid to Fortress in connection with the Founders' Agreement, stock compensation expense of $0.3 million and $0.5 million related to legal fees, primarily in connection with the acquisition and maintenance of our licenses.

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 employees and non-employees;
- support of business development activities; and
- increased professional fees, insurance costs, and other costs associated with the regulatory requirements and increased compliance associated with being a publicly reporting company.

Comparison of the Year Ended December 31, 2015 and the Period from November 10, 2014 (Inception) to December 31, 2014

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 an upfront licensing fee for the collaboration agreement and $0.1 million related to patent costs.

Research and Development Expenses

For the year ended December 31, 2015, research and development expenses were $11.3 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, $3.0 million relates to the non-cash annual equity fee in connection with the Founders' Agreement and $3.0 million relates to stock compensation expense.

General and Administrative 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 non-cash equity fees paid to Fortress in connection with the Founders' Agreement. In addition, of the remaining $1.0 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 were nominal general and administrative expenses.

Change in Fair Value of Warrant Liabilities

For the year ended December 31, 2015, the change in fair value of warrant liabilities was $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

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, 2016, we had an accumulated deficit of $36.4 million.

In March 2015, Fortress closed a private placement of a promissory note for $10 million through National Securities Corporation (the "NSC Note"). National Securities Corporation ("NSC"), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note.

Fortress used the proceeds from the NSC Note to acquire medical technologies and products.

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 $2.8 million 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 $2.8 million, 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.

On February 23, 2016, we closed on proceeds of $0.6 million 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.

We expect to continue 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 and cash equivalents balances at December 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 18 to 21 months.

Cash Flows for the Years Ended December 31, 2016 and 2015

Operating Activities

Net cash used in operating activities was $10.0 million for the year ended December 31, 2016, compared to $1.1 million for the year ended December 31, 2015. The increase in net cash used in operating activities was due primarily to increased expenditures associated with our preclinical, clinical and other product development activities for our product candidates.

Investing Activities

Net cash used in investing activities was $3.2 million for the year ended December 31, 2016, compared to $2.5 million for the year ended December 31, 2015, representing the acquisition costs of acquired licenses.

Financing Activities

Net cash used in financing activities was $2.2 million for the year ended December 31, 2016, compared to $54.1 million of net cash provided by financing activities for the year ended December 31, 2015. In February 2016, we repaid our debt of $2.8 million, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment. The issuance of common stock provided $0.6 million during the year ended December 31, 2016. Net cash provided by our third party offering and the NSC note was $51.5 million and $2.6 million, net of fees, respectively, during the year ended December 31, 2015.

Recently Issued Accounting Standards

In January 2017, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") 2017-01, " *Business Combinations (Topic 805) Clarifying the Definition of a Business* ". The amendments in this ASU clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. We are currently evaluating the impact of adopting this guidance.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments* , which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. We are currently in the process of evaluating the impact of this new pronouncement on its statements of cash flows.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public entities, the amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. We do not expect this standard to have a material impact on our financial statements upon adoption.

In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations" ("ASU 2016-08"). The purpose of ASU 2016-08 is to clarify the implementation of guidance on principal versus agent considerations. The amendments in ASU 2016-08 are effective for interim and annual reporting periods beginning after December 15, 2017. We are currently evaluating the impact of implementation and transition approach of ASU 2016-08 on our financial statements and related disclosures, including the impact the new ASU will have on our collaborative arrangements accounted for pursuant to ASC 808.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which supersedes FASB Accounting Standards Codification ("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. As we have no leases currently, 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 adopted ASU No. 2015-17 in the fourth quarter of 2016, and its adoption did not 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, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU No. 2014-15") that will require management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued on both an interim and annual basis. Management will be required to provide certain footnote disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. We adopted ASU No. 2014-15 in the fourth quarter of 2016, and its adoption did not 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 7A. Quantitative and Qualitative Disclosures About Market Risks

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of December 31, 2016, our portfolio of financial instruments consists of cash equivalents, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Our assets and liabilities are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the consolidated financial statements and notes thereto beginning at page F-1 of this Annual Report on Form 10-K.

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

On September 27, 2016, we dismissed EisnerAmper LLP ("EisnerAmper") as our independent registered public accounting firm. Our Audit Committee participated in and approved this decision.

The reports of EisnerAmper on the consolidated financial statements of the Company for the fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, did not contain an adverse opinion or a disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope, or accounting principles.

During our fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, and through September 27, 2016, we did not have any disagreements with EisnerAmper on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of EisnerAmper, would have caused it to make reference to the subject matter of the disagreements in connection with its reports on the consolidated financial statements for such time periods.

During our fiscal year ended December 31, 2015 and the fiscal period from November 10, 2014 (inception) to December 31, 2014, and through September 27, 2016, no "reportable events" as defined in Item 304(a)(1)(v) of Regulation S-K have occurred.

EisnerAmper has indicated to us that it concurs with the foregoing statements contained in the second, third and fourth paragraphs above as they relate to EisnerAmper and has furnished a letter to the Securities and Exchange Commission to this effect. A copy of the letter from EisnerAmper is attached to this Form 10-K as Exhibit 16.1.

Effective October 20, 2016, we engaged BDO USA, LLP as our new independent registered public accounting firm. Our Audit Committee participated in and approved this decision.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2016, management carried out, under the supervision and with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2016, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2016, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference from our Proxy Statement for our 2017 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements.

The following financial statements are filed as part of this report:

(b) Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.3	Bylaws of Checkpoint Therapeutics, Inc., filed as Exhibit 3.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.1	Specimen certificate evidencing shares of common stock, filed as Exhibit 4.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.2	Form of warrant agreement, filed as Exhibit 4.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.1	Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.2	Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated July 11, 2016 and effective as of March 17, 2015, filed as Exhibit 10.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.3	Management Services Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.4	Promissory Note to NSC Biotech Venture Fund I, LLC dated February 27, 2015, filed as Exhibit 10.4 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.5	Common Stock Warrant issued by Checkpoint Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC dated July 30, 2015, filed as Exhibit 10.5 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.6	License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc. dated March 2, 2015, filed as Exhibit 10.6 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.7	Amendment 1 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 5, 2015, filed as Exhibit 10.7 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.8	Amendment 2 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated April 12, 2016.
10.9	Amendment 3 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 24, 2016.
10.10	License Agreement by and between NeuPharma Inc. and Coronado Biosciences, Inc. (Fortress' predecessor) dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015), filed as Exhibit 10.8 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.11	Amendment 1 to License Agreement by and between NeuPharma Inc. and Checkpoint Therapeutics, Inc. dated February 21, 2017.
10.12	Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated March 3, 2015, filed as Exhibit 10.9 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.13	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.10 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.14	Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated October 13, 2015, filed as Exhibit 10.11 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.15	Amendment to Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated September 27, 2016, filed as Exhibit 10.1 to Form 8-K filed on October 3, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.16	Amendment No. 2, dated December 15, 2016, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III. #
10.17	License Agreement by and between Cephalon, Inc. and Fortress Biotech, Inc. dated December 18, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated December 18, 2015), filed as Exhibit 10.12 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *

10.18	Non-Employee Directors Compensation Plan, filed as Exhibit 10.13 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.19	Board Advisory Services Agreement by and between Caribe BioAdvisors, LLC and Checkpoint Therapeutics, Inc. dated January 1, 2017. #
10.20	Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015); extended as of September 11, 2015; extended as of December 15, 2015; extended as of January 11, 2016; extended as of July 8, 2016, filed as Exhibit 10.14 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.21	Extension dated December 30, 2016, to Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015).
10.22	Research Agreement by and between Fortress Biotech, Inc. and NeuPharma, Inc., dated September 15, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015), filed as Exhibit 10.15 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.23	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015, filed as Exhibit 10.16 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.24	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated December 18, 2015, filed as Exhibit 10.17 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.25	License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.18 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.26	Amendment 1 to License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc. dated December 13, 2016.
10.27	Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.19 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.28	Amendment 1 to Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc. dated December 13, 2016.
10.29	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.20 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference.
10.30	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.21 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference.
16.1	Letter from EisnerAmper LLP to the Securities and Exchange Commission dated October 3, 2016, filed as Exhibit 16.1 to Form 8-K filed on October 3, 2016 (File No. 000-55506) and incorporated herein by reference.
24.1	Power of Attorney (included on signature page).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Subject to a request for confidential treatment.
\# Management Compensation Arrangement.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Checkpoint Therapeutics, Inc.
New York, NY

We have audited the accompanying balance sheet of Checkpoint Therapeutics, Inc. (the "Company") as of December 31, 2016 and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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, 2016, and the results of its operations and its cash flows for the year ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

March 17, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Checkpoint Therapeutics, Inc.

We have audited the accompanying balance sheet of Checkpoint Therapeutics, Inc. (the "Company") as of December 31, 2015 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 and for the period from November 10, 2014 (inception) to December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
July 11, 2016

CHECKPOINT THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 35,086	$ 50,418
Prepaid expenses and other assets	71	171
Other receivables - related party	821	65
Total current assets	35,978	50,654
Total Assets	**$ 35,978**	**$ 50,654**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 3,355	$ 1,288
Accounts payable and accrued expenses - related party	318	502
Total current liabilities	3,673	1,790
Note payable, long-term (net of debt discount of $0 and $324 at December 31, 2016 and December 31, 2015, respectively)	-	2,468
Total Liabilities	**3,673**	**4,258**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	1	1
Common shares, 17,426,876 shares and 15,989,315 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	2	1
Common stock issuable,721,699 and 688,755 shares as of December 31, 2016 and December 31, 2015, respectively	3,919	3,024
Additional paid-in capital	64,736	57,262
Accumulated deficit	(36,353)	(13,892)
Total Stockholders' Equity	32,305	46,396
Total Liabilities and Stockholders' Equity	**$ 35,978**	**$ 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)

	Year Ended December 31,		For the period from November 10, 2014 (inception) to December 31,
	2016	**2015**	**2014**
Revenue - related party	$ 2,570	$ 590	$ -
Operating expenses:			
Research and development	20,267	11,323	-
General and administrative	4,467	2,488	-
Total operating expenses	24,734	13,811	-
Loss from operations	(22,164)	(13,221)	-
Other income (expense)			
Interest income	47	2	-
Interest expense and debt amortization	(344)	(235)	-
Change in fair value of warrant liabilities	-	(438)	-
Total other expense	(297)	(671)	-
Net Loss	**$ (22,461)**	**$ (13,892)**	$ -
Loss per Share:			
Basic and diluted net loss per common share outstanding	$ (1.04)	$ (1.41)	$ -
Basic and diluted weighted average number of common shares outstanding	21,544,205	9,855,668	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		Common Shares Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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	-	-	289,085	-	-	1,269	-	1,269
Common shares issuable - Founders Agreement	-	-	-	-	3,024	-	-	3,024
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	-	-	-	-	-	613	-	613
Net loss	-	-	-	-	-	-	(13,892)	(13,892)
Balances at December 31, 2015	**7,000,000**	**$ 1**	**15,989,315**	**$ 1**	**$ 3,024**	**$ 57,262**	**$ (13,892)**	**$ 46,396**
Issuance of common shares and warrants for cash	-	-	126,640	-	-	570	-	570
Stock-based compensation expenses	-	-	619,000	-	-	3,867	-	3,867
Common shares issuable - Founders Agreement	-	-	-	-	3,919	-	-	3,919
Issuance of common shares - Founders Agreement	-	-	691,921	1	(3,024)	3,037	-	14
Net loss	-	-	-	-	-	-	(22,461)	(22,461)
Balances at December 31, 2016	**7,000,000**	**$ 1**	**17,426,876**	**$ 2**	**$ 3,919**	**$ 64,736**	**$ (36,353)**	**$ 32,305**

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

CHECKPOINT THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		For the period from November 10, 2014 (inception) to December 31,
	2016	**2015**	**2014**
Cash Flows from Operating Activities:			
Net loss	$ (22,461)	$ (13,892)	$ -
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expenses	3,867	3,252	-
Change in fair value of warrant liabilities	-	438	-
Issuance of common shares - Founders Agreement	14	1,269	-
Common shares issuable - Founders Agreement	3.919	3,024	-
Issuance of common shares for license expenses	-	633	-
Amortization of debt discount	324	89	-
Research and development-licenses acquired, expensed	3,160	2,525	
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	100	(171)	-
Other receivables - related party	(756)	(65)	-
Accounts payable and accrued expenses	1,883	1,790	-
Net cash used in operating activities	(9,950)	(1,108)	-
Cash Flows from Investing Activities:			
Purchase of research and development licenses	(3,160)	(2,525)	-
Net cash used in investing activities	(3,160)	(2,525)	-
Cash Flows from Financing Activities:			
Proceeds from note payable, net of debt discount	-	2,554	-
Payment of note payable	(2,792)	-	-
Proceeds from issuance of common stock, net of offering costs of $0 and $6,321, respectively	570	51,496	-
Cash received for issuance of founders shares	-	1	-
Net cash (used in) provided by financing activities	(2,222)	54,051	-
Net (decrease) increase in cash	(15,332)	50,418	-
Cash at beginning of period	50,418	-	-
Cash at end of period	**$ 35,086**	**$ 50,418**	$ -
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 20	$ 56	$ -
Supplemental disclosure of noncash investing and financing activities:			
Debt discount associated with 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, Plan of Business Operations

Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") was incorporated in Delaware on November 10, 2014. Checkpoint is 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. The Company may also enter into collaboration agreements with third and related parties including sponsored research agreements to develop these technologies for liquid tumors while retaining the rights in solid tumors.

The Company is a majority controlled subsidiary of Fortress Biotech, Inc. ("Fortress").

The Company's common stock is quoted on the OTCQX market and trades under the symbol "CKPT."

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 cell death ligand 1 ("PD-L1"), glucocorticoid-induced TNFR-related protein ("GITR") and carbonic anhydrase IX ("CAIX"). These antibodies are currently in preclinical 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 an investigational new drug ("IND") application for its anti-PD-L1 antibody in 2017, and for its anti-GITR and anti-CAIX antibodies in 2018 (see Note 3).

In connection with the license agreement with Dana-Farber, 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. In August 2016, the Company filed an IND application with the U.S. Food and Drug Administration ("FDA") for CK-101, which was approved by the FDA, and in September 2016 the Company dosed the first patient in a Phase 1/2 clinical trial (see Note 3).

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. Checkpoint 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. The Company plans to evaluate a reformulation of the CK-102 drug product to improve its bioavailability prior to commencing a clinical program (see Note 3).

In May 2016, Checkpoint entered into a license agreement with Jubilant Biosys Limited ("Jubilant") for an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, including CK-103. CK-103 is currently in preclinical development. The Company plans to complete the required chemistry, manufacturing and control, pharmacology and toxicology activities to support an IND application to the FDA in 2017 (see Note 3).

In connection with the license agreement with Jubilant, the Company entered into a Sublicense Agreement with TGTX to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retains the right to develop and commercialize these compounds in the field of solid tumors (see Note 3).

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, 2016, the Company had an accumulated deficit of $36.4 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. 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, 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 (see Note 7).

The Company expects to continue to use the 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 and cash equivalents balances at December 31, 2016, are sufficient to fund its anticipated operating cash requirements for approximately the next 18 to 21 months.

Note 2 — Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. The Company has no subsidiaries.

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.

Other Receivables – Related Party

Other receivables consist of amounts due to the Company from TGTX, a related party, and are recorded at the invoiced amount (see Note 3).

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.

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development* , 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. Such 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.

Annual Equity Fee

Under the Founder's Agreement with Checkpoint dated March 17, 2015, and amended and restated on July 11, 2016, Fortress is entitled to an annual equity fee on each anniversary of the Agreement equal to 2.5% of fully diluted outstanding equity, payable in Checkpoint common shares ("Annual Equity Fee"). The Annual Equity Fee was part of the consideration payable for formation of the Company, identification of certain assets, including the license contributed to Checkpoint by Fortress.

The Company records the Annual Equity Fee in connection with the Founders Agreement with Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee due to the nature of its assets and the Company's stage of development. Due to these uncertainties, the Company has concluded that it is unable to reasonably estimate the contingent consideration until shares are actually issued on March 17 of each year. Because the issuance of shares on March 17, 2017 and 2016 occurred prior to the issuance of the December 31, 2016 and 2015 financial statements, the Company recorded $3.9 million and $3.0 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the years ended December 31, 2016 and 2015, respectively.

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.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model or 409A valuations as necessary. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

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

Collaborative Arrangements

The Company is paid by TGTX, a related party, a share of the cost of the license, development and future milestone payments that are payable under the agreements as described in Note 3. The gross amount of these payments are reported as revenue in the accompanying Statements of Operations. The Company acts as a principal, bears credit risk, obtains subcontractors and may perform part of the services required in the transactions. Consistent with ASC 605-45-15 these payments are treated as revenue to the Company. The actual expenses creating the payments by TGTX 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 our collaborative research, 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 our 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.

Revenue Recognition - Milestone Method

The Company follows ASC 605-28, *Revenue Recognition-Milestone Method* to evaluate whether each milestone under a license agreement is substantive. This evaluation includes an assessment of whether (i) the consideration is commensurate with either (a) the entity's performance to achieve the milestone, or (b) the enhancement of the value of the delivered item as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the preclinical, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. If a substantive milestone is achieved, the Company would recognize revenue related to the milestone in its entirety in the period in which the milestone was achieved, assuming all other revenue recognition criteria were met. Commercial milestones would be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria were met.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

The Company files a separate tax return under Subchapter C of the Internal Revenue Code. Prior to October 1, 2015, the Company was a subsidiary included in the consolidated tax return of Fortress. As a result of issuances of its common stock, the Company exited the consolidated tax group for federal and state income tax purposes. For financial reporting purposes, the Company calculated income tax provision and deferred income tax balances for the year ended December 31, 2015 as if it was a separate entity and had filed its own separate tax return under Subchapter C of the Internal Revenue Code.

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 been granted in connection with the promissory note through National Securities Corporation (the “NSC Note”) transferred to the Company in various tranches 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 (see Note 9). 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 stock options and warrants, as their inclusion would be anti-dilutive. There are 2,533,063 shares of unvested restricted stock, 4,331,106 warrants and 60,000 options outstanding as of December 31, 2016, which are not included in the computation of net loss per share.

For the years ended December 31, 2016 and 2015, the Company had a net loss of $1.04 and $1.41 per share, respectively, on 21,544,205 and 9,855,668 weighted average common shares outstanding, respectively.

Recently Issued Accounting Standards

In January 2017, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") 2017-01, " *Business Combinations (Topic 805) Clarifying the Definition of a Business* ". The amendments in this ASU clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating the impact of adopting this guidance.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments* , which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its statements of cash flows.

In March 2016, the FASB issued ASU No. 2016-09 *Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09") . The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public entities, the amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company does not expect this standard to have a material impact on our financial statements upon adoption.

In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations" ("ASU 2016-08"). The purpose of ASU 2016-08 is to clarify the implementation of guidance on principal versus agent considerations. The amendments in ASU 2016-08 are effective for interim and annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of implementation and transition approach of ASU 2016-08 on its financial statements and related disclosures, including the impact the new ASU will have on its collaborative arrangements accounted for pursuant to ASC 808.

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. Since the Company currently does not have any leases, it 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 adopted ASU No. 2015-17 in the fourth quarter of 2016, and its adoption did not have a material impact on the Company's 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, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU No. 2014-15") that will require management to evaluate whether there are conditions and events that raise substantial doubt about an entity's ability to continue as a going concern within one year after the financial statements are issued on both an interim and annual basis. Management will be required to provide certain footnote disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. The Company adopted ASU No. 2014-15 in the fourth quarter of 2016, and its adoption did not have a material impact on the Company's 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, the Company 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, the Company granted Dana-Farber 500,000 shares, valued at $32,500 or $0.065 per share. The agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that the Company raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, the Company 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 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 to 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, the Company 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 the Company retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the collaboration agreement, TGTX paid the Company $0.5 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments 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. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. 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. The Company recognized $42,000 and $0.5 million, respectively, for the years ended December 31, 2016 and 2015, in revenue from its 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 assigned all of its right and interest in the EGFR inhibitors to the Company. Under the terms of the license agreement, the Company 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 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.

In September 2016, the Company dosed the first patient in a Phase 1/2 clinical study of CK-101. Under the terms of the license agreement with NeuPharma, the Company expensed a non-refundable milestone payment of $1.0 million, which is included in the Statements of Operations for the year ended December 31, 2016.

In connection with the license agreement with NeuPharma, in March 2015, Fortress entered into an option agreement with TGTX, a related party, which agreement was assigned to the Company by Fortress on the same date, for a global collaboration of certain compounds licensed. The option agreement will expire on December 31, 2017, unless both parties agree to extend the option period.

Also in connection with the license agreement with NeuPharma, the Company entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid the Company for all amounts previously paid by the Company. For the year ended December 31, 2016, the Company recognized approximately $1.0 million in revenue in connection with the Sponsored Research Agreement in the Statements of Operations. There was no related revenue recognized during 2015.

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"). This agreement was assigned to the Company by Fortress on the same date. 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. 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.

Jubilant Biosys Limited

In May 2016, the Company entered into a license agreement with Jubilant Biosys Limited ("Jubilant"), whereby the Company obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, including CK-103. Under the terms of the agreement, the Company paid Jubilant an up-front licensing fee of $2.0 million, included in research and development expenses on the Company's Statements of Operations for the year ended December 31, 2016, and Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon the Company's successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 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.

In connection with the license agreement with Jubilant, the Company entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retains the right to develop and commercialize these compounds in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Sublicense Agreement, TGTX paid the Company $1.0 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.5 million upon TGTX's successful achievement of preclinical, clinical development, and regulatory milestones. This is comprised of up to approximately $0.3 million upon TGTX's successful achievement of one preclinical milestone, up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, the Company is eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of three sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays the Company 50% of IND enabling costs and patent expenses. For the year ended December 31, 2016, the Company recognized $1.5 million in revenue related to the sublicense agreement in the Statements of Operations. There was no related revenue recognized during 2015.

Note 4 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, the Company entered into a Founders Agreement with Fortress, which was amended and restated on July 11, 2016 (the "Founders Agreement"). The Founders Agreement provides, that in exchange for the time and capital expended in the formation of Checkpoint and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, 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 the Company shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one-half percent (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%). The Founders Agreement has a term of fifteen years, after which it automatically renews for one year periods unless Fortress gives the Company notice of termination. The Founders Agreement also will automatically terminate upon a change of control.

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 our 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 our actions or inactions based upon their advice. Fortress and its affiliates, including all members of its 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 years ended December 31, 2016 and 2015, the Company recognized approximately $500,000 and $396,000, respectively in expense on its Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board.

Note 5 – Notes Payable

NSC Note

In March 2015, Fortress closed the private placement of a promissory note for $10 million through National Securities Corporation ("NSC") and used the proceeds to acquire medical technologies and products. 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 the Company pursuant to which the Company executed an identical NSC Note in favor of NSC. Accordingly, the Company assumed $2.8 million under the NSC Note as part of the Founders Agreement (see Note 4) and issued NSC 139,592 warrants to purchase its common stock, which was equal to twenty-five percent (25%) of the amount of NSC Note proceeds the Company received from Fortress divided by the lowest price at which the Company next sold common stock. The warrant issued has a term of 10 years and an exercise price equal to the par value of the Company's common stock. 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. Approximately $324,000 of unamortized debt discount was accelerated into interest expense upon payment.

As of December 31, 2016, the Company's portion of the NSC Note was $0. For the years ended December 31, 2016 and 2015, the Company recorded costs of approximately $324,000 and $89,000, respectively, related to the amortization of the debt discount and $20,000 and $146,000, respectively of interest expense at 8%, both recorded in interest expense in the Statements of Operations.

The following table summarizes the Company's Amended NSC Note activities as of December 31, 2016 ($ in thousands).

	NSC Note Payable	Discount	NSC Note Payable, Net
December 31, 2015 balance	$ 2,792	$ (324)	$ 2,468
Payment of NSC debt	(2,792)	-	(2,792)
Amortization of debt discount	-	324	324
December 31, 2016 balance	$ -	$ -	$ -

Note 6 – Commitments and Contingencies

Leases

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

License Agreements

The Company has undertaken to make contingent milestone payments to the licensors of its portfolio of product candidates. In addition, the Company would pay royalties to such licensors based on a percentage of net sales of each product 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, 2016, 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 15,000,000 shares are designated as "Class A common stock". As of December 31, 2016, there were 7,000,000 shares of Class A common stock issued and outstanding to Fortress. 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. Accordingly, the holder of shares of Class A common stock 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. Each share of Class A common stock is 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

In December 2015, the Company 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, the Company closed on proceeds of $0.6 million 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, which included the payment of fees and issuance of warrants to a placement agent.

Pursuant to the Founders Agreement, the Company issued 3,166 shares to Fortress, representing 2.5% of the aggregate number of shares of common stock issued in the offering noted above. For the year ended December 31, 2016, the Company recorded expense of approximately $14,000, related to this stock grant, which is included in general and administrative expenses in the Company's Statements of Operations.

Also pursuant to the Founders Agreement, the Company issued 721,699 and 688,755 shares of common stock to Fortress, representing 2.5% of the fully-diluted outstanding equity of Checkpoint, on March 17, 2017 and 2016, respectively (see Note 4). The Company recorded the Annual Equity Fee in connection with the Founders Agreement with Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee due to the nature of its assets and the Company's stage of development. Due to these uncertainties, the Company concluded that it could not reasonably estimate the contingent consideration until shares were actually issued on March 17. Because the issuance of shares on March 17, 2017 and 2016 occurred prior to the issuance of the December 31, 2016 and 2015 financial statements, the Company recorded $3.9 million and $3.0 million in research and development expenses during the years ended December 31, 2016 and 2015, respectively.

Equity Incentive Plan

The Company has in effect the Amended and Restated 2015 Incentive Plan ("2015 Incentive Plan'). The 2015 Incentive Plan was adopted in March 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan authorizes grants to issue up to 2,000,000 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 321,000 shares at December 31, 2016.

Restricted Stock

In March 2015, the Company issued a restricted stock grant to Dr. Marasco for services in connection with its Scientific Advisory Board. Dr. Marasco was issued a grant for 1.5 million shares of common stock, which vested 25% on the first anniversary of the grant date and monthly thereafter for 48 months. The Company valued the restricted stock 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 on grant date. At December 31, 2015, the Company re-measured this non-employee restricted stock utilizing a market approach, based upon a third party financing. Such valuation resulted in a value of $4.39 per share utilizing a volatility of 83%, a risk free rate of return of 1.5% and a term of five years. At December 31, 2016, the Company re-measured this non-employee restricted stock utilizing a market approach, based primarily upon a third party financing. Such valuation resulted in a value of $5.43 per share utilizing a volatility of 80%, a risk free rate of return of 2.10% and a term of five years. For the years ended December 31, 2016 and 2015, in connection with this grant, the Company recorded expense of $2.5 million and $3.0 million, respectively, in research and development expenses on the Company's Statements of Operations.

Certain employees and directors have been awarded restricted stock under the 2015 Incentive Plan. The Company incurred approximately $1.3 million and $0.3 million, respectively, related to stock-based compensation expense for the years ended December 31, 2016 and 2015, which is included in general and administrative expenses on the Company's Statements of Operations. The Company incurred approximately $58,000 related to stock-based compensation expense for the year ended December 31, 2016, which is included in research and development expenses on the Company's Statements of Operations There were no related expense recognized during the same period in 2015.

The following table summarizes restricted stock award activity for the year ended December 31, 2016.

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2015	2,500,000	$ 1.73
Granted	619,000	5.03
Vested	(585,937)	0.07
Nonvested at December 31, 2016	2,533,063	$ 2.93

As of December 31, 2016, there was $4.3 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over weighted-average period of 1.8 years. This amount does not include 333,334 shares of restricted stock outstanding as of December 31, 2016 which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for these awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Options

During 2016, 60,000 stock options were granted to a consultant under the 2015 Incentive Plan with a $5.43 exercise price and a ten-year life. The stock options were valued using a Black-Scholes model with the following assumptions; volatility of 100.65%, risk free rate of 2.6% and effective life of 10 years.

The following table summarizes stock option award activity for the year ended December 31, 2016.

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2015	-	$ -	-
Granted	60,000	5.43	
Outstanding as of December 31, 2016	60,000	$ 5.43	9.96

The weighted average remaining amortization period is approximately 10.0 years at December 31, 2016.

Warrants

A summary of warrant activities for year ended December 31, 2016 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2015	4,286,782	$ 6.61	5.68
Granted	44,324	7.00	
Outstanding as of December 31, 2016	4,331,106	$ 6.62	4.67

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 years ended December 31, 2016 and 2015 ($ in thousands).

	Year Ended December 31,	
	2016	2015
Research and development	$ 2,557	$ 2,987
General and administrative	1,310	265
Total stock-based compensation expense	$ 3,867	$ 3,252

Note 8 - Income Taxes

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit during the years ended December 31, 2016 and 2015.

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

	For the years ended December 31,	
	2016	**2015**
Statutory federal income tax rate	35%	35%
State taxes, net of federal tax benefit	1%	5%
Annual equity fee	-	(9)%
Credits	3%	1%
Rate change	(2)%	-
Provision to return	5%	-
Stock based compensation shortfall	(4)%	-
Other	(2)%	-
Change in valuation allowance	(36)%	(32)%
Income taxes provision (benefit)	-	-

The components of the net deferred tax asset as of December 31, 2016 and 2015 are the following (in thousands):

	As of December 31,	
	2016	**2015**
Deferred tax assets:		
Net operating loss carryovers	$ 5,148	$ 1,657
Stock compensation and other	1,624	1,299
Change in fair value of warrant liabilities	157	175
Amortization of license	4,656	1,210
Accruals and reserves	25	-
Tax credits	733	115
Start Up Costs	54	-
Total deferred tax assets	12,397	4,456
Less valuation allowance	(12,397)	(4,456)
Deferred tax asset, net of valuation 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 its net deferred tax asset. A valuation allowance of approximately $12.4 million and $4.5 million was recorded for the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, the Company had federal and state net operating loss carryforwards of approximately $14.3 million and $3.0 million, respectively. The federal and state net operating loss carryforwards will begin to 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, as amended and similar state provisions. In December 2015, the Company experienced an 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 ASC 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, 2016. 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 period ended December 31, 2016.

The federal and state tax returns for the periods ended December 31, 2016 and 2015 are currently open for 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 at December 31, 2015 (in thousands):

	Contingently Issuable Warrants
Fair value, January 1, 2015	$ -
Additions	175
Change in fair value	438
Issuance of Warrants (October 30, 2015)	(613)
Fair value, December 31, 2015	$ -

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%

Note 10 – Accounts Payable and Accrued Expenses

At December 31, 2016 and 2015, accounts payable and accrued expenses consisted of the following:

	Year Ended December 31,	
	2016	2015
Accounts payable	$ 2,473	$ 917
Accrued compensation	291	43
Research and development	378	262
Other	213	66
Accounts payable and accrued expenses - related party	318	502
Total accounts payable and accrued expenses	$ 3,673	$ 1,790

Note 11 – Quarterly Financial Data (Unaudited)

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2016				
Total Revenue	$ 277	$ 1,249	$ 546	$ 498
Operating expenses	$ 3,549	$ 6,667	$ 5,685	$ 8,833
Other income/(expense)	$ (333)	$ 13	$ 11	$ 12
Net loss	$ (3,605)	$ (5,405)	$ (5,128)	$ (8,323)
Basic and diluted net loss per common share	$ (0.17)	$ (0.25)	$ (0.24)	$ (0.38)
2015				
Total Revenue	$ 500	$ -	$ 25	$ 65
Operating expenses	$ 2,117	$ 475	$ 3,704	$ 7,515
Other income/(expense)	$ -	$ -	$ (70)	$ (601)
Net loss	$ (1,617)	$ (475)	$ (3,749)	$ (8,051)
Basic and diluted net loss per common share	$ (0.20)	$ (0.06)	$ (0.44)	$ (0.55)

SIGNATURES

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

Checkpoint Therapeutics, Inc.

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

March 17, 2017

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Checkpoint Therapeutics, Inc., hereby severally constitute and appoint James F. Oliviero, acting singly, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign this report and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report 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/ James F. Oliviero James F. Oliviero	President and Chief Executive Officer (Principal Executive Officer)	March 17, 2017
/s/ Garrett Gray Garrett Gray	Vice President, Finance and Accounting (Principal Financial Officer)	March 17, 2017
/s/ Michael S. Weiss Michael S. Weiss	Chairman of the Board	March 17, 2017
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 17, 2017
/s/ Scott Boilen Scott Boilen	Director	March 17, 2017
/s/ Neil Herskowitz Neil Herskowitz	Director	March 17, 2017
/s/ Barry Salzman Barry Salzman	Director	March 17, 2017

Amendment 2 to Exclusive License Agreement between
Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc.

This second amendment ("Amendment 2"), made effective as of April 12, 2016 ("Amendment 2 Effective Date"), is between the Dana-Farber Cancer Institute, Inc., a Massachusetts non-profit organization having offices at 450 Brookline Avenue, Boston, MA 02215 ("DFCI"), and Checkpoint Therapeutics, Inc., a Delaware corporation with offices at 3 Columbus Circle, New York, NY 10019 ("CTI"), collectively the "Parties" with reference to the following:

WHEREAS, DFCI and CTI entered into an Exclusive License Agreement made effective as of March 2, 2015 and amended as of October 5, 2015 (collectively, "Agreement") covering intellectual property developed in the laboratory of Dr. Wayne Marasco at DFCI with respect to PD-L1, GITR and CAIX antibodies;

WHEREAS, the Parties now wish to add additional GITR antibodies, know-how and intellectual property developed in the laboratory of Dr. Wayne Marasco to the DFCI Technology licensed under the original Agreement, and include additional fees in consideration thereof;

WHEREAS, the Parties hereto agree that this Amendment 2 is hereby made an integral part of the Agreement, incorporated therein by this reference;

WHEREAS, capitalized terms used herein and not otherwise defined shall have the respective meanings assigned to such terms in the Agreement;

NOW, THEREFORE, in consideration of the premises contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Schedules 2 (DFCI Know-How) and 4 (DFCI Antibodies) are hereby amended to include intellectual property, know-how and GITR Antibodies pertaining to DFCI C2195, developed in the laboratory of Dr. Wayne Marasco, and more specifically described in Exhibit A, which is incorporated herein by reference and attached hereto.

2. Article 3.2c (Milestone Dates for a Licensed Product Targeting GITR) is hereby amended to include the following additional diligence milestone:

Milestone	**Achievement Date**
Developability Assessment	One hundred eighty (180) days from the Amendment 2 Effective Date

"Developability Assessment" means in-silico or in-vitro assessment of affinity, productivity, aggregation, stability, heterogeneity, solubility, viscosity, and potential for immunogenicity of an antibody sequence or protein included in this Amendment 2.

3. Article 5 (Financial Provisions) is hereby amended to include the following payments, in consideration of the additional rights granted by DFCI to CTI under this Amendment 2:

   a. **Amendment Upfront Fee** . A non-creditable, non-refundable Amendment Upfront Fee in the sum of ten thousand U.S. dollars ($10,000) shall be due and payable by CTI to DFCI upon execution of this Amendment 2.

   b. **Developability Assessment Milestone Payment.** Upon conclusion of the one hundred eighty (180) day Developability Assessment period, CTI shall pay to DFCI a Milestone Payment in the sum of one hundred thousand U.S. dollars ($100,000) if CTI elects to continue with research and clinical development of Antibodies containing any fragment, variant, derivative, or improvement of the novel GITR antibodies contained hereunder in Exhibit A.

4. Article 10 (Term and Termination) is hereby amended to include the following termination provision:

   a. **Amendment 2 Termination.** Upon conclusion of the one hundred eighty (180) day Developability Assessment period, if CTI elects not to continue with research and clinical development of Antibodies containing any fragment, variant, derivative, or improvement of the novel GITR antibodies contained hereunder in Exhibit A, this Amendment 2 shall immediately terminate.

Except as amended above, all other terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment 2 to be duly executed by their respective authorized representatives.

Dana-Farber Cancer Institute, Inc.		**Checkpoint Therapeutics, Inc.**	
By:	/s/ Gary M. Sclar	By:	/s/ James Oliviero
Name:	Gary M. Sclar, JD	Name:	James Oliviero
Title:	Chief Research Business Dev Officer, Interim	Title:	President & CEO
Date:	4/12/16	Date:	4/12/2016

EXHIBIT A

DFCI Invention #C2195 entitled "Isolation of new Human Anti-GITR monoclonal antibodies by phage display":

We used the extensively validated Mehta I/II human antibody-phage display libraries to pan against human GITR for the purpose of isolating new human anti-GITR mAbs. We have identified circa 40 antibodies that bind to GITR. Their DNA and amino acid sequences have been determined, as well as their relative affinities.

Amendment 3 to Exclusive License Agreement between
Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc.

This third amendment ("Amendment 3"), made effective as of October 24, 2016 ("Amendment 3 Effective Date"), is between the Dana-Farber Cancer Institute, Inc., a Massachusetts non-profit organization having offices at 450 Brookline Avenue, Boston, MA 02215 ("DFCI"), and Checkpoint Therapeutics, Inc., a Delaware corporation with offices at 2 Gansevoort Street | 9th Floor, New York NY 10014 ("CTI"), collectively the "Parties" with reference to the following:

WHEREAS, DFCI and CTI entered into an Exclusive License Agreement made effective as of March 2, 2015 and amended as of October 5, 2015 (Amendment 1) and April 12, 2016 (Amendment 2) (all three collectively, "Agreement") covering intellectual property developed in the laboratory of Dr. Wayne Marasco at DFCI with respect to PD-L1, GITR and CAIX antibodies;

WHEREAS, the Parties wish to include the title of the patent application referenced and to name the corresponding provisional patent applications;

WHEREAS, the Parties hereto agree that this Amendment 3 is hereby made an integral part of the Agreement, incorporated therein by this reference;

NOW, THEREFORE, in consideration of the premises contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

Exhibit A of Amendment 2 is hereby amended to read in full, as indented below:

EXHIBIT A

DFCI Invention #C2195 entitled "Isolation of new Human Anti-GITR monoclonal antibodies by phage display":

The Marasco lab used the extensively validated Mehta I/II human antibody-phage display libraries to pan against human GITR for the purpose of isolating new human anti-GITR mAbs., and has identified circa 40 antibodies that bind to GITR. Their DNA and amino acid sequences have been determined, as well as their relative affinities.

The title of the corresponding patent applications filed is "GLUCOCORTICOID-INDUCED TUMOR NECROSIS FACTOR RECEPTOR (GITR) ANTIBODIES AND METHODS OF USE THEREOF." The licensed patent rights include provisional application serial number 62/365,712, filed July 22, 2016 (DFCI-0141/PO1US; 322270-2613) and provisional application serial number 62/375,634, filed August 16, 2016 (DFCI-0141/PO2US; 322270-2621) and any convention date filings and subsequent domestic or foreign counterparts thereof claiming the benefit of their respective priority dates.

Except as amended above, all other terms and conditions of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment 3 to be duly executed by their respective authorized representatives.

Dana-Farber Cancer Institute, Inc.		**Checkpoint Therapeutics, Inc.**	
By:	/s/ Gary M. Sclar	By:	/s/ James Oliviero
Name:	Gary M. Sclar, JD	Name:	James Oliviero
Title:	Vice President, Dana-Farber Innovations	Title:	President and CEO
Date:	10/24/16	Date:	11/3/2016

Exhibit 10.11

FIRST AMENDMENT TO
LICENSE AGREEMENT

This First Amendment to License Agreement (the " **Amendment** ") is effective as of February 21, 2017 and amends that certain License Agreement, dated March 17, 2015, (the " **Agreement** ") by and between NeuPharma, Inc. (" **Licensor** ") and Checkpoint Therapeutics, Inc. (" **Checkpoint** "). Licensor and Checkpoint are each referred to individually as a " **Party** " and together as the " **Parties** ."

BACKGROUND

A. Licensor and Fortress Biotech, Inc. (f/k/a Coronado Biosciences, Inc.) ("Fortress") entered into the Agreement.

B. Fortress subsequently assigned to Checkpoint all of its right, title and interest in and to the Agreement pursuant to an Assignment and Assumption Agreement dated March, 17, 2015.

C. Checkpoint and Licensor now wish to amend the Agreement as provided herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, the sufficiency of which is acknowledged by both Parties, the Parties agree as follows:

1. **Definitions** . Unless otherwise defined in this Amendment, initially capitalized terms used herein shall have the meanings given to them in the Agreement.

2. **Amendments** .

a) The introductory paragraph of the Agreement shall be amended by deleting "Coronado Biosciences, Inc., a Delaware corporation with its place of business at 3 Columbus Circle, 15th Floor, New York, New York 10019 (" **Coronado** ")" and replacing it with the following:

> "Checkpoint Therapeutics, Inc., a Delaware corporation with its place of business at 2 Gansevoort Street, 9 th Floor, New York, NY 10014 (" **Checkpoint** ")

b) The Agreement shall be amended by deleting all references to Coronado and replacing them with "Checkpoint."

c) The Agreement shall be amended by adding the following new paragraph as the second paragraph of Section 2.1:

> "Without limiting the rights granted to Checkpoint in the foregoing paragraph, Licensor hereby grants to Checkpoint and its Affiliates, and Checkpoint and its Affiliates hereby accept, a nonexclusive, royalty-free right and license (with the right to sublicense through multiple tiers of sublicensees in accordance with the provisions of Section 2.2) under the Licensor Technology to Develop and have Developed the Licensed Products in and for the Field in Thailand, and to import and use the Licensed Products in Thailand in connection with such Development."

d) Article III of the Agreement shall be amended by adding the following new Section 3.8:

"3.8 **Clinical Studies in Thailand** . Notwithstanding anything to the contrary in this Agreement, Checkpoint shall (i) have sole responsibility for, and control over, clinical studies involving a Licensed Product that it sponsors in Thailand (including, without limitation clinical monitoring, provision of reports and communications with Regulatory Authorities) (the " **Thailand Study(ies)** "), (ii) provide Licensor with a copy of any final clinical study report that Checkpoint possesses for each such Thailand Study; (iii) own all Regulatory Filings in Thailand relating to Thailand Studies; and (iv) notify Licensor of Adverse Events and Serious Adverse Events occurring with respect to Thailand Studies in accordance with Section 4.5 hereof.

Notwithstanding the foregoing, upon (i) Checkpoint determining that it has completed any Thailand Study with respect to a Licensed Product, and (ii) written request by Licensor, Checkpoint shall, to the extent permitted by applicable laws, rules and regulations, use commercially reasonable efforts to transfer ownership of all Regulatory Filings in Thailand pertaining solely to such Thailand Studies to Licensor, provided that Licensor first agrees in writing to assume all obligations and liabilities associated with such Regulatory Filings. Prior to such assignment and assumption of Regulatory Filings, Licensor shall have a right of reference to such Regulatory Filings for use in the Licensor Territory, and following such assignment and assumption of Regulatory Filings, Licensor shall be entitled to use any such Regulatory Filings in the Licensor Territory. Checkpoint and its Sublicensees shall retain a right of reference to any such Regulatory Filing that is assigned to Licensor solely for use in the Territory.

To the extent permitted by applicable laws, rules and regulations, Checkpoint shall use commercially reasonable efforts to: (i) allow Licensor to be present at Checkpoint-attended meetings or teleconferences with Regulatory Authorities in Thailand, clinical investigators, or contract research organizations ("CRO(s)") contracted by Checkpoint for Thailand Studies that Licensor in its sole discretion determines are material to the Development of the Licensed Product, provided that (a) such meetings or teleconferences pertain to Thailand Studies, (b) Licensor shall not actively participate (i.e., Licensor shall be an observer) in such meetings or teleconferences unless pre-approved in writing by Checkpoint, (ii) provide Licensor with periodic reports, by electronic mail or teleconferences, no less frequently than monthly, regarding Thailand Studies, which reports shall include data and findings in Checkpoint's possession related to the Thailand Studies, (iii) promptly provide, but in no case less than ten (10) business days from Checkpoint's receipt thereof, Licensor with copies of all communications it or its CRO provides to and receives from Regulatory Authorities in Thailand with respect to the Thailand Studies; and (iv) upon Licensor's request, provide Licensor with view-only access to any clinical database for the Thailand Studies whether maintained by Checkpoint or any third party (including any CRO) on behalf of Checkpoint. Nothing in this Section 3.8 shall be deemed to provide Licensor with any authority or decision-making power regarding the Thailand Studies, which authority and decision-making power shall be retained solely by Checkpoint, provided that Checkpoint will consider in good faith comments and suggestions made by Licensor with respect to the Thailand Studies. For the avoidance of doubt, all information regarding the Thailand Studies shall be deemed Checkpoint's Confidential Information, subject to Licensor's right of reference to Regulatory Filings in Thailand for use in the Licensor Territory; provided, however, that upon assignment of Regulatory Filings in Thailand to Licensor as provided in Section 3.8, all information related to the applicable Thailand Studies shall be deemed both Parties' Confidential Information ("Joint Information").

Notwithstanding anything to the contrary in this Agreement following such assignment, each Party shall have the right to:

(a) use and disclose Joint Information in connection with: (i) researching, Developing, having Developed, manufacturing, having manufactured, using, importing and Commercializing and having Commercialized the Licensed Products in the Field and in such Party's respective territory (i.e., the Territory for Checkpoint and Licensor Territory for Licensor); (ii) complying with applicable laws, rules and regulations, (iii) filing, prosecuting, defending or otherwise obtaining and maintaining patents, and (iv) publishing the results of the applicable Thailand Studies; and

(b) without limiting the generality of the immediately preceding clause (a), disclose Joint Information: to (w) its Affiliates, (x) Third Parties involved or potentially involved in the research, Development, manufacture, use, or Commercialization of the Licensed Product (who may then further disclose the Joint Information to other such Third Parties), (y) its or its Affiliate's actual or bona fide potential collaborators, manufacturers, licensees, licensors, sublicensees, investors, acquirers, merger or acquisition candidates, partners, lenders or financing sources, in each case for use of such information for business purposes relating to this Agreement or for due diligence in connection with potential development, manufacturing, commercialization, licensing, investment, merger or acquisition, loan or financing transactions and (z) Regulatory Authorities in such Party's respective territory (i.e., the Territory for Checkpoint and Licensor Territory for Licensor) in connection with the research, Development, manufacture, use, or Commercialization of the Licensed Products."

e) The first sentence of Section 4.5 shall be amended to add the following new clause at the end:

", provided, however, that Licensor shall not have such responsibility with respect to clinical studies involving a Licensed Product that Checkpoint sponsors in Thailand."

f) Section 10.4(e) of the Agreement shall be amended to add the following new clause at the end:

"; provided, however, that the transfer of any Regulatory Filings from any Thailand Studies shall not be contingent upon such written agreement, and shall be transferred to Licensor immediately on termination without payment or royalty obligation on Licensor.

g) Section 11.8 of the Agreement shall be amended to delete Checkpoint's notice address and replace it with the following:

"Checkpoint Therapeutics, Inc.
2 Gansevoort Street
9 th Floor
New York, NY 10014
Attention: President"

3. **No Other Modifications** . Except as specifically set forth in this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. No waiver of the performance of any obligation under this Amendment shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Amendment may be amended or modified other than by a written document signed by authorized representatives of each Party.

   THIS AMENDMENT AND THE AGREEMENT AS AMENDED BY THIS AMENDMENT SET FORTH THE ENTIRE AGREEMENT AND UNDERSTANDING OF THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF, AND SUPERCEDES ALL PRIOR DISCUSSIONS, AGREEMENTS AND WRITINGS IN RELATION THERETO.

4. **Miscellaneous** . This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF , the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero
Name: James Oliviero
Title: CEO

NEUPHARMA, INC.

By: /s/ Shawn Qian
Name: Shawn Qian
Title: CEO

Exhibit 10.16

SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

Second Amendment (this "Amendment") dated as of December 15, 2016 to the Executive Employment Agreement (the "Agreement") dated October 13, 2015, as amended, by and between Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") and James F. Oliviero III ("Oliviero"). All capitalized terms not otherwise defined herein shall have the meanings given to them in the Agreement.

WHEREAS, on October 13, 2015, Oliviero received a grant of 1,000,000 restricted shares of Checkpoint common stock, $0.0001 par value, and pursuant to the Agreement 333,333 of such shares (the "Shares") were set to vest over time in four equal annual installments beginning on the Effective Date;

WHEREAS, on September 27, 2016, Oliviero and the Company entered into a first amendment to the Agreement, effective as of such date, to amend the vesting schedule;

WHEREAS, on December 15, 2016, Oliviero and the Company agreed to further amend the vesting schedule in the Agreement;

WHEREAS, the Company believes that it is in its best interest to further amend the vesting schedule in the Agreement; and

WHEREAS, the Company and Oliviero have agreed to amend the Agreement.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth, the parties agree as follows:

1. Amendments .

Section 3.4.3 of the Agreement with regard to the Shares shall be amended by deleting the following vesting schedule:

Vesting Date		Number of Shares Vested
October 13, 2017		166,667
October 13, 2018		83,333
October 13, 2019		83,333
The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $250,000,000		111,111
The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $500,000,000		111,111

The first date that the Company achieves a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $750,000,000		111,111
The earlier to occur of: (A) the Company's first Corporate Development Transaction (as defined in the Employment Agreement) or (B) the first FDA approval of a Company product or medical device		166,667
The earlier to occur of: (A) the Company's second Corporate Development Transaction (as defined in the Employment Agreement) or (B) a second FDA approval of a Company product or medical device		166,667

and inserting the following vesting schedule:

Vesting Date		Number of Shares Vested
The earlier to occur of: (A) July 1, 2018 or (B) the termination of Executive's (as defined in the Employment Agreement) employment as a result of his death or Disability (as defined in the Employment Agreement)		166,667
October 13, 2018		83,333
October 13, 2019		83,333

The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $250,000,000 or (B) April 1, 2018, *provided* , however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111
The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $500,000,000 or (B) April 1, 2018, *provided* , however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111

The later to occur of: (A) the Company's achievement of a fully-diluted Market Capitalization (as defined in the Employment Agreement) of $750,000,000 or (B) April 1, 2018, *provided* , however, that should Executive's (as defined in the Employment Agreement) employment with the Company terminate as a result of his death or Disability (as defined in the Employment Agreement) and prior to such termination or within four months of such termination (as provided by Section 4.5.4(iii)), any Market Capitalization milestone is achieved, the respective Shares for such achieved Market Capitalization milestone(s) shall immediately vest and become non-forfeitable.		111,111
The earlier to occur of: (A) the Company's first Corporate Development Transaction (as defined in the Employment Agreement) or (B) the first FDA approval of a Company product or medical device		166,667
The earlier to occur of: (A) the Company's second Corporate Development Transaction (as defined in the Employment Agreement) or (B) a second FDA approval of a Company product or medical device		166,667

2. Effect on the Agreement .

(a) Upon the effectiveness of this Amendment, each reference in the Agreement to "this Agreement" "hereunder", "hereof", "herein" or words of like import shall mean and be a reference to the Agreement as amended hereby.

(b) Except as expressly amended, the Agreement and all other documents and agreements executed and/or delivered in connection therewith, shall remain in full force and effect.

3. Governing Law .

This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns and shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of laws principles.

4. Counterparts .

This Amendment may be executed by the parties hereto in one or more counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same agreement.

IN WITNESS WHEREOF, Checkpoint Therapeutics, Inc. and James F. Oliviero III have executed this Amendment to the Executive Employment Agreement as of the date first written above.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ Michael S. Weiss
Michael S. Weiss
Chairman of the Board of Directors

/s/ James F. Oliviero III
James F. Oliviero III

Exhibit 10.19

BOARD ADVISORY SERVICES AGREEMENT

THIS BOARD ADVISORY SERVICES AGREEMENT (this " Agreement ") is made as of January 1, 2017, by and between Checkpoint Therapeutics, Inc., a Delaware corporation (the " Company "), and Caribe BioAdvisors, LLC, a Puerto Rico limited liability company (the "Advisor" and individually a " Party " or collectively the " Parties ").

WHEREAS, on the terms and subject to the conditions contained in this Agreement, the Company desires to obtain certain board advisory services from the Advisor, and the Advisor has agreed to perform such board advisory services;

WHEREAS, this Agreement has been approved by the Company's Board of Directors (the "Board").

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Board Advisory Services.

1.1 Approval and Authority . Where not required by applicable law or regulation, the Advisor shall not require the prior approval of the Board to perform its duties under this Agreement. Notwithstanding the foregoing, the Advisor shall not have the authority to bind the Company, and nothing contained herein shall be construed to create an agency relationship between the Company and the Advisor.

1.1 Services .

1.1.1 Scope . Subject to any limitations imposed by applicable law or regulation, the Advisor shall render or cause to be rendered board advisory services to the Company, which services may include, without limitation, participation on the Board of the Company in the capacity of Chairman of the Board by one of Advisor's employees and related advice and assistance by Advisor and its employees (collectively, the " Services "). The Advisor shall provide and devote to the performance of this Agreement such employees, Affiliates and agents of the Advisor as the Advisor shall deem appropriate to the furnishing of the Services hereunder, which employees (other than Mr. Weiss) shall be billed separately (quarterly in arrears) at the hourly rates designated on Schedule 1.1.1. Such billings shall not exceed $10,000 per year without prior authorization of the Company. "Affiliate" means a person or entity that controls, is controlled by or is under common control with a party, but only for so long as such control exists. For the purposes of the definition of Affiliate, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such person or entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise.

1.1.2 Board Services . The Company hereby requests and Advisor hereby agrees to provide Mr. Weiss to serve as Chairman of the Board of the Company. In order to enable Advisor to provide Mr. Weiss, one of its employees, to deliver the requested Services as Chairman of the Board of the Company, the Company agrees to use its best efforts to cause Michael S. Weiss, to be elected as a member of the Company's Board, and to be selected as Chairman of the Board, throughout the Term and shall include him in the slate for election as a director at every stockholders meeting during the Term at which his term as a director would otherwise expire.

1.2 Non-exclusivity, Freedom to Pursue Opportunities and Limitation on Liability .

1.2.1 Non Exclusivity . The Advisor shall devote such time and efforts to the performance of Services contemplated hereby as the Advisor deems reasonably necessary or appropriate; provided, however, that no minimum number of hours is required to be devoted by the Advisor on a weekly, monthly, annual or other basis. The Company acknowledges that the Services are not exclusive to the Company and that the Advisor will render similar Services to other persons and entities.

1.2.2 Freedom to Pursue Opportunities . In recognition that the Advisor and its Affiliates currently have, and will in the future have or will consider working with or investing in numerous companies with respect to which the Advisor or its Affiliates may serve as an advisor, a director, officer or in some other capacity, and in recognition that the Advisor and its Affiliates have a myriad of duties to these other companies and their shareholders, and in anticipation that the Company and the Advisor (or one or more Affiliates or clients of the Advisor) may engage in the same or similar activities or lines of business and have an interest in the same areas of corporate opportunities, and in recognition of the benefits to be derived by the Company hereunder and in recognition of the difficulties that may confront any Advisor who desires and endeavors fully to satisfy such Advisor's duties in determining the full scope of such duties in any particular situation, the provisions of this Section 1.2.2 are set forth to regulate, define and guide the conduct of certain affairs of the Company as they may involve the Advisor.

Except as the Advisor may otherwise agree in writing after the date hereof:

(i) the Advisor will have the right: (A) to directly or indirectly engage in any business including, without limitation, any business activities or lines of business that are the same as or similar to those pursued by, or competitive with, any of the Company's, (B) to directly or indirectly do business with any client or customer of the Company, (C) to take any other action that the Advisor believes in good faith is necessary to or appropriate to fulfill its obligations as described in the first sentence of this Section 1.2.2 , and (D) not to present potential transactions, matters or business opportunities to the Company, and to pursue, directly or indirectly, any such opportunity for itself, and to direct any such opportunity to another person.

(ii) the Advisor and its officers, employees, partners, members, other clients, Affiliates and other associated entities will have no duty (contractual or otherwise) to communicate or present any corporate opportunities to the Company or to refrain from any action specified in Section 1.2.2(i) , and the Company on its own behalf and on behalf of its Affiliates, hereby renounces and waives any right to require the Advisor or any of its Affiliates to act in a manner inconsistent with the provisions of this Section 1.2.2 .

(iii) Neither the Advisor nor any officer, director, employee, partner, member, stockholder, Affiliate or associated entity thereof will be liable to the Company for breach of any duty (contractual or otherwise) by reason of any activities or omissions of the types referred to in this Section 1.2.2 or of any such person's participation therein.

2. Term . The Advisor shall provide the Services set forth in Section 1 above from the date hereof until the earlier of (a) termination of this Agreement by mutual agreement of the Advisor and the Company and (b) the date on which Advisor is no longer a member of the Board of the Company (such period, the " Term "). If this Agreement is terminated as a result of (i) the Board not nominating Advisor for reelection to the Board or (ii) the shareholders not voting to reelect Advisor to the Board, then any outstanding but unvested equity grants shall immediately vest.

No termination of this Agreement, whether pursuant to this Section 2 or otherwise, will affect the Company's duty to pay any Management Fee (as defined herein in Section 3) accrued, or to reimburse any cost or expense incurred pursuant to Section 4 hereof, prior to the effective date of such termination. Upon termination of this Agreement, the Advisor's right to receive any further Management Fee or reimbursement for costs and expenses that have not accrued or been incurred to the date of termination shall cease and terminate. Additionally, the obligations of the Company under Section 4 (Expenses), Section 7 (Indemnification), the provisions of Section 1.2.2 above (whether in respect of or relating to Services rendered prior to termination of this Agreement or in respect of or relating to any Services provided after termination of this Agreement) and the provisions of Section 14 (Governing Law) will also survive any termination of this Agreement to the maximum extent permitted under applicable law.

3. Compensation .

3.1 Commencing on the date hereof, in consideration of the board advisory and consulting services to be rendered, the Company will pay to the Advisor an annual consulting fee in cash in the aggregate amount equal to $60,000 (the " Annual Consulting Fee "), payable in advance in equal quarterly installments within twenty (20) business days of the beginning of each calendar quarter in each year. In addition, Advisor shall receive any and all annual equity incentive grants paid to other members of the Board of Directors, as, if and when paid to the other Board members.

3.2 Any payment pursuant to this Section 3 shall be made either (i) in cash by wire transfer(s) of immediately available funds to or among one or more accounts as designated from time-to-time by the Advisor to the Company in writing or (ii) by corporate check delivered by U.S. mail or overnight delivery service.

4. Expenses . Actual and direct out-of-pocket expenses reasonably incurred by the Advisor and its personnel in performing the Services shall be reimbursed to the Advisor by the Company upon the delivery to the Company of an invoice, receipt or such other supporting data as the Company reasonably shall require. The Company shall reimburse the Advisor by wire transfer of immediately available funds or by corporate check for any amount paid by the Advisor, which shall be in addition to any other amount payable to the Advisor under this Agreement.

5. Reserved .

6. Decisions and Authority of the Advisor .

6.1 No Liability . In no event will the Advisor or any of its Affiliates be liable to the Company for any indirect, special, incidental or consequential damages, including, without limitation, lost profits or savings, whether or not such damages are foreseeable, or for any third party claims (whether based in contract, tort or otherwise), relating to the Services to be provided by the Advisor hereunder. The Company reserves the right to make all decisions with regard to any matter upon which the Advisor has rendered advice and consultation, and there shall be no liability of the Advisor for any such advice accepted by the Company pursuant to the provisions of this Agreement. The Advisor will not be liable for any mistakes of fact, errors of judgment or losses sustained by the Company or for any acts or omissions of any kind (including acts or omissions of the Advisor), except to the extent caused by intentional misconduct of the Advisor as finally determined by a court of competent jurisdiction. In such case, the Advisor's liability shall be limited to direct damages not to exceed the total fees paid to Advisor for the Services provided to the Company through the date of any claim.

6.2 Independent Contractor . The Advisor shall act solely as an independent contractor and shall have complete charge of its respective personnel engaged in the performance of the Services under this Agreement. Neither the Advisor nor its officers, employees or agents will be considered employees or agents of the Company or any of its respective subsidiaries as a result of this Agreement. As an independent contractor, the Advisor shall have authority only to act as an advisor to the Company and shall have no authority to enter into any agreement or to make any representation, commitment or warranty binding upon the Company or to obtain or incur any right, obligation or liability on behalf of the Company. Nothing contained in this Agreement shall result in the Advisor or any of its partners or members or any of their Affiliates, investment Advisors, investment advisors or partners being a partner of or joint venturer with the Company.

7. Indemnification .

7.1 Indemnification . The Company shall (i) indemnify the Advisor and its respective Affiliates, directors, officers, employees and agents (collectively, the " Indemnified Party "), to the fullest extent permitted by law, from and against any and all actions, causes of action, suits, claims, liabilities, losses, damages and costs and expenses in connection therewith, including without limitation reasonable attorneys' fees and expenses (" Indemnified Liabilities ") to which the Indemnified Party may become subject, directly or indirectly caused by, related to or arising out of the Services or any other advice or Services contemplated by this Agreement or the engagement of the Advisor pursuant to, and the performance by such Advisor of the Services contemplated by, this Agreement, and (ii) promptly reimburse the Indemnified Party for Indemnified Liabilities as incurred, in connection with the investigation of, preparation for or defense of any pending or threatened claim or any action or proceeding arising therefrom, whether or not such Indemnified Party is a party and whether or not such claim, action or proceeding is initiated or brought by or on behalf of the Company or Advisor and whether or not resulting in any liability. If and to the extent that the foregoing undertaking may be unenforceable for any reason, the Company hereby agrees to make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities that is permissible under applicable law.

7.2 Limitations on Indemnity; Restrictions on Liability . The Company shall not be liable under the indemnification contained in Section 7.1 hereof with respect to the Indemnified Party to the extent that such Indemnified Liabilities are found in a final non-appealable judgment by a court of competent jurisdiction to have resulted directly from the Indemnified Party's willful misconduct. The Company further agrees that no Indemnified Party shall have any liability (whether direct or indirect, in contract, tort or otherwise) to the Company, holders of its securities or its creditors related to or arising out of the engagement of the Advisor pursuant to, or the performance by the Advisor of the Services contemplated by, this Agreement.

8. Notices . All notices, demands, or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given or made when (i) delivered personally to the recipient, (ii) telecopied to the recipient (with a hard copy sent to the recipient by reputable overnight courier service (charges prepaid)) if telecopied before 5:00 p.m. Eastern Standard Time on a business day, and otherwise on the next business day, (iii) one (1) business day after being sent to the recipient by reputable overnight courier service (charges prepaid) or (iv) received via electronic mail by the recipient if received via electronic mail before 5:00 p.m. Eastern Standard Time on a business day, and otherwise on the next business day after such receipt. Such notices, demands and other communications shall be sent to the address for such recipient indicated below or to such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party.

Notices to the Advisor

Caribe Plaza
25 Avenida Ponce de Leon, Suite 1201
San Juan, Puerto Rico 00901
Attn: Michael S. Weiss
e-mail: msw@caribebio.com

Notices to the Company :

2 Gansevoort Street,
9 th Floor
New York, NY
Attention: James Oliviero
e-mail: jfo@checkpointtx.com

9. Severability . If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the Parties hereto shall use their best efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the Parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any such terms, provisions, covenants and restrictions which may be hereafter declared invalid, illegal, void or unenforceable.

10. Entire Agreement . This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes any prior communication or agreement with respect thereto.

11. Counterparts . This Agreement may be executed in multiple counterparts, and any Party may execute any such counterpart, each of which when executed and delivered will thereby be deemed to be an original and all of which counterparts taken together will constitute one and the same instrument. The delivery of this Agreement may be effected by means of an exchange of facsimile or portable document format (.pdf) signatures.

12. Amendments and Waiver. No amendment or waiver of any term, provision or condition of this Agreement will be effective, unless in writing and executed by both the Company and the Advisor. No waiver on any one occasion will extend to, effect or be construed as a waiver of any right or remedy on any future occasion. No course of dealing of any person nor any delay or omission in exercising any right or remedy will constitute an amendment of this Agreement or a waiver of any right or remedy of any Party hereto.

13. Successors and Assigns . All covenants and agreements contained in this Agreement by or on behalf of any of the Parties hereto will bind and inure to the benefit of the respective successors and assigns of the Parties hereto whether so expressed or not. Neither the Company nor the Advisor may assign its rights or delegate its obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, that the Advisor may assign this Agreement to any of its Affiliates.

14. Governing Law . This Agreement shall be governed by and construed in accordance with the substantive laws of the state of Delaware, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the state of Delaware.

15. Waiver of Jury Trial . To the extent not prohibited by applicable law which cannot be waived, each of the Parties hereto hereby waives, and covenants that it will not assert (whether as plaintiff, defendant or otherwise), any right to trial by jury in any forum in respect of any issue, claim, demand, cause of action, action, suit or proceeding arising out of or based upon this Agreement or the subject matter hereof, in each case whether now existing or hereafter arising and whether in contract or tort or otherwise. Any of the Parties hereto may file an original counterpart or a copy of this Agreement with any court as written evidence of the consent of each of the Parties hereto to the waiver of its right to trial by jury.

16. No Strict Construction . The Parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties hereto, and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

17. Headings; Interpretation . The headings in this Agreement are for convenience and reference only and shall not limit or otherwise affect the meaning hereof. The use of the word "including" in this Agreement will be by way of example rather than by limitation.

* * * * * *

IN WITNESS WHEREOF, the Parties hereto have executed this Advisory Services Agreement as of the date first written above.

CARIBE BIOADVISORS, LLC

By: /s/ Michael S. Weiss
Name: Michael S. Weiss
Title: Chief Executive Officer

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero
Name: James Oliviero
Title: CEO

Schedule 1.1.1

Assistant - $50

Junior Associate - $75

Associate - $100

Senior Associate - $150

Exhibit 10.21

December 30, 2016

Mr. James Oliviero
Checkpoint Therapeutics, Inc.
2 Gansevoort Street, 9 th Floor
New York, NY 10014

EXTENSION OF OPTION AGREEMENT

Dear James:

As discussed, we would like to extend the Option Period in the Option Agreement dated March 17, 2015 (the "Option Agreement") between TG Therapeutics, Inc. and Fortress Biotech, Inc. ("Fortress"), as previously extended on September 11, 2015, December 15, 2015, January 11, 2016 and July 8, 2016.

1. Parties. Effective March 17, 2015, Fortress and Checkpoint Therapeutics, Inc. ("Checkpoint") entered into an agreement pursuant to which Fortress assigned to Checkpoint all of its right and interests under the License Agreement.

2. Option Period. Pursuant to Section 1.5 of the Option Agreement, the Option Period shall mean the date that is 180 days following the Effective Date; subject to a 3-month extension upon prior written request, not to be unreasonably withheld. The parties agree to further extend the Option Period to December 31, 2017.

3. Terms . This Extension of Option Agreement shall be governed under all of the same terms as the Option Agreement.

4. Defined Terms . Any capitalized term not defined in this Amendment shall be defined as defined in the Option Agreement.

5. Counterparts . This Amendment may be executed by any party by PDF file signature, and on one or more counterparts, and by different parties on separate counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, all of which together shall constitute but one and the same instrument.

Sincerely,
TG Therapeutics, Inc.

/s/ Michael S. Weiss
By: Michael S. Weiss
Title: Executive Chairman, Interim CEO

Agreed and Accepted by:
Checkpoint Therapeutics, Inc.

/s/ James Oliviero
By: Mr. James Oliviero
Title: CEO and President

Exhibit 10.26

FIRST AMENDMENT TO LICENSE AGREEMENT

THIS FIRST AMENDMENT TO LICENSE AGREEMENT (this " Amendment ") is made as of December 13, 2016 (the " Effective Date ") between Jubilant Biosys Limited, a company organized under the laws of India, having its principal place of business at No. 96, Industrial Suburb, 2 nd Stage, Yeshwanthpur, Bangalore – 560022, India (" Licensor "), and Checkpoint Therapeutics, Inc, a Delaware corporation with its place of business at 2 Gansevoort Street, 9 th Floor, New York, New York 10014 (" Checkpoint ").

WHERE AS, Licensor and Checkpoint are party to that certain License Agreement, dated as of May 26, 2016 (the " License Agreement "); and

WHEREAS, Licensor and Checkpoint desire to amend the License Agreement to alter one of the Milestones and its corresponding Milestone Payment (as defined, in each case, in the License Agreement).

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the mutual premises and covenants herein contained, and other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows.

1. Amendment to Section 5.2 of the License Agreement . The first row of the table contained in Section 5.2 of the License Agreement are hereby deleted and restated in their entirety as follows:

Milestone Event	**First Achievement Milestone Payment**	**Second Product Milestone Payment**
1. Complete toxicology studies with data meeting the success criteria set forth in Schedule 7 on or before:(i) March 31, 2017 or (ii) any earlier date agreed upon mutually between the Parties pursuant to a duly authorized separate writing.	$400,000	N/A

2. Remainder of License Agreement . Except as expressly set forth in this Amendment, the provisions of the License Agreement will remain in full force and effect, in their entirety, in accordance with their terms.

3. Miscellaneous . This Amendment shall be governed, construed, and interpreted in accordance with the laws of the State of New York, without giving effect to conflicts of laws principles of any jurisdiction. The parties agree that this Amendment may only be modified in a signed writing executed by each of the parties hereto. This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, successors and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Facsimile or PDF reproductions of original signatures will be deemed binding for the purpose of the execution of this Amendment.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment to be effective as of the Effective Date.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero

Name: James Oliviero

Title: CEO

JUBILANT BIOSYS LIMITED

By: /s/ Benny Thomas

Name: Benny Thomas

Title: Head - Finance

Exhibit 10.28

FIRST AMENDMENT TO SUBLICENSE AGREEMENT

THIS FIRST AMENDMENT TO SUBLICENSE AGREEMENT (this " Amendment ") is made as of December 13, 2016 (the " Effective Date ") between Checkpoint Therapeutics, Inc, a Delaware corporation with its place of business at 2 Gansevoort Street, 9 th Floor, New York, New York 10014 (" Checkpoint "), and TG Therapeutics, Inc, a Delaware corporation with its place of business at 2 Gansevoort Street, 9 th Floor, New York, New York 10014 (" TGTX ").

WHERE AS, Checkpoint and TGTX are party to that certain Sublicense Agreement, dated as of May 26, 2016 (the " Sublicense Agreement "); and

WHEREAS, Checkpoint and TGTX desire to amend the Sublicense Agreement to alter one of the Milestones and its corresponding Milestone Payment (as defined, in each case, in the Sublicense Agreement).

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the mutual premises and covenants herein contained, and other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows.

1. Amendment to Section 5.2 of the Sublicense Agreement . The first row of the table contained in Section 5.2 of the Sublicense Agreement are hereby deleted and restated in their entirety as follows:

Milestone Event	**First Achievement Milestone Payment**	**Second Product Milestone Payment**
1. Complete toxicology studies with data meeting the success criteria set forth in Schedule 7 on or before:(i) March 31, 2017 or (ii) any earlier date agreed upon mutually between the Parties pursuant to a duly authorized separate writing.	$200,000	N/A

2. Remainder of Sublicense Agreement . Except as expressly set forth in this Amendment, the provisions of the Sublicense Agreement will remain in full force and effect, in their entirety, in accordance with their terms.

3. Miscellaneous . This Amendment shall be governed, construed, and interpreted in accordance with the laws of the State of New York, without giving effect to conflicts of laws principles of any jurisdiction. The parties agree that this Amendment may only be modified in a signed writing executed by each of the parties hereto. This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, successors and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Facsimile or PDF reproductions of original signatures will be deemed binding for the purpose of the execution of this Amendment.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment to be effective as of the Effective Date.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero

Name: James Oliviero

Title: CEO

TG THERAPEUTICS, INC.

By: /s/ Michael Weiss

Name: Michael Weiss

Title: CEO

EXHIBIT 31.1

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James F. Oliviero certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2016 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 17, 2017

By: /s/ James F. Oliviero

James F. Oliviero
President and Chief Executive Officer
Principal Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garrett Gray, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2016 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 17, 2017

By: /s/ Garrett Gray
Garrett Gray
Vice President, Finance and Accounting
Principal Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James F. Oliviero, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 17, 2017

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrett Gray, Principal Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 17, 2017

By: /s/ Garrett Gray
Garrett Gray
Vice President, Finance and Accounting
Principal Financial Officer