

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

FORM 10/A  
(Amendment No. 2)

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

CHECKPOINT THERAPEUTICS, INC.  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

47-2568632  
(I.R.S. Employer  
Identification No.)

2 Gansevoort Street, 9<sup>th</sup> Floor  
New York, New York  
(Address of Principal Executive Offices)

10014  
(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)  
n/a

(Name of exchange on which registered)  
n/a

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

(Title of Class)

Common Stock, par value \$0.0001 per share

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

**Item 1: Business**

**OVERVIEW**

We are an immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel, non-chemotherapy, immune-enhanced combination treatments for patients with solid tumor cancers. We aim to acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently we are developing a portfolio of fully human immuno-oncology targeted antibodies generated in the laboratory of Dr. Wayne Marasco, MD, PhD, a professor in the Department of Cancer Immunology and AIDS at the Dana-Farber Cancer Institute (“Dana-Farber”). The portfolio of antibodies we licensed from Dana-Farber includes antibodies targeting programmed death-ligand 1 (“PD-L1”), glucocorticoid-induced TNFR related protein (“GITR”) and carbonic anhydrase IX (“CAIX”) (together, the “Dana-Farber Antibodies”). We plan to develop these novel immuno-oncology and checkpoint inhibitor antibodies on their own and in combination with each other, as published literature suggests that combinations of these targets may work synergistically together. We expect to submit investigational new drug (“IND”) applications for our anti-PD-L1, anti-GITR and anti-CAIX antibodies in 2017. We have also licensed and are developing two oral targeted anti-cancer therapies, consisting of a small molecule inhibitor of poly (ADP-ribose) polymerase (“PARP”) and a small molecule inhibitor of epidermal growth factor receptor (“EGFR”) mutations. We plan to submit an IND application for our EGFR inhibitor, CK-101, in the first half of 2016, followed by the commencement of a Phase 1/2 clinical study. We are currently developing a clinical program for our PARP inhibitor, CK-102, which we expect to commence in the next six to twelve months. Additionally, we will seek to add additional immuno-oncology drugs as well as other targeted therapies to create wholly-owned proprietary combinations that leverage the immune system and other complimentary mechanisms. To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of March 31, 2016, we have an accumulated deficit of \$14.5 million.

In December 2015, we closed on gross proceeds of \$57.8 million, before commissions and expenses, in a series of private placement financings. Net proceeds from this offering were approximately \$51.5 million. The financing involved the sale of Units, each consisting of 10,000 shares of common stock and a warrant exercisable for 2,500 shares of common stock at an exercise price of \$7.00 per share, for a purchase price of \$50,000 per Unit. The warrants have a five year term and are only exercisable for cash. We expect to use the net proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at March 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 24 months.

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

**CORPORATE INFORMATION**

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

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

**PRODUCTS UNDER DEVELOPMENT**

**Immuno-Oncology Agents**

***Anti-PD-L1 Research Program***

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

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

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

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

#### ***Anti-GITR Research Program***

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

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

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

#### **Targeted Anti-Cancer Agents**

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

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

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

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

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

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

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

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

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

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

- Study 1065, a first-in-human study of CK-102, was an open-label, non-randomized, dose-escalating Phase 1 study to identify the maximum tolerated dose of CK-102 and to evaluate the safety, pharmacokinetics, and pharmacodynamics of the combination treatment of CK-102 and temozolomide, administered at 150 mg/m<sup>2</sup>/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<sup>2</sup>/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<sup>2</sup> intravenously on day 1 and day 8 of each 21-day cycle. Cisplatin was administered at 75 mg/m<sup>2</sup> intravenously on day 1 of each cycle, after the infusion of gemcitabine. The study was stopped before reaching its objective of determining the maximum tolerated dose of CK-102 when given in combination with cisplatin and gemcitabine due to the limited tolerability of the cisplatin and gemcitabine regimen and the variable exposure to the active moiety of CK-102 during the study.
- Study 2051 was a Phase 1, multicenter, open-label study to determine the maximum tolerated dose of CK-102 when administered as a single-agent in patients with advanced or metastatic solid tumors. In the study, conducted at four sites in the United States, 44 patients were enrolled and received at least one dose of CK-102. Though twelve patients had stable disease in the study, the variable systemic exposure to the active moiety of CK-102 within each cohort precluded any definitive efficacy conclusions. A dose of 750 mg administered twice daily was determined to be the maximum tolerated dose for CK-102 administered as a single agent.

We plan to develop CK-102 as both a monotherapy and in combination with other anti-cancer agents, including our novel immuno-oncology and checkpoint inhibitor antibodies currently in development. Currently, the transfer of ownership of the CK-102 active IND is in process, and the transfer to us should be completed in the second quarter of 2016. Due to the variable systemic exposure of the active moiety of CK-102 in the prior Phase 1 studies, we plan to evaluate a reformulation of the CK-102 drug product to improve its bioavailability, following which, we plan to commence a Phase 1b clinical study in advanced or metastatic solid tumors with existing DNA repair defects, such as BRCA1 and BRCA2.

#### ***Anti-CAIX Research Program***

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

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

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

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

## COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

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

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

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

## INTELLECTUAL PROPERTY AND PATENTS

### *General*

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

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

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

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

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

We in-licensed in March 2015 intellectual property related to certain antibodies from Dana-Farber. The intellectual property includes issued patents in a number of countries, including the United States and Europe, as well as pending patent applications in several countries elsewhere. The issued patents and pending patent applications relate generally to compositions and methods of treatment involving antibodies against CAIX, PD-L1 and GITR. In particular, we have exclusive rights under U.S. Patent No. 8,466,263, directed to CAIX antibodies, which is scheduled to expire no earlier than July 2029. Its European counterpart is in force in Switzerland, Liechtenstein, Germany, France and the United Kingdom. A Canadian counterpart patent has also issued. Both the European and Canadian counterpart patents, as well as any pending applications outside the United States, are scheduled to expire no sooner than December 2026. The PD-L1 segment of the portfolio includes patent applications pending in the United States, Australia, Canada, Europe, Israel and Korea. Any patents maturing from these pending applications will expire no sooner than October 2033. The GITR segment of the portfolio includes 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, we in-licensed intellectual property from NeuPharma, which is directed to technology involving small molecules that are inhibitors of EGFR and kinase mutants. EGFR is a receptor tyrosine kinase of the ErbB family and is also known as “Her1” and “ErbB1.” The in-licensed patent estate includes an international application and a pending U.S. non-provisional application. In February 2016, we filed separate national stage applications in the relevant territories worldwide. Any patents maturing from this patent estate are expected to expire no sooner than August 2034.

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

#### ***Other Intellectual Property Rights***

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



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

## **LICENSING AGREEMENTS AND COLLABORATIONS**

### ***Dana-Farber Cancer Institute, Inc.***

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

### ***NeuPharma, Inc.***

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

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 NeuPharma patent containing a valid claim to the product in such country.

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 reimbursed the Company for all amounts paid previously by the Company. Accordingly, TGTX reimbursed us \$260,000 in the three months ended March 31, 2016.

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

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

### ***Collaboration Agreement and Option Agreement with TGTX***

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

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

## COMPETITION

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

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. Other companies have products or product candidates in various stages of pre-clinical or clinical development, or with marketing approvals, to treat conditions for which we are also seeking to discover and develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier.

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

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

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

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

## **EMPLOYEES**

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

## **SUPPLY AND MANUFACTURING**

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

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

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

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

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

## **GOVERNMENT AND INDUSTRY REGULATIONS**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### ***Other Healthcare Laws and Compliance Requirements***

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

#### **Pharmaceutical Coverage, Pricing and Reimbursement**

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

#### **International Regulation**

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

#### **Item 1A. Risk Factors**

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

#### **Risks Related to Our Business and Industry**

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

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

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

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

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

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

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

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

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

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

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

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

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, however, we will have limited influence over their actual performance.

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

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

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

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



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

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to “payments or other transfers of value” made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

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

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

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

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

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

#### **Risks Related to Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Risks Related to Our Finances and Capital Requirements**

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

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing our product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in November 2014, and have an accumulated deficit of \$14.5 million as of March 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 variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;

- there are any regulatory developments affecting product candidates of our competitors; and
- one or more of our product candidate receives regulatory approval.

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

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

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

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

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

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

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. In December 2015, we closed on gross proceeds of \$57.8 million, before commissions and expenses, in a series of private placement financings. Net proceeds from this offering were approximately \$51.5 million. We expect to use the net proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at March 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 24 months.

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

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

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

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

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

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

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

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

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

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

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

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

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

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

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

#### **Risks Relating to Securities Markets and Investment in Our Stock**

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

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

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

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

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

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

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

***Fortress controls a voting majority of our common stock.***

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

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

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

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

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

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

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

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.

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

We share some directors with Fortress, and in addition, under the Management Services Agreement, we will also share some officers with Fortress. This could create conflicts of interest between the two companies in the future. While we believe that the Founders Agreement and the Management Services Agreement were negotiated by independent parties on both sides on arm's length terms, and the fiduciary duties of both parties were thereby satisfied, in the future situations may arise under the operation of both agreements that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, under the Management Services Agreement, Fortress and its affiliates are free to pursue opportunities which could potentially be of interest to Checkpoint, and they are not required to notify Checkpoint prior to pursuing the opportunity. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Checkpoint could expose us to claims by our investors and creditors, and could harm our results of operations.

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

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



## **Item 2. Financial Information.**

### **Management's Discussion and Analysis of the Results of Operations**

#### **Forward-Looking Statements**

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

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

#### **Overview**

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

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of March 31, 2016, we have an accumulated deficit of \$14.5 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<sup>th</sup> Floor, New York, NY 10014. Our telephone number is (781) 652-4500 and our email address is [ir@checkpointtx.com](mailto:ir@checkpointtx.com).

#### **Critical Accounting Policies and Use of Estimates**

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

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

## Results of Operations

### *Comparison of the Three Months Ended March 31, 2016 and 2015*

#### *Revenue*

In connection with our License Agreement with Dana-Farber, we entered into a Global 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. We retain the right to develop and commercialize these antibodies in solid tumors. For the three months ended March 31, 2016, we generated \$17,000 of revenues in connection with this collaboration agreement for the reimbursement of patent costs.

In connection with our License Agreement with Neupharma, we entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX, a related party, agreed to assume all costs associated with this Sponsored Research Agreement and reimbursed the Company for all amounts paid previously by the Company. For the three months ended March 31, 2016, we generated \$260,000 of revenues from TGTX in connection with our Sponsored Research Agreement with NeuPharma.

#### *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 three months ended March 31, 2016, research and development expenses were \$2.4 million, which primarily consisted of \$1.5 million relates to pre-clinical development activities for our product candidates and \$0.8 million relates to stock compensation expense.

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

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

#### *General and Administrative Expenses*

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

For the three months ended March 31, 2016, general and administrative expenses were \$1.2 million, which primarily consisted of stock compensation expense of \$0.3 million, \$0.2 million related to salary expenses and \$0.4 million related to legal fees.

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

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

### *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 a reimbursement for TGTX's share of the licensing fee under the Dana Farber license agreement and \$0.1 million related to the reimbursement of patent fees in connection with this agreement.

#### *Research and Development Expenses*

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

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

#### *General and Administrative Expenses*

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

For the year ended December 31, 2015, general and administrative expenses were \$2.5 million, which primarily consisted of stock compensation expense of \$1.5

million, of which \$1.3 million related to fees paid to Fortress in connection with the Founders' Agreement. In addition, of the remaining \$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 was 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 were \$0.4 million, which expense was a result of the change in probability from 25% to 100% related to contingently issuable warrants.

#### **Liquidity and Capital Resources**

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 March 31, 2016, we had an accumulated deficit of \$14.5 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 \$2,791,831 under the NSC Note and issued NSC 139,592 warrants to purchase our common stock, which was equal to twenty-five percent (25%) of the amount of NSC Note proceeds we received from Fortress divided by the lowest price at which we next sold common stock. The warrant issued has a term of 10 years and an exercise price equal to the par value of our common stock. In February 2016, we paid NSC \$2,811,412, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment.

In September 2015, we launched a private placement of common stock and warrants for common stock the principal purpose of which was to provide us with working capital to continue our development and testing of our product candidates. As of December 31, 2015, we closed on gross proceeds of \$57.8 million before offering expenses. Net proceeds from this offering were approximately \$51.5 million.

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 use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at March 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 24 months.

### **Operating Activities**

Net cash used in operating activities was \$1.1 million for the year ended December 31, 2015, primarily related to preliminary research and development activities related to our licenses.

Net cash used in operating activities was \$2.2 million for the three-month period ended March 31, 2016, primarily due to \$3.6 million in net loss, partially offset by \$1.1 million of stock-based compensation expenses and \$0.3 million of amortization of debt expenses.

### **Investing Activities**

Net cash used in investing activities was \$2.5 million for the year ended December 31, 2015, related to the acquisition costs of the Dana-Farber, NeuPharma and Teva licenses.

There were no investing activities for the three-month period ended March 31, 2016.

### **Financing Activities**

Net cash provided from our third party offering and the NSC note was \$51.5 million and \$2.6 million, net of fees, respectively, for the year ended December 31, 2015.

Net cash provided by the issuance of common stock was \$0.6 million for the three months ended March 31, 2016. In February 2016, we repaid our NSC Debt of \$2.8 million, representing repayment of the assumed NSC Note principal and accrued interest as of the date of payment. There was no financing activities for the three months ended March 31, 2015.

### **Recently Issued Accounting Standards**

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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 are currently assessing the impact of ASU 2016-09 on our condensed financial statements and related disclosures.

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 assessing the impact of ASU 2016-08 on our condensed financial statements and related disclosures.

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

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

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

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

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

#### **Off-Balance Sheet Arrangements**

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

#### **Item 3. Properties.**

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

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock, and, as indicated, our Class A common stock and vested warrants, as of May 9, 2016, for:

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

As of May 9, 2016, there were 16,957,876 shares of our common stock outstanding and 7,000,000 shares of our Class A Common Stock outstanding. In order to calculate a stockholder’s percentage of beneficial ownership, we include in the calculation those shares underlying options or warrants beneficially owned by that stockholder that are vested or that will vest within 60 days of May 9, 2016. Shares of restricted stock are deemed to be outstanding. Options or warrants held by other stockholders that are not attributed to the named beneficial owner are disregarded in this calculation. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of our common stock. Except as indicated in footnotes to this table, we believe that the stockholders named in this table will have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Checkpoint Therapeutics, Inc., 2 Gansevoort Street, 9<sup>th</sup> Floor, New York, NY 10014.

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

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

\* Less than 1% of outstanding common stock.

- (1) Includes 500,000 warrants issued by Fortress to each of Mr. Weiss and Dr. Rosenwald that cover shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.
- (2) Includes 7,777 vested warrants exercisable at \$7.00 per share.
- (3) Includes 7,777 vested warrants held by Mr. Boilen exercisable at \$7.00 per share. The total calculation for all executive officers and directors as a group does not include Mr. Weiss' and Dr. Rosenwald's warrants, which have not yet been exercised. The shares underlying the warrants are currently held by Fortress and are included in the 1,981,006 shares of common stock shown as held by Fortress.
- (4) Includes 1,000,000 shares of common stock underlying the warrants granted by Fortress to Mr. Weiss and Dr. Rosenwald.

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

**Item 5. Directors and Executive Officers.**

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

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

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

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

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

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

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

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

*David J. Horin – Interim Chief Financial Officer*

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

**Non-Executive Directors**

*Lindsay A. Rosenwald, M.D.*

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

*Neil Herskowitz*

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

*Barry Salzman*

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

*Scott Boilen*

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

**Family Relationships**

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



### Composition of our Board of Directors

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

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

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

### Communicating with the Board of Directors

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

### Code of Ethics

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

### Item 6. Executive Compensation.

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

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

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

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

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

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

### Compensation Arrangements for Executive Officers

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

### Employment Agreement, CEO

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

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

### Employee Benefit and Incentive Plans

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

*2014 and 2015 Director Compensation*

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

*2016 Director Compensation Program*

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

Cash Compensation:

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

Equity Compensation:

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

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

### *Compensation Committee Interlocks and Insider Participation*

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

### **Equity Incentive Plan**

#### 2015 Incentive Plan

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Certain Federal Tax Effects

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In connection with the license agreement with NeuPharma, Inc., 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. Under the terms of the Option Agreement, TGTX paid us \$25,000, representing consideration for granting the option. If the option is exercised, we are eligible to receive up to an aggregate of approximately \$14.5 million upon TGTX's successful achievement of certain clinical development and regulatory milestones under a collaboration agreement. In addition, we are eligible to receive up to an aggregate of \$40.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales by TGTX. The Option Agreement will expire on July 17, 2016, unless both parties agree to extend the option period.

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 reimbursed the Company for all amounts paid previously by the Company. Accordingly, TGTX reimbursed us \$260,000 in the three months ended March 31, 2016.

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 OPPM, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of \$7.00 per share, for a purchase price of \$45,000 per unit. The warrants have a five year term and are only exercisable for cash. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, us were consistent with terms of the December 2015 third-party financing which included the payment of fees and issuance of warrants to a placement agent.

### ***Fortress Financing Arrangements Affecting our Company***

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

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

### **Director Independence**

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

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

### **Item 8. Legal Proceedings.**

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

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

**Market information**

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

**Equity Compensation Plans**

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

**Holders**

As of March 31, 2016, there were approximately 16.9 million shares of common stock outstanding held by 566 record stockholders and 7.0 million shares of Class A common stock outstanding held by one record stockholder.

**Dividends**

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

**Stock Not Registered Under the Securities Act; Rule 144 Eligibility**

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

**Rule 144**

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

*Affiliates*

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

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

*Non-Affiliates*

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



## **Rule 701**

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

## **Securities Authorized for Issuance under Equity Compensation Plans**

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

### **Item 10. Recent Sales of Unregistered Securities.**

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

In February 2016, we closed on 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 use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash balances at March 31, 2016, are sufficient to fund our anticipated operating cash requirements for approximately the next 24 months.

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

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

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

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

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

Other features of our common stock include:

- *Dividend Rights.* The holders of outstanding shares of our common stock, including Class A common stock, are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine. All dividends are non-cumulative.
- *Voting Rights.* The holders of our common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors, except as to the Class A Directors during the Class A Director Period. Our certificate of incorporation and bylaws do not provide for cumulative voting rights.
- *No Preemptive or Similar Rights.* The holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock.
- *Right to Receive Liquidation Distributions.* Upon our liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock, including Class A common stock, outstanding at that time after payment of other claims of creditors, if any.
- *Fully Paid and Non-Assessable.* All of the outstanding shares of our common stock, including Class A common stock, are, and the shares of our common stock to be issued pursuant to this offering will be, duly issued, fully paid and non-assessable.

**Item 12. Indemnification of Directors and Officers.**

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

- any breach of their duty of loyalty to the corporation or the stockholder;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

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

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

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

**Item 13. Financial Statements and Supplementary Data.**

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

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

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

**Item 15. Financial Statements and Exhibits**

**(a) Financial Statements.**

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

**Interim Financial Statements (Unaudited):**

Condensed Balance Sheets	F-2
Condensed Statements of Operations	F-3
Condensed Statements of Stockholders' Equity	F-4
Condensed Statements of Cash Flows	F-5
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**Financial Statements (Audited)**

Report of Independent Registered Public Accounting Firm	F-15
Balance Sheets	F-16
Statements of Operations	F-17
Statements of Stockholders' Equity	F-18
Statements of Cash Flows	F-19
Notes to Financial Statements	F-20 – F-30

**(b) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc.
3.2	Certificate of Amendment to Certificate of Incorporation of Checkpoint Therapeutics, Inc.
3.3	Bylaws of Checkpoint Therapeutics, Inc.
4.1	Specimen certificate evidencing shares of common stock.
4.2	Form of warrant agreement.
10.1	Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015.
10.2	Management Services Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015.
10.3	Promissory Note to NSC Biotech Venture Fund I, LLC dated February 27, 2015.
10.4	Common Stock Warrant issued by Checkpoint Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC dated July 30, 2015.
10.5	License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc. dated March 2, 2015.*
10.6	Amendment 1 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 5, 2015.*

- 10.7 License Agreement by and between NeuPharma Inc. and Coronado Biosciences, Inc. (Fortress' predecessor) dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Founders Agreement).\*
- 10.8 Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated March 3, 2015.\*
- 10.9 Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan.
- 10.10 Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated October 13, 2015.
- 10.11 License Agreement by and between Cephalon, Inc. and Fortress Biotech, Inc. dated December 18, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Founders Agreement).\*
- 10.12 Non-Employee Directors Compensation Plan
- 10.13 Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint, Inc. under the Founders Agreement); extended as of September 11, 2015; extended as of December 15, 2015; extended as of January 11, 2016.\*
- 10.14 Research Agreement by and between Fortress Biotech, Inc. and NeuPharma, Inc., dated September 15, 2015 (assigned to Checkpoint, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015).
- 10.15 Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015.
- 10.16 Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated December 18, 2015.

\* Subject to a request for confidential treatment.

## INDEX TO FINANCIAL STATEMENTS

Interim Financial Statements (Unaudited):	
<a href="#">Condensed Balance Sheets</a>	F-2
<a href="#">Condensed Statements of Operations</a>	F-3
<a href="#">Condensed Statements of Stockholders' Equity</a>	F-4
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**Checkpoint Therapeutics, Inc.**  
**Condensed Balance Sheets**  
(in thousands, except share and per share amounts)

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current Assets:		
Cash	\$ 45,969	\$ 50,418
Prepaid expenses	4	171
Other receivables	82	65
Total current assets	<u>46,055</u>	<u>50,654</u>
<b>Total Assets</b>	<b><u>\$ 46,055</u></b>	<b><u>\$ 50,654</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,402	\$ 1,288
Accrued expenses - related party	190	502
Total current liabilities	<u>1,592</u>	<u>1,790</u>
Note payable, long-term (net of debt discount of \$0 and \$324 at March 31, 2016 and December 31, 2015, respectively)	-	2,468
<b>Total Liabilities</b>	<b><u>1,592</u></b>	<b><u>4,258</u></b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	1	1
Common shares, 16,907,876 shares and 15,989,315 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	2	1
Additional paid-in capital	58,933	57,262
Accumulated deficit	<u>(14,473)</u>	<u>(10,868)</u>
Total Stockholders' Equity	<u>44,463</u>	<u>46,396</u>
<b>Total Liabilities and Stockholders' Equity</b>	<b><u>\$ 46,055</u></b>	<b><u>\$ 50,654</u></b>

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

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenue - related party	\$ 277	\$ 500
Operating expenses:		
Research and development	2,365	2,035
General and administrative	1,184	82
Total operating expenses	<u>3,549</u>	<u>2,117</u>
Loss from operations	<u>(3,272)</u>	<u>(1,617)</u>
Interest expense and amortization of debt discount	333	-
<b>Net Loss</b>	<b><u>\$ (3,605)</u></b>	<b><u>\$ (1,617)</u></b>
<b>Loss per Share:</b>		
Net loss per common share outstanding, basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.20)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>20,775,130</u>	<u>8,000,000</u>

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

**Checkpoint Therapeutics, Inc.**  
**Condensed Statement of Stockholders' Equity**  
(in thousands, except share amounts)  
(Unaudited)

	Class A Common Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2015</b>	<b>7,000,000</b>	<b>\$ 1</b>	<b>15,989,315</b>	<b>\$ 1</b>	<b>\$ 57,262</b>	<b>\$ (10,868)</b>	<b>\$ 46,396</b>
Issuance of common shares for cash	-	-	126,640	-	570	-	570
Stock-based compensation expenses	-	-	100,000	-	1,088	-	1,088
Issuance of common shares - Founders Agreement (see Note 4)	-	-	691,921	1	13	-	14
Net loss	-	-	-	-	-	(3,605)	(3,605)
<b>Balances at March 31, 2016</b>	<b>7,000,000</b>	<b>\$ 1</b>	<b>16,907,876</b>	<b>\$ 2</b>	<b>\$ 58,933</b>	<b>\$ (14,473)</b>	<b>\$ 44,463</b>

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



**Checkpoint Therapeutics, Inc.**  
**Condensed Statements of Cash Flows**  
(Dollars in thousands)  
(Unaudited)

	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,605)	\$ (1,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expenses	1,088	-
Issuance of common shares - Founders Agreement	14	-
Issuance of restricted stock and warrants for services	-	3
Amortization of debt discount	324	-
Research and development-licenses acquired, expensed	-	2,000
Changes in operating assets and liabilities:		
Prepaid expenses	167	-
Other receivables	(17)	-
Accounts payable and accrued expenses	(198)	1,664
Net cash (used in) provided by operating activities	<u>(2,227)</u>	<u>2,050</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of research and development licenses	-	(2,000)
Net cash used in investing activities	<u>-</u>	<u>(2,000)</u>
<b>Cash flows from financing activities:</b>		
Payment of NSC debt	(2,792)	-
Proceeds from issuance of common stock	570	-
Net cash used in financing activities	<u>(2,222)</u>	<u>-</u>
Net change in cash	(4,449)	50
Cash, beginning of period	50,418	-
<b>Cash, end of period</b>	<b><u>\$ 45,969</u></b>	<b><u>\$ 50</u></b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 20	\$ -

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

## **Note 1 — Organization and Description of Business Operations**

Checkpoint Therapeutics, Inc. (the “Company” or “Checkpoint”) was incorporated in Delaware on November 10, 2014, as a wholly owned subsidiary of Fortress Biotech, Inc. (“Fortress” or “Parent”) and commenced its principal operations in March 2015. Checkpoint 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.

### ***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 March 31, 2016, the Company had an accumulated deficit of \$14.5 million.

On February 23, 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. 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.

The Company expects to use the net proceeds from the above transaction primarily for general corporate purposes, which may include financing the Company’s growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash balances at March 31, 2016, are sufficient to fund its anticipated operating cash requirements for approximately the next 24 months.

## **Note 2 — Significant Accounting Policies**

### ***Basis of Presentation and Principles of Consolidation***

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The unaudited condensed financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these unaudited condensed financial statements should be read in conjunction with the Company’s audited financial statements for the preceding fiscal year, from which the Company derived the balance sheet data at December 31, 2015.

### ***Use of Estimates***

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

### ***Cash and Cash Equivalents***

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. There were no cash equivalents at March 31, 2016 and December 31, 2015.

### ***Research and Development Costs***

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

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

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.

### ***Stock-Based Compensation Expenses***

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

### ***Fair Value Measurement***

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

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

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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

## **Revenue Recognition**

### *Reimbursement Arrangements and Collaborative Arrangements*

The Company is reimbursed by TG Therapeutics, Inc. ("TGTX"), a related party, for their share of the cost of the license and future milestone payments that are payable to Dana-Farber Cancer Institute pursuant to the license agreement (see Note 3). The Company is also reimbursed by TGTX for the Sponsored Research Agreement between the Company and NeuPharma (see Note 3). The gross amount of these reimbursed costs are reported as revenue in the accompanying Statements of Operations. The Company acts as a principal, bears credit risk and may perform part of the services required in the transactions. Consistent with ASC 605-45-15 these reimbursements are treated as revenue to the Company. The actual expenses creating the reimbursements are reflected as research and development expenses.

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

The Company follows ASC 605-25, *Revenue Recognition - Multiple-Element Arrangements* and ASC 808, *Collaborative Arrangements*, if applicable, to determine the recognition of revenue under 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.

### **Income Taxes**

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

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

### ***Net Loss per Share***

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants, as their inclusion would be anti-dilutive. There are 2,225,000 shares of unvested restricted stock and 4,331,106 warrants outstanding as of March 31, 2016, which are not included in the computation of net loss per share.

In previous filings, the Company included unvested restricted stock in the calculation of basic earnings per share and weighted average number of common shares outstanding. As a result, net loss per common share outstanding, basic and diluted, and weighted average number of common shares outstanding were misstated by an immaterial amount. This does not affect stockholders' equity, net loss, nor change any forecast or outlook of the fiscal health of the Company, nor influence any actions or inactions nor affect carrying out the Company's business plan. In accordance with the SEC's Staff Accounting Bulletin Nos. 99 ("SAB 99"), the Company evaluated this error and, based on an analysis of quantitative and qualitative factors, determined that the error was immaterial to the prior reporting period affected. Therefore, as permitted by SAB 99, the Company corrected, in the current filing, the calculation of basic earnings per share and weighted average number of common shares outstanding three months ended March 31, 2015. The impact of the correction was an increase in net loss per common share outstanding of \$0.01 and a decrease in the weighted average number of common shares outstanding of 483,333 for the three months ended March 31, 2015, when compared to the previously calculated amounts.

### ***Recently Issued Accounting Standards***

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 is currently assessing the impact of ASU 2016-09 on its condensed financial statements and related disclosures.

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 assessing the impact of ASU 2016-08 on the condensed financial statements and related disclosures.

In February 2016, the FASB issued 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 our financial statements. When adopted, the Company does not expect this guidance to have a material impact on our condensed 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, the Company paid Dana-Farber an up-front licensing fee of \$1.0 million in 2015 and, on May 11, 2015, granted Dana-Farber 500,000 shares, valued at \$32,500 or \$0.065 per share. Dana-Farber is eligible to receive payments of up to an aggregate of approximately \$21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of \$60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the license agreement, Dana-Farber will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due Dana-Farber. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX.

In connection with the license agreement with Dana-Farber, 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, Executive Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, Interim President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Global Collaboration Agreement, TGTX paid the Company \$0.5 million, representing a reimbursement for their share of the licensing fee, and the Company is eligible to receive up to an aggregate of approximately \$21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, the Company is eligible to receive up to an aggregate of \$60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, the Company will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to the Company. For the three months ended March 31, 2016, the Company recognized \$17,000 in revenue related to the reimbursement of patent fees in connection with this collaboration agreement with TGTX in the Condensed Statements of Operations.

#### ***NeuPharma, Inc.***

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma to develop and commercialize novel irreversible, 3rd generation EGFR inhibitors, including CK-101, on a worldwide basis other than certain Asian countries. On the same date, Fortress and the Company entered into a Founders Agreement pursuant to which Fortress assigned all of its right and interest in the EGFR inhibitors to the Company in exchange for certain consideration (see Note 4). Under the terms of the agreement, the Company paid NeuPharma an up-front licensing fee of \$1.0 million in 2015, 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 connection with the license agreement with NeuPharma, in March 2015 the Company entered into an option agreement with TGTX, a related party, for a global collaboration with the future development of the certain compounds licensed. The option was extended on January 11, 2016 for an additional 180 days, to July 17, 2016.

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, a related party, agreed to assume all costs associated with this Sponsored Research Agreement and reimbursed the Company for all amounts paid previously by the Company. For the three months ended March 31, 2016, the Company recognized \$260,000 in revenue in connection with the reimbursement of costs related to the Sponsored Research Agreement in the Condensed Statements of Operations.

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

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

**Note 4 – Related Party Agreements**

***Founders Agreement and Management Services Agreement with Fortress***

Effective March 17, 2015, Fortress and the Company entered into a Founders Agreement pursuant to which Fortress assigned to Checkpoint all of its right and interest (i) under Fortress’ license agreement for the EGFR inhibitors and (ii) to a license agreement for a PARP inhibitor that was under negotiation, as set forth in the Founders Agreement. As consideration for the Founders Agreement, the Company assumed \$2.8 million in debt that Fortress accumulated under the NSC Note (see Note 5) for expenses and costs of forming Checkpoint and obtaining the Dana-Farber antibodies and the EGFR inhibitors. As additional consideration for the transfer of rights under the Founders Agreement, the Company will also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to 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%). For the three months ended March 31, 2016, the Company issued 688,755 shares to Fortress (or 2.5% of the fully diluted outstanding equity at the time of issuance) pursuant to the Founders Agreement as a distribution as Fortress is not performing any services in return for these shares. An additional 3,166 shares of stock were issued pursuant to the Founders Agreement for the private placement by Opus Point Healthcare Fund GP, LLC during February 2016.

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 the Company’s Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of \$0.5 million (the “Annual Consulting Fee”), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which the Company has net assets in excess of \$100 million at the beginning of the calendar year. For the three months ended March 31, 2016, the Company recognized approximately \$125,000 in expense in its Statements of Operations related to the MSA.

## Note 5 – NSC Note

In March 2015, Fortress closed the private placement of a promissory note for \$10 million through National Securities Corporation (the “NSC Note”) and used the proceeds to acquire medical technologies and products. National Securities Corporation (“NSC”), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note. The NSC Note allowed Fortress to transfer a portion of the proceeds from the NSC Note to us pursuant to which we executed an identical NSC Note in favor of NSC. Accordingly, we assumed \$2.8 million under the NSC Note as part of the Founders Agreement (see Note 4) 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. Approximately \$0.3 million of unamortized debt discount was accelerated into interest expense upon payment.

The NSC Note had a maturity of 36 months, provided that during the first 24 months the maturity date could be extended by six months. No principal amount was due for the first 24 months (or the first 30 months if the maturity date was extended). Thereafter, the NSC Note would have been repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the note was 8% payable quarterly during the first 24 months (or the first 30 months if the note was extended) and payable monthly during the last 12 months.

As of March 31, 2016, the Company’s portion of the NSC Note was \$0. For the three months ended March 31, 2016, the Company recorded costs of approximately \$0.3 million related to the amortization of the debt discount and \$20,000 of interest expense at 8%, both recorded in interest expense in the Condensed Statements of Operations.

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

	<u>NSC Note Payable</u>	<u>Discount</u>	<u>NSC Note Payable, Net</u>
<b>December 31, 2015 balance</b>	\$ 2,792	\$ (324)	\$ 2,468
Payment of NSC debt	(2,792)	-	(2,792)
Amortization of debt discount	-	324	324
<b>March 31, 2016 balance</b>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

## Note 6 — 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 March 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 and Issuances of Common Stock and Warrants**

On February 23, 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.

In accordance with the Founders Agreement, on March 17, 2016, the Company issued 688,755 shares, or 2.5% of the fully diluted outstanding equity of Checkpoint at the time of issuance, to Fortress for the annual equity fee (see Note 4). The Company recorded the issuance of these shares as a distribution as Fortress is not performing services in return for these shares. Additionally, on February 23, 2016, the Company issued 3,166 shares to Fortress and recorded stock based compensation of \$14,000 based upon 2.5% of the gross amount of equity raised during the three months ended March 31, 2016, which is included in general and administrative expenses in the Company's Condensed Statements of Operations.

### **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 March 31, 2016, in connection with this grant, the Company re-measured this non-employee grant and recorded expense of \$0.8 million for the three months ended March 31, 2016, based upon a fair value of \$4.39 in research and development expenses on the Company's Condensed Statements of Operations.

Certain employees and directors have been awarded restricted stock under our 2015 Incentive Plan. The Company incurred approximately \$0.3 million related to stock-based compensation expense for the three months ended March 31, 2016, which is included in general and administrative expenses on the Company's Condensed Statements of Operations.

The following table summarizes restricted stock award activity for the three months ended March 31, 2016.

	<b>Number of Units</b>	<b>Weighted Average Grant Date Fair Value</b>
Nonvested at December 31, 2015	2,500,000	\$ 1.73
Granted	100,000	4.39
Vested	(375,000)	0.07
Nonvested at March 31, 2016	<u>2,225,000</u>	<u>\$ 2.13</u>

The remaining weighted-average life of unvested restricted stock was 2.19 years.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 900,000 shares at March 31, 2016.

**Warrants**

A summary of warrant activities for three months ended March 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	4.90
Outstanding as of March 31, 2016	<u>4,331,106</u>	<u>\$ 6.62</u>	<u>5.42</u>

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 three months ended March 31, 2016 (in thousands).

	Research and Development	General and Administrative	Total
Employee awards	\$ -	\$ 321	\$ 321
Non-employee awards	767	-	767
Fortress - Founders Agreement (see Note 4)	-	14	14
Total stock-based compensation expense	<u>\$ 767</u>	<u>\$ 335</u>	<u>\$ 1,102</u>

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Checkpoint Therapeutics, Inc.

We have audited the accompanying balance sheets of Checkpoint Therapeutics, Inc. (the "Company") as of December 31, 2015 and 2014 and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2015 and for the period from November 10, 2014 (inception) to December 31, 2014. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Checkpoint Therapeutics, Inc. as of December 31, 2015, and the results of its operations and its cash flows for the year ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

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

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

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

*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)

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

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

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

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

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

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

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

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

## **Note 1 — Organization and Description of Business Operations**

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

### ***Portfolio of Immuno-Oncology and Anti-Cancer Agents***

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

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

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

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

### ***Liquidity and Capital Resources***

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

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

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

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



## **Note 2 — Significant Accounting Policies**

### ***Basis of Presentation and Principles of Consolidation***

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

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

### ***Use of Estimates***

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

### ***Cash and Cash Equivalents***

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

### ***Research and Development Costs***

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

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

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

### ***Stock-Based Compensation Expenses***

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

### ***Fair Value Measurement***

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

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

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

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

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

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

### ***Revenue Recognition***

#### ***Reimbursement Arrangements and Collaborative Arrangements***

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

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

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

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

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

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

#### ***Income Taxes***

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

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

#### ***Valuation of Warrant Related to NSC Note***

In accordance with ASC 815, the Company classified the fair value of the warrant ("Contingently Issuable Warrants") that may have been granted in connection with 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. At each reporting period, as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants, the Contingently Issuable Warrants should be revalued and any difference from the previous valuation date would be recognized as a change in fair value in the Company's Statement of Operations.

#### ***Net Loss per Share***

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

#### ***Recently Issued Accounting Standards***

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

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

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

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

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

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

### **Note 3 – License Agreements**

#### ***Dana-Farber Cancer Institute***

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

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

### ***NeuPharma, Inc.***

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

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

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

## **Note 4 – Related Party Agreements**

### ***Founders Agreement and Management Services Agreement with Fortress***

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

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

## Note 5 – NSC Note

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

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

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

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

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

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

## **Note 6 – Commitments and Contingencies**

### ***Leases***

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

### ***NeuPharma Sponsored Research Agreement***

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

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

### ***License Agreements***

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

### ***Litigation***

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

## **Note 7 — Stockholders' Equity**

### ***Common Stock***

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

### ***Offerings of Common Stock and Warrants***

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

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

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

### Restricted Stock

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

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

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

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

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

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

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



### **Warrants**

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

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

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

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

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

## Stock-Based Compensation

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

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

## Note 8 – Income Taxes

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

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

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

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

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

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

As of December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately \$4.1 million and \$3.9 million, respectively. The federal and state net operating loss carryforwards will expire, if not utilized, by 2035 and 2025, respectively. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986. In December 2015, the company experienced 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 740 "Income Taxes" ("ASC 740"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the year ended December 31, 2015. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

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

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

## Note 9 – Fair Value Measurement

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

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

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

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

	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%



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

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## LICENSE AGREEMENT

**THIS LICENSE AGREEMENT** (the “**Agreement**”) is dated as of March 2, 2015 (the “**Effective Date**”) by and between Checkpoint Therapeutics, Inc., a Delaware corporation organized having its place of business at 3 Columbus Circle, New York, NY 10019 (“**CTI**”), and Dana-Farber Cancer Institute, Inc. located at 450 Brookline Ave., Boston, MA 02115 (“**DFCI**”). CTI, on the one hand, and DFCI, on the other hand, shall each be referred to herein as a “**Party**” or, collectively, as the “**Parties**.”

### RECITALS:

**WHEREAS**, DFCI is the owner of certain rights in technologies as later defined; and

**WHEREAS**, CTI is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and CTI is interested in developing and commercializing products based on the Licensed Patents; and

**WHEREAS**, DFCI desires to grant a license to DFCI Patents to CTI in order to benefit the public by disseminating the results of its research via the commercial development, manufacture, distribution and use of Licensed Products (as defined below).

**WHEREAS**, CTI desires to license from DFCI and DFCI wishes to license to CTI, on an exclusive basis, the right to use, develop and commercialize DFCI Patents in and for a defined field of use.

**NOW, THEREFORE**, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

### ARTICLE I DEFINITIONS

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

**1.1** “**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 this Section 1.1, 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. TG Therapeutics, Inc. shall be deemed an Affiliate.

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**1.2** "Antibody" means any antibody, any gene expressing such an antibody, any hybridoma producing such antibody, or any fragment, variant, derivative or construct thereof, or antibody fusion protein produced therefrom (including PEDgylated or multimeric versions thereof, whether polyclonal, monoclonal, multi-specific antibodies (e.g., bi-specific antibodies), human, humanized, chimeric, murine, synthetic, or from any other source), including without limitation (a) the full immunoglobulin molecules (e.g. the IgG, IgM, IgE, IgA, and IgD molecules), and (b) the antigen binding portions including Fab, Fab', F(ab')<sub>2</sub>, Fv, dAb, and CDR fragments, chimeric antibodies, diabodies, polypeptides, linear antibodies and single-chain antibodies (scFv) that contain any portion of an immunoglobulin that is sufficient to confer specific binding to an antigen.

**1.3** "Calendar Quarter" means each three month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

**1.4** "Calendar Year" means the period beginning on the 1st of January and ending on the 31st of December of the same year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**1.5** "Combination Product" means a product (a) containing a Licensed Product together with one or more other active ingredients, or (b) with one or more products, devices, pieces of equipment or components, but sold for an integrated price (e.g., with the purchase of one product the customer gets a coupon for the other) or for a single price.

**1.6** "Commercialization" or "Commercialize" means any and all activities undertaken at any time for a particular Licensed Product and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.

**1.7** "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party or such Party's applicable Affiliate with respect to any objective, such reasonable, diligent, and good faith efforts normally used to accomplish a similar objective under similar circumstances by a similarly-situated company. Commercially Reasonable Efforts will not mean that a Party commits that it or such Party's applicable Affiliate will actually accomplish the applicable task.

**1.8** "Controlled" means, with respect to (a) DFCI Patents, (b) Know-How, (c) Antibodies, or (d) DFCI Materials, that a Party or one of its Affiliates owns or has a license or sublicense to such DFCI Patents, Know-How, Antibodies or DFCI Material (or in the case of DFCI Material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such DFCI Patents, Know- How, Antibodies, or DFCI Material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

**1.9** “**Covered**” means, with respect to a Licensed Product, that the practicing, manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted hereunder under DFCI’s relevant DFCI Patents, infringe a Valid Claim of DFCI’s relevant DFCI Patents in the country in which the activity occurs (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

**1.10** “**Derivative**” means a DFCI Antibody that has (a) been modified via isotype switching; (b) undergone a modification of effector function; (c) been adapted to enable the antibody to carry payloads; (d) been altered to change the expression characteristics, stability or biological half-life of the antibody; or (e) been mutated using an affinity maturation strategy designed to modify the affinity of either the variable regions and/or the constant regions of the antibody for any ligands, antigens or receptors. Derivatives may be full length antibodies, monoclonal and polyclonal antibodies, multispecific antibodies (e.g., bi-specific antibodies) and antibody fragments (including Fab, Fab', F(ab')<sub>2</sub>, Fy fragments, diabodies, linear antibodies and single-chain antibodies), in each case, of any origin, whether human, humanized, chimeric or otherwise.

**1.11** “**Development**” or “**Develop**” means, with respect to a Licensed Product, the performance of all preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product.

**1.12** “**DFCI Antibodies**” means the Antibodies supplied by or on behalf of DFCI to CTI under this Agreement as identified in Schedule 4.

**1.13** “**DFCI Know-How**” means any and all Know-How that (a) is Controlled by DFCI or any of its Affiliates as of the Effective Date and (b) was developed in the laboratory of Dr. Wayne Marasco in the performance of research directly pertaining to the DFCI Patents and (c) is necessary for CTI to research, Develop, manufacture, use, or Commercialize Licensed Products. The DFCI Know-How is described in Schedule 2 hereto.

**1.14** “**DFCI Materials**” means all materials Controlled by DFCI and supplied by DFCI to CTI under this Agreement as identified in Schedule 3, together with any progeny or unmodified derivatives that may be developed by CTI or DFCI. For the avoidance of doubt, “DFCI Materials” excludes the DFCI Antibodies and Derivatives.

**1.15** “**DFCI Patents**” means (a) those patents and patent applications set forth on Schedule 1 hereto; (b) any additions, divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patents and patent applications mentioned in clause (a) above; (c) all patents issuing from any of the patents and patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and inter partes review.

**1.16** “**DFCI Technology**” means the DFCI Patents, DFCI Know-How, DFCI Antibodies, Derivatives, or DFCI Materials.

**1.17** “**EMA**” means the European Medicines Agency or any successor agency.

**1.18** “**European Commission**” means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

**1.19** “**FDA**” means the United States Food and Drug Administration, or a successor federal agency thereto.

**1.20** “**Field**” means all prophylactic, palliative, therapeutic or diagnostic uses in humans or animals, excluding use in chimeric antigen receptor technology.

**1.21** “**First Commercial Sale**” means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in such country to a Third Party, by CTI, by an Affiliate of CTI or by a Sublicensee after Regulatory Approval therefor has been obtained in such country, for cash or non-cash consideration to which a fair market value can be assigned for purposes of determining Net Sales.

**1.22** “**GAAP**” means United States generally accepted accounting principles.

**1.23** “**Governmental Body**” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

**1.24** “**Know-How**” means any scientific or technical information, results and data of any type whatsoever, in any intangible form whatsoever, that is not in the public domain or otherwise publicly known and is not claimed or disclosed in a patent or pending patent application, including practices, protocols, regulatory filings, scientific techniques, works of authorship, plans, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, the FDA or other Regulatory Authorities, and manufacturing process and development information. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. “Know-How” excludes DFCI Patents, DFCI Antibodies, and DFCI Materials.



**1.25** “**Law**” or “**Laws**” means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

**1.26** “**Licensed Product**” means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration, (a) that is Covered in whole or in part by a Valid Claim in the DFCI Patents, (b) that incorporates, constitutes, or contains DFCI Antibodies or Derivatives as an active ingredient, or (c) that shares at least \*% of the amino acid sequence identity (combined or in the aggregate) to all the complementarity determining regions (CDRs) of any DFCI Antibodies or Derivatives and made using DFCI Technology.

**1.27** “**Licensed Process**” means processes which, (a) in the course of being practiced, is Covered in whole or in part by a Valid Claim in the DFCI Patents, or (b) which incorporates or uses DFCI Antibodies or Derivatives in whole or in part.

**1.28** “**NDA**” means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

**1.29** “**NDA Approval**” means the receipt of notice from the relevant US Regulatory Authority that an NDA for a Licensed Product has met all the criteria for marketing approval.

**1.30** “**Net Sales**” means the gross income derived by CTI or its Affiliates or Sublicensees to unrelated Third Parties for a Licensed Product in bona-fide arms-length transactions, less the following deductions, which may not exceed reasonable and customary amounts in the country in which the transaction occurs:

- (a) Normal and customary trade, quantity, cash and discounts and credits allowed and taken;
- (b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price, including, without limitation, Medicaid rebates, institutional rebates or volume discounts;
- (c) P r o d u c t returns and allowances;
- (d) Administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;
- (e) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced;

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\* Confidential material redacted and filed separately with the Commission.

- (f) Any tax, tariff or duties imposed on the sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced.
- (g) Bad debt actually written off during the accounting period (provided, that any bad debt write-off so taken which is later reversed shall be added back to Net Sales in the accounting period in which the reversal occurs).

No deduction shall be made for any item of cost incurred by CTI, its Affiliates or Sublicensees in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) through (g) of the foregoing.

Net Sales includes the fair market value of any non-cash consideration from sale of Licensed Products received by CTI, its Affiliates or Sublicensees. Licensed Products are considered "sold" when billed, invoiced, or payment is received, whichever occurs first.

Notwithstanding the foregoing, amounts invoiced by CTI and its Affiliates and Sublicensees for sales of Licensed Products among CTI and its Sublicensees and their respective Affiliates for resale shall not be included in the computation of Net Sales except where such purchasing party is an end user or consumer of Licensed Products.

Net Sales of any Combination Product (as defined below) for the purpose of calculating royalties due under this Agreement shall be determined on a country-by-country basis as follows: the Net Sales of the Combination Product (prior to application of the following adjustment) shall be multiplied by the fraction  $A/(A+B)$ , where A is the net selling price in such country of a Licensed Product without the additional active ingredient in the Combination Product, if sold separately for the same dosage as contained in the Combination Product, and B is the net selling price in such country of any other active ingredients (or delivery device) in the combination if sold separately for the same dosage (or form) as contained in the Combination Product. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of the said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country, no separate sale of either such above-designated Licensed Product (containing only such Licensed Product and no other active ingredients) or any one or more of the active ingredients included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales for purposes of determining payments under this Agreement shall be calculated by multiplying the sales price of the Combination Product by the fraction  $C/(C+D)$  where C is the standard fully-absorbed manufacturing cost of the Licensed Product portion of the combination, and D is the standard fully-absorbed manufacturing cost of the other active ingredients or components included in the Combination Product, as determined by CTI using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed manufacturing cost of the Licensed Product and/or the other active ingredients or components included in such Combination Product cannot be determined, Net Sales allocable to the Licensed Product in each such country shall be determined by mutual agreement reached in good faith by the parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, all relevant factors (including variations in potency, the relative contribution of each active ingredient in the combination, and relative value to the end user of each active ingredient).

**1.31** “**Person**” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

**1.32** “**Phase I Trial**” means a clinical trial of a Licensed Product in human patients designated as a Phase I Trial and conducted primarily for the purpose of determining the safety of and/or the metabolism and pharmacologic actions of the Licensed Product in humans, as described under 21 CFR § 312.21(a) (as hereafter modified or amended) and any of its foreign equivalents. For purposes of this definition, Phase I Trial shall specifically exclude trials in healthy volunteers.

**1.33** “**Phase II Trial**” means a clinical trial of a Licensed Product, designated as a Phase II Trial and the principal purpose of which is to make a preliminary determination that such Licensed Product is safe and active in a patient population for its intended use and is designed to obtain sufficient information about such Licensed Product’s efficacy to permit the design of a Phase III Trial(s), and generally consistent with 21 CFR § 312.21(b). For purposes of this definition, Phase II trial shall specifically exclude expansion cohorts from Phase I Trial(s).

**1.34** “**Phase III Trial**” means a clinical trial of a Licensed Product in human patients, which is designated as a Phase III Trial or a pivotal trial and is designed (a) to establish that the Licensed Product is safe and efficacious for its intended use; (b) to define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) to be, either by itself or together with one or more other clinical trials having a comparable design and size, the final human clinical trial in support of Regulatory Approval of the Licensed Product, and (d) consistent with 21 CFR § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents.

**1.35** “**Regulatory Authority**” means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

**1.36** “**Regulatory Approval**” means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, necessary for the Development, manufacture, use, storage, import, transport and Commercialization of a given Licensed Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Licensed Product in the Field.

**1.37** “**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 (i) ten (10) years after First Commercial Sale of the applicable Licensed Product in such country, or (ii) the expiry of the last-to-expire DFCI Patent containing a Valid Claim to the Licensed Product in such country.

**1.38** “**Sale Event**” means a (i) a merger, share exchange or other reorganization (“**Merger**”), (ii) the sale by one or more stockholders of a majority of the voting power of the CTI (“**Stock Sale**”) or (iii) a sale of all or substantially all of the assets of CTI (or that portion of its assets related to the subject matter of this Agreement) (“**Asset Sale**”) in which for (i), (ii), and (iii) above, the stockholders of CTI prior to such transaction do not own a majority of the voting power of the acquiring, surviving or successor entity, as the case may be. Notwithstanding the foregoing, a Sale Event shall not include a bona fide financing transaction in which voting control of CTI transfers to one or more persons or entities who acquire shares of CTI capital stock from CTI in exchange for either an investment in CTI.

**1.39** “**Sublicense Revenue**” means any payments or other consideration that CTI actually receives from a Sublicensee as consideration for the grant of a Sublicense, including, without limitation, milestone payments, license fees, license maintenance fees and equity. Sublicense Revenue excludes (i) purchases of equity or debt of CTI, (ii) payments made for CTI’s performance of any research, Development, or Commercialization of any Licensed Product, (iii) royalties on Net Sales (or, in the case of a profit sharing deal structure, shares of net profits) which are covered in Section 5.9, and (iv) any payment or reimbursement of any costs or expenses incurred by CTI for filing, prosecution, maintenance, or defense of any DFCI Patents. In the event such consideration received from a Sublicensee is not cash, Sublicense Revenue shall be calculated by CTI based on the fair market value of such consideration, at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business

**1.40** “**Sublicensee**” means a Person, other than an Affiliate of CTI, to which CTI (or its Affiliate) has, pursuant to Section 2.3, granted sublicense rights under any of the license rights granted under Section 2.1. “**Sublicense**” shall be construed accordingly.

**1.41** “**Tax**” or “**Taxes**” means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

**1.42** “**Third Party**” means any Person other than DFCI, CTI or Affiliates of either of them, or any Sublicensees.

**1.43** “**Third Party Action**” means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, Development, manufacture or sale infringes such Third Party’s intellectual property rights.

**1.44** “**United States**” or “**US**” means the United States of America and its territories and possessions.

**1.45** “Valid Claim” means (a) a claim of an issued and unexpired patent that has not been held permanently revoked, invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e. only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue or (b) a claim of a pending patent application within DFCI Patents that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, provided that (i) Valid Claim shall exclude any such pending claim in an application that has not been granted within the latter of five (5) years after the Effective Date or seven (7) years following the earliest priority filing date for such application (unless and until such claim is granted) and (ii) Valid Claim will exclude any such pending claim that does not have a reasonable bona fide basis for patentability, in either case of (i) or (ii), unless and until such claim is granted. Notwithstanding the foregoing, in the event that a claim in a pending patent application is involved in an interference action declared by the US Patent and Trademark Office or any analogous patentability determination by any other national patent office, and, at the time such proceeding is filed or initiated such claim is a Valid Claim, the time period set forth in subsection (i) above will be stayed for the pendency of such proceeding.

## **ARTICLE II LICENSES AND OTHER RIGHTS**

### **2.1 Grant of License to CTI.**

(a) Subject to the terms and conditions of this Agreement and the reserved rights described in Section 2.4, DFCI hereby grants to CTI, and CTI hereby accepts, an exclusive, worldwide, royalty-bearing right and license (with the right to sublicense, subject to the provisions of Section 2.4) under the DFCI Patents to (i) research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products, in and for the Field and (ii) to practice and have practiced any Licensed Processes, in and for the Field. DFCI and its Affiliates grant no licenses or rights by implication, estoppel or otherwise under any other patent applications or patents owned in whole or in part by DFCI other than as expressly set forth herein.

(b) Subject to the terms and conditions of this Agreement, DFCI hereby grants CTI a non-exclusive license under DFCI’s rights in and to the DFCI Materials listed in Schedule 3 solely in support of the exercise of CTI’s license rights under Section 2.1(a). CTI shall not have the right and shall be prohibited from selling, transferring, or distributing the DFCI Materials to end users, except in the case where such end users are CTI Affiliates or Sublicensees under this Agreement. This Section 2.1(b) shall not affect the rights granted to CTI hereunder to research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized Licensed Products made from or using such DFCI Materials.

**2.2 Affiliates.** CTI is entitled to extend its licenses under this Article II to its Affiliates, consistent with all of the terms and conditions of this Agreement. If CTI does extend its license and an Affiliate assumes obligations under the Agreement, CTI shall be responsible and liable for the acts or omissions of the Affiliate in the exercise of rights under this Agreement. If DFCI has a claim arising under this Agreement against an Affiliate, DFCI may seek a remedy directly against CTI and may, but is not required to, seek a remedy against the Affiliate. Any termination of the Agreement under Article X as to CTI also constitutes termination as to any Affiliates.

**2.3 Grant of Sublicenses by CTI.** CTI shall have the right, in its sole discretion, to grant Sublicenses, in whole or in part, under the license granted in Section 2.1; provided, however, that the granting by CTI of a Sublicense shall not relieve CTI of any of its obligations hereunder; and provided, further, that CTI's right to grant a Person a Sublicense shall be subject to CTI including within such Sublicense express provisions binding the Sublicensee to terms and conditions consistent with those contained herein. CTI shall be and remain fully responsible and primarily liable for the compliance by Sublicensees with the terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were CTI hereunder. CTI shall promptly provide a copy of each executed sublicense agreement and any modifications of the sublicense agreement (provided that such copy may be redacted to remove commercially sensitive terms that are not necessary to confirm compliance with the terms and conditions of this Agreement) following execution of such agreement.

**2.4 Reserved Rights.** The licenses granted by DFCI are subject to the following reserved rights.

(a) The rights of the United States of America, as set forth in Public laws 96- 517 and 98-620, the regulations promulgated thereunder, and the policy of any funding agencies. Any rights granted hereunder, which are greater than permitted by Public Laws 96-517 and 98- 620, are subject to modification as required to conform to the provisions of those statutes.

(b) DFCI's right to make and use the DFCI Know-How, DFCI Antibodies, and DFCI Materials for its own teaching, education and research purposes, both laboratory and clinical. Additionally, DFCI reserves the rights to practice under the DFCI Technology for its own internal research, public service, teaching and educational purposes, without payment of royalties, provided that the exercise of such reserved rights by DFCI shall not (a) be subject to any intellectual property rights granted to any commercial third party nor (b) include any human use or clinical administration without prior written approval from CTI.

(c) DFCI's right to supply DFCI Know How, DFCI Antibodies, and DFCI Materials to other academic, governmental or not-for-profit organizations for non-commercial research purposes.

**2.5 Government Rights and Requirements.** Notwithstanding anything hereunder, any and all licenses and other rights granted hereunder are limited by and subject to the rights and requirements of the United States Government which may arise out of its sponsorship of the research which led to the conception or reduction to practice of inventions covered by the DFCI Patents. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Title 37 of the Code of Federal Regulations: (i) to a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on the behalf of the United States Government any of the DFCI Patents throughout the world and (ii) to exercise march in rights on DFCI Patents.

**2.6 Delivery of DFCI Know-How, DFCI Antibodies, and DFCI Materials.** DFCI shall deliver to CTI DFCI Know-How, DFCI Antibodies, and DFCI Materials within sixty (60) days of the Effective Date of this Agreement.

**ARTICLE III  
DILIGENCE**

**3.1 Diligence by CTI.** CTI shall use Commercially Reasonable Efforts to Develop and to Commercialize Licensed Products targeting CA-IX, PD-L1 and G1TR in the Field. The Parties acknowledge that CTI may Develop and Commercialize Licensed Products that are a Combination Product containing one or more DFCI Antibodies or Derivatives.

**3.2 Projected Milestone Dates.** CTI shall use its commercially reasonable efforts to meet the following milestones ("Milestones") by the dates specified in this paragraph, subject to annual adjustment as described below.

(a) Milestone Dates for a Licensed Product Targeting CA-IX

<u>Milestone</u>	<u>Achievement Date</u>
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date

For purposes of this Section 3.2, DFCI will consider efforts of an Affiliate or Sublicensee as efforts of CTI.

(b) Milestone Dates for a Licensed Product Targeting PD-L1

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\* Confidential material redacted and filed separately with the Commission.

<b>Milestone</b>	<b>Achievement Date</b>
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date

(c) Milestone Dates for a Licensed Product Targeting GTR

<b>Milestone</b>	<b>Achievement Date</b>
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date
— *	* from the Effective Date

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\* Confidential material redacted and filed separately with the Commission.



**3.3 Adjustments.** The parties acknowledge that since the program is in early pre-clinical development that the dates included in the Milestone table above are rough estimates to provide DFCI a preliminary projection of what can be achieved by what dates, the accuracy of which the parties agree is impossible to predict and will be based on many factors completely outside the control of CTI and its Diligence Efforts. On an annual basis, with its report contained below, CTI will, in good faith, update the dates in the Milestones table above to provide DFCI an updated assessment of the timing of the upcoming milestones. Upon providing such update, the table above shall be deemed amended notwithstanding Section 11.5 hereof.

**3.4 Development and Commercialization Reports.** Within 60 days of the Effective Date and on or before each anniversary of the Effective Date, CTI shall provide to DFCI a written report describing the efforts by CTI, or any Affiliates or Sublicensees, to bring one or more Licensed Products to the marketplace. The report must be in sufficient detail to permit DFCI to monitor CTI's compliance with the due diligence provisions of this Agreement.

CTI shall include at least the following in these reports: (a) a summary of CTI's progress toward meeting the goals and objectives that had been established for the previous year; (b) a summary of CTI's goals and objectives for the ensuing year for developing and commercializing Licensed Products, including an identification of Licensed Products that CTI intends to develop, if any; and (c) to the extent not covered by the foregoing, a summary of CTI's progress in meeting the Milestone timelines above.

If multiple technologies are covered by this Agreement, the progress report must provide the information set forth above for each Licensed Product.

**3.5 Failure to Perform.** CTI's failure to use commercially reasonable efforts to perform any due diligence requirement provided in Section 3.1 through 3.4 is grounds for DFCI to terminate this Agreement according to Section 10.2(d); provided that DFCI shall only have the right to terminate this Agreement with respect to the specific Licensed Product for which such failure is claimed and the License shall remain in full force and effect for the remaining Licensed Products. In the alternative, DFCI may convert the exclusive licenses granted under this Agreement to a non-exclusive license, as further provided in Section 3.6, as to the specific Licensed Product for which such failure is claimed.

**3.6 Conversion to Non-exclusive License.** If the exclusive license granted under this Agreement is converted to a non-exclusive license for any Licensed Product, this Agreement is automatically amended as follows as it relates to such Licensed Product; (a) the exclusive license of Section 2.1 becomes a non-exclusive license, (b) CTI loses the right to grant sublicenses under Section 2.3; provided that any sublicense granted prior to such conversion shall continue and not be affected by such conversion, (c) the obligations of Sections 3.1 through 3.4 continue to apply, (d) the obligation under Section 3.10 no longer applies, (e) CTI has no further rights or obligations under Article VI; provided that DFCI shall keep CTI apprised of any new filings of patent applications and issuance of patents that fall within the DFCI Patents, and (f) DFCI has the sole right to pursue apparent infringements and the terms of Article VI no longer apply.

**3.7 Costs and Expenses.** As between DFCI and CTI, CTI shall be solely responsible for all costs and expenses related to Development, manufacture and Commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to Licensed Product.

**3.8 Patent Marking.** CTI agrees that with respect to each unit or package of Licensed Products sold in a given country, CTI shall comply with the customary patent marking laws and practices of such country as to the applicable DFCI Patents.

**3.9 Trademarks.** As between DFCI and CTI, CTI shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks. DFCI does not grant CTI the right to use any trademarks of DFCI or its Affiliates.

**3.10 U.S. Manufacture.** CTI shall manufacture Licensed Products leased, used or sold in the United States substantially in the United States as required by 35 U.S.C. 204 and 37 C.F.R. 401 et. seq., as amended. CTI shall also require any Affiliate(s) or Sublicensee(s) to comply with this U.S. manufacture requirement. Notwithstanding the foregoing, if CTI or its Affiliate(s) or Sublicensee(s) determines that it is not commercially feasible or reasonable to manufacture such Licensed Products in the United States or determines that it is necessary to have additional manufacturers outside the United States for back-up supply or to supply Licensed Products outside the United States, then DFCI agrees to make reasonable efforts to assist CTI, or its Affiliate(s) or Sublicensee(s), as applicable, at CTI' expense, in obtaining any necessary permission from the appropriate government authorities to manufacture such Licensed Products outside the United States.

**3.11 Other Government Laws.** CTI shall comply with, and ensure that its Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Licensed Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

**3.12 Publicity.** CTI, its Affiliate and Sublicensees are not permitted to use the names of DFCI, its related entities or its employees, or any adaptations thereof, in any advertising, promotional or sales literature, or in any securities report required by the Securities and Exchange Commission (except as required by law), without the prior written consent of DFCI in each case. However CTI may (a) refer to publications in the scientific literature by employees of DFCI or (b) state that a license from DFCI has been granted as provided in this Agreement.

**3.13 Other Agreements.** In the event that CTI determines to conduct a clinical trial of a Licensed Product in the Field of Use in the United States, CTI shall consider in good faith and discuss with DFCI the potential of engaging DFCI to serve as a clinical site for such clinical trial; provided that (a) DFCI has the appropriate expertise and patient population to conduct the clinical trial, and (b) DFCI is economically competitive with other sites having substantially similar expertise and patient populations to conduct such clinical trial.

**ARTICLE IV  
REGULATORY MATTERS**

**4.1 Regulatory Filings.** As between CTI and DFCI, CTI (or its applicable Affiliate) shall own and maintain all regulatory filings made after the Effective Date for Licensed Products and all Regulatory Approvals for Licensed Products. Once per year, representatives from DFCI may visit CTI and review all such regulatory filings, provided such representatives do not have a conflict of interest or involvement with any competitive companies or technologies and agree to CTI's confidentiality agreement.

**ARTICLE V  
Financial Provisions**

**5.1 Upfront Fee.** Within thirty (30) days of the Effective Date, CTI shall pay DFCI an up-front, non-creditable, non-refundable license fee in the amount of One Million Dollars (\$1,000,000).

**5.2 Maintenance Fee.** Within thirty (30) days following the second anniversary of the Effective Date and each anniversary thereafter, CTI shall pay DFCI an annual license maintenance fee in the amount of \* Dollars (\$\*). Such fees are creditable against milestone payments due pursuant to Section 5.8, royalties due pursuant to Section 5.9 or Sublicense Revenue Share Payments (as defined in Section 5.11).

**5.3 Equity.** Within thirty (30) days after the Effective Date, CTI shall issue to DFCI five percent (5%) of the common stock of CTI on a Fully-Diluted Basis (as defined below), after giving effect to such issuance (collectively, the "Shares"), provided, however, that DFCI shall execute a Share Purchase Agreement in a form mutually agreeable to DFCI and CTI. The Shares shall be of the same class (and be subject to the same rights) as the shares issued to CTI's non-corporate founders, which is CTI's common stock. It is acknowledged that the corporate founders will receive class A common stock, which is identical to the common stock but for super majority voting rights.

**5.4 Equity Representations and Warranties.** CTI hereby represents and warrants to DFCI that:

(a) the capitalization table attached hereto as Appendix X (the "Cap Table") sets forth all of the outstanding capital stock of CTI on a Fully-Diluted Basis as of the Effective Date of this Agreement;

(b) Other than as set forth in the Cap Table, as of the Effective Date, there are no outstanding shares of capital stock, convertible securities, outstanding warrants, options or other rights to subscribe for, purchase or acquire from CTI any capital stock of CTI and there are no contracts or binding commitments providing for the issuance of, or the granting of rights to acquire, any capital stock of CTI or under which CTI is, or may become, obligated to issue any of its securities; and

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\* Confidential material redacted and filed separately with the Commission.

(c) the Shares, when issued pursuant to the terms hereof, shall, upon such issuance, be duly authorized, validly issued, fully paid and non-assessable.

**5.5 Equity Anti-Dilution.** If, at any time, prior to the achievement of the Funding Threshold (as defined below), CBI issues Additional Securities (as defined below), CBI shall issue additional shares of common stock to DFCI such that DFCI's shareholdings in CBI shall not fall below five percent (5%), on a Fully Diluted Basis, as calculated after giving effect to the dilutive issuance (the "Anti-Dilution Shares"). Any issuances of Anti-Dilution Shares shall be in partial consideration for the license granted under the Agreement and DFCI shall not be required to pay any further consideration for such shares. Such issuances shall continue until such time as CTI has achieved the Funding Threshold. Thereafter, no additional Anti-Dilution Shares shall be due to DFCI pursuant to this Section 5.5 and DFCI's shareholdings in CTI will be subject to dilution.

**5.6 Equity Definitions.** The following terms shall have the following meanings:

(a) "Additional Securities" shall mean shares of capital stock, convertible securities, warrants, options or other rights to subscribe for, purchase or acquire from CBI any capital stock of CTI, except shares issued to employees, directors or consultants provided that such shares are issued pursuant to a stock option plan approved by CTI and provided further that the transaction is primarily for non-financing purposes.

(b) "Fully Diluted Basis" shall mean, as of a specified date, the number of shares of common stock of CTI then outstanding (assuming conversion of all outstanding stock other than common stock into common stock) plus the number of shares of common stock of CTI issuable upon exercise or conversion of then outstanding convertible securities, options, rights or warrants of CTI (which shall be determined without regard to whether such securities are then vested, exercisable or convertible) but shall exclude shares issued to employees, directors or consultants provided that such shares are issued pursuant to a stock option plan approved by CTI and provided further that the transaction is primarily for non-financing purposes.

(c) "Funding Threshold" shall mean a total gross investment, since the date of CTI's incorporation, of Ten Million U.S. Dollars (\$10,000,000) in cash in exchange for CBI capital stock.

**5.7 Equity Participation Rights.** Until an IPO, DFCI shall, in addition, have the opportunity to participate on a pro-rata basis as an investor in any additional rounds of equity raised by CTI. Until an IPO, if CTI proposes to sell any equity securities or securities that are convertible into equity securities of CTI (excluding customary exceptions, such as (but not limited to) the grant or issuance of compensatory equity to employees, consultants, etc., equity issuances in connection with strategic transactions, vendor financing, loans, etc.), then DFCI and/or its Assignee (meaning (a) any entity to which DFCI's participation rights under this section have been assigned either by DFCI or another entity, or (b) any entity that is controlled by DFCI) will have the right to purchase up to DFCI's pro rata share (as of the date of the offering) of the securities issued in each offering on the same terms and conditions as are offered to the other purchasers in each such financing. CTI shall provide ten days advanced written notice of each such financing, including reasonable detail regarding the terms and purchasers in the financing. DFCI rights under this Section 5.7 shall terminate upon a public offering covering the offer and sale of any of CTI's equity to the public ("IPO") or acquisition by a Third Party.

**5.8 Milestone Payments.**

(a) **Product-based Milestones.** As further partial consideration for DFCI's grant of the rights and licenses to CTI hereunder, CTI shall pay to DFCI the following one-time, product-based milestone payments with regard to each Licensed Product (as specifically set forth below) to achieve the respective event, up to three (3) Licensed Products per product-based milestone. CTI will pay the relevant milestone payment within 90 days of such achievement.

<b>Product-based Milestones</b>	<b>Milestone Payment</b>
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *

If any of the above milestones are triggered as a result of a combination approval of two or more Licensed Products or combination clinical trial of two or more Licensed Products, only one milestone payment shall be due to DFCI as if the combination was a single Licensed Product.

b. **Aggregate Net Sales Achievement Milestones** As further consideration for DFCI's grant of the rights and licenses to CTI hereunder, CTI shall pay to DFCI the following one-time milestone payments upon first achievement of worldwide Net Sales (as specifically set forth below) by CTI and its Affiliates and Sublicensees. CTI will pay the relevant milestone payment within 90 days of such achievement.

<b>Aggregate Net Sales Achievement Milestones</b>	<b>Milestone Payment</b>
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$ *
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$ *
The first time aggregate worldwide Net Sales for all Licensed Products exceeds \$* in any Calendar Year	\$ *

\* Confidential material redacted and filed separately with the Commission.

## 5.9 Royalty, Etc. Payments for Licensed Products.

(a) With respect to Net Sales of all Licensed Products: As further consideration for DFCI's grant of the rights and licenses to CTI hereunder, CTI shall pay to DFCI a royalty on aggregate annual worldwide Net Sales of all such Licensed Products by CTI and its Affiliates and Sublicensees (but excluding Net Sales of a given Licensed Product after its applicable Royalty Term), at the percentage rates set forth below:

<b>Annual Worldwide Net Sales of All Licensed Products per Calendar Year (US Dollars)</b>	<b>Incremental Royalty Rate</b>
For that portion of Net Sales of such Licensed Products from \$* up to and including \$*	*%
For that portion of Net Sales of such Licensed Products from \$* up to and including \$*	*%
For that portion of Net Sales of such Licensed Products that is greater than \$*	*%

(b) In no event shall the manufacture of a Licensed Product give rise to a royalty/payment in the nature of royalties obligation until the particular unit of Licensed Product is sold; but if Net Sales of a particular unit of Licensed Product might or might not be subject to a royalty/payment in the nature of royalties payment (e.g., manufactured in Country A where the Royalty Term has expired but sold in Country B where the Royalty Term has not expired), the sale shall be deemed to be subject to a royalty/payment in the nature of royalties payment. For clarity, CTI's obligation to pay royalties to DFCI under Section 5.9(a) is imposed only once with respect to the same unit of Licensed Product regardless of the number of DFCI Patents pertaining thereto or the number of times such Licensed Product has been sold or transferred to a Person.

(c) On a Licensed Product by Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights, licenses and sublicenses granted to CTI hereunder with respect to such Licensed Product in such country shall continue in effect but become fully paid-up, royalty-free, and perpetual.

(d) In the event the total royalty burden payable by CTI on Licensed Products exceeds\*% (i.e., the total percentage royalties on net sales payable to DFCI and any Third Person), then CTI may deduct all Third Party Royalties from any royalty amounts due DFCI hereunder, provided that in no event shall the royalty rates set forth in Section 5.9(a) (as adjusted pursuant to Section 5.9(b)) be reduced by more than \*% pursuant to this Section 5.9(d).

(e) In the event that the DFCI Patents do not contain any Valid Claim Covering the composition of matter for any of the active pharmaceutical ingredients of a Licensed Product in a particular country, royalties due to DFCI will be reduced by \* percent (\*%) of the applicable royalty rate as set forth in Section 5.9(a) for that Licensed Product in such country.

(f) In the event that a Licensed Product in a country is not Covered by a Valid Claim of a Licensed Patent, royalties with respect to such Licensed Product in such country shall be reduced by \* percent (\*%) of the applicable royalty rate as set forth in Section 5.9(a) and shall be due for the period commencing with the First Commercial Sale of such Licensed Product in such country and ending \* (\*) years from date of such First Commercial Sale.

\* Confidential material redacted and filed separately with the Commission.

(g) Notwithstanding the above, in no event shall the royalty rates set forth in Section 5.9(a) be reduced under 5.9(d), (e), and (f) above by more than\*% collectively.

**5.10 Timing of Royalty Payment.** Royalties/payments in the nature of royalties payable under Section 5.9 shall be payable on actual Net Sales and shall accrue at the time provided therefor by US GAAP. Royalty/payment in the nature of royalties obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within 90 days after the end of each Calendar Quarter during which the royalty/payment in the nature of royalties obligation accrued; provided that within 50 days after the conclusion of each Calendar Year CTI shall provide notice to DFCI of any adjustments necessary to account for any royalties/payment in the nature of royalties which were overpaid or underpaid for such prior Calendar Year's Calendar Quarters, and the Parties shall promptly true-up based on such adjustments, provided however, the lapse of such 50-day period shall not impact the right of CTI to credit any over-payments discovered during an audit against future royalties due under Section 5.9 hereof.

**5.11 Sublicense Revenue.** CTI shall pay to DFCI \* percent (\*%) of all Sublicense Revenue received by CTI ("**Sublicense Revenue Share Payments**"). Sublicense Revenue Share Payments shall be paid, on a Calendar Quarter basis, within 90 days after the end of each Calendar Quarter during which the respective Sublicense Revenue is received.

**5.12 Royalty Reports and Records Retention.** Within 60 days after the end of each Calendar Quarter during which Licensed Products have been sold, CTI shall deliver to DFCI, together with the applicable royalty/payment in the nature of royalties payment due, a written report, on a Licensed Product-by-Licensed Product (and specifying non-Covered status, as applicable) and country-by-country basis, of (a) (a) Number of Licensed Products manufactured and sold by CTI, and any Affiliates or Sublicensees, in each country; (b) gross invoiced (or otherwise charged) amounts of sales, by CTI and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such Calendar Quarter (and, if non-Covered, subject to royalty/payment in the nature of royalties payments for such Calendar Quarter), (c) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (d) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such Calendar Quarter and Calendar Year to date, and (e) the corresponding royalty or royalty/payment in the nature of royalties, and (f) the nature and amount of Sublicense Revenue received by CTI. Such report shall be deemed "Confidential Information" of CTI subject to the obligations of Article VII of this Agreement. For three years after each sale of a Licensed Product (whether Covered or not), CTI shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty or royalty/payment in the nature of royalties calculations hereunder.

**5.13 Sale Event Payment.** Upon the occurrence of a Liquidation Event, CTI shall pay DFCI a one-time fee within thirty (30) days of the closing of such Liquidation Event (the "**Sale Event Payment**"), the amount of which shall be dependent on the date of such closing, as follows:

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\* Confidential material redacted and filed separately with the Commission.

Date of Closing of Sale Event	Fee
If such closing occurs prior to the second anniversary of the Effective Date	\$ *
If such closing occurs on or after the second anniversary of the Effective Date but before the third anniversary of the Effective Date	\$ *
If such closing occurs on or after the third anniversary of the Effective Date but before the fourth anniversary of the Effective Date	\$ *
If such closing occurs on or after the fifth anniversary of the Effective Date but before the expiration or termination of this Agreement	\$ *

Notwithstanding anything to the contrary, the Sale Event Payment is payable only once under this Agreement, with respect to the initial occurrence thereof, regardless of the number of Sale Events that occur.

**5.14 Books and Audits.**

CTI shall keep, and shall require its Affiliates and Sublicensees to keep, true books of account containing an accurate record (together with supporting documentation) of all data necessary for determining the amounts payable to DFCL. CTI shall keep its records at its principal place of business or the principal place of business of the appropriate division of CTI to which this Agreement relates and shall require its Affiliates and Sublicensees to keep their books and records in the same manner.

(a) Commencing on the earlier of (i) the First Commercial Sale (of the first Licensed Product to have a First Commercial Sale) or (ii) receipt of Sublicense Revenue, and continuing until one Calendar Year after the conclusion of the final Royalty Term, upon the written request of DFCL, and not more than once in each Calendar Year, CTI shall permit, shall cause its Affiliates to permit, an independent certified public accounting firm of nationally recognized standing selected by DFCL (who has not been engaged by DFCL to provide services in any other capacity at any time during the three-year period before such selection), and reasonably acceptable to CTI or such Affiliate, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of CTI and its Affiliates to verify the accuracy of the royalty payments and Sublicense Revenue Share Payments. Such review may cover: (i) the records for the Calendar Year ending not more than three years before the date of such request, and (ii) only those periods that have not been subject to a prior audit.

(b) If such accounting firm concludes that additional amounts were owed during such period, CTI shall pay the additional royalties and/or royalties/payment in the nature of royalties within 15 days after the date such public accounting firm delivers to CTI such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods. If CTI disagrees with such calculation, CTI may contest such calculation in writing – at which point the parties will work in good faith to submit the matter to a mediator for resolution. If the parties are unable to reach an agreement via mediation, then CTI may initiate a court action to seek to recover the additional payment or to increase the amount of credit or reimbursement. DFCL shall pay for the cost of any audit by DFCL, unless CTI has underpaid DFCL by 5% or more for a specific royalty period, in which case CTI shall pay for the reasonable costs of audit, as well as any additional sum that would have been payable to DFCL had the CTI reported correctly, plus interest as set forth in Section 5.16.

\* Confidential material redacted and filed separately with the Commission.



(c) Each Party shall treat all information that it receives under this Section 5.12 in accordance with the confidentiality provisions of Article VII of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for a Party to enforce its rights under the Agreement.

**5.15 Mode of Payment and Currency.** All payments to DFCI under this Agreement, whether or not in respect of Net Sales or milestone events, shall be made by deposit of US Dollars in the requisite amount to the following, which DFCI may from time to time amend by advance written notice to CTI.

**by check:**

Fiscal Manager  
Office of Research and Technology Ventures Dana Farber Cancer Institute  
450 Brookline Ave.  
Boston, MA 02215  
Ref: \*

**by wire transfer:**

Bank: Bank of America  
Bank Address: 100 Federal Street, Boston, MA 02110 Account #\*  
ABA #\*  
Reference: \*

Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with CTI's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Based on the resulting Net Sales in US Dollars, the then applicable royalties/payment in the nature of royalties shall be calculated.

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\* Confidential material redacted and filed separately with the Commission.

**5.16 Late Payments.** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the lesser of (a) US dollar one- month LIBOR plus 300 basis points, or (b) the maximum rate permissible under applicable Law. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment. Waiver or deferral by DFCI of any payment owed under any paragraph under this Article V may not be construed as a waiver or deferral of any subsequent payment owed by CTI to DFCI.

**5.17 Taxes.** All amounts due hereunder exclude all applicable sales, use, and other taxes and duties, and CTI shall be responsible for payment of all such taxes (other than taxes based on DFCI's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, payments in the nature of royalties, milestone payments, and other payments made by CTI to DFCI under this Agreement. To the extent CTI is required to withhold taxes on any payment to DFCI, CTI shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to DFCI official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as DFCI may reasonably request, to establish that such taxes have been paid. DFCI shall provide CTI any tax forms that may be reasonably necessary in order for CTI to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. DFCI shall use Commercially Reasonable Efforts to provide any such tax forms to CTI at least 45 days before the due date for any payment for which DFCI desires that CTI apply a reduced withholding rate. Each Party shall provide the others with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. DFCI shall indemnify and hold CTI harmless from and against any penalties, interest or other tax liability arising from any failure by CTI (at the express request of DFCI) to withhold or by reduction (at the express request of DFCI) in its withholding.

**5.18 Currency Conversion.** If any currency conversion is required in connection with any payment owed to DFCI, the conversion will be made at the buying rate for the transfer of such other currency as quoted by the Wall Street Journal on the last business day of the applicable accounting period in the case of any payment payable with respect to a specified accounting period or, in the case of any other payment, the last business day before the date the payment is due.

## **ARTICLE VI Patents**

### **6.1 Patent Prosecution and Maintenance.**

( a ) **DFCI Patents.** DFCI shall use commercially reasonable efforts to file, prosecute and maintain DFCI Patents in DFCI's name. CTI shall bear the cost of all reasonable, documented patent expenses incurred prior to the Effective Date and associated with the filing, prosecuting, and maintenance of all patent applications and patents included within the DFCI Patents, and such amounts shall be due to DFCI within thirty (30) days of the Effective Date. The amount owed for Past Patent Expenses incurred as of February 10, 2015 is \$215,959.77. CTI shall bear the cost of all reasonable, documented patent expenses incurred on or after the Effective Date, continuing for the life of this Agreement, and associated with the filing, prosecuting, and maintenance of all patent applications and patents included within the DFCI Patents. Said amounts for on-going patent expenses shall be paid to DFCI within thirty (30) days of CTI's receipt of an invoice from DFCI Patents. Notwithstanding the foregoing, if DFCI grants any third party a license to any patent or patent application included within the DFCI Patents, CTI's obligation to bear ongoing patent costs shall be reduced by a pro rata amount, based on the number of licensees having rights with respect to such patent or patent application.

( b ) **New or Revised Applications.** DFCI will, upon forming an intention to file or revise one or more patent applications which are DFCI Patents subject to the License grant in Article II, promptly inform CTI of such intention, and will provide CTI with the opportunity to comment on the content of such DFCI patent application before so filing or revising. DFCI shall consider any such reasonable CTI comments in good faith.

( c ) **Liaising.** DFCI shall keep CTI promptly and regularly informed of the course of the filing and prosecution of DFCI Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and to reasonably take into consideration the advice and recommendations of CTI.

( d ) **Election Not to File/Prosecute/Maintain DFCI Patents** CTI acknowledges and agrees that DFCI shall not be required to file, prosecute or maintain the DFCI Patents, provided, however, if DFCI decides to not pursue or maintain any such DFCI Patents then DFCI shall provide CTI with at least 30 days' notice before discontinuing the filing, prosecution or maintenance of such DFCI Patents so that CTI may assume responsibility for such activities in DFCI's name but at CTI's expense. In such event, CTI will no longer owe any royalty obligation on account of such (country-level) DFCI Patents assumed by CTI. Similarly, to the extent CTI does not want to continue funding the patent costs of any portion of DFCI Patents, then such portion of DFCI Patents will no longer be included as DFCI Patents.

**6.2 Certification under Drug Price Competition and Patent Restoration Act.** Each of DFCI and CTI shall provide within a reasonable time written notice to the other of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any DFCI Patents covering a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the US of a Licensed Product by a Third Party.

**6.3 Listing of Patents.** CTI shall have the sole right to determine which of the DFCI Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country. DFCI will co- operate with CTI to list any of said DFCI Patents.

#### 6.4 Enforcement of Patents.

(a) **Notice.** If either DFCI or CTI believes that a DFCI Patent is being infringed in the Field by a Third Party or if a Third Party claims that any DFCI Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement, misappropriation or claim that are known by such Party.

(b) **Action by DFCI.**

(i) **Procedure.** DFCI is responsible for enforcing its DFCI Patents and prosecuting apparent infringers when, in its judgment, such action may be reasonably necessary and justified. CTI may request DFCI to take steps to protect the DFCI Patents from an apparent infringement. However, before DFCI must respond to the request, CTI shall supply DFCI (i) an opinion of qualified legal counsel demonstrating to DFCI's reasonable satisfaction that an infringement of the DFCI Patents exists in a particular country and (ii) with written evidence demonstrating to DFCI's reasonable satisfaction that a Substantial Infringement of the DFCI Patents exists in a particular country ("Substantial Infringer").

(ii) DFCI has three months from the date of receiving satisfactory written evidence from CTI of a Substantial Infringement to decide whether it will seek to terminate the Substantial Infringement. DFCI shall give CTI notice of its decision by the end of this three-month period. If DFCI notifies CTI that it intends to prosecute the alleged infringer, then DFCI has six (6) months from the date of its notice to CTI to either (a) cause the Substantial Infringement to terminate or (b) initiate legal proceedings against the infringer. If any such suit is brought by DFCI in its own name, or jointly with CTI if required by law, it will be at DFCI's expense and on its own behalf, but DFCI shall not be obligated to bring more than one such suit at a time.

(iii) **CTI's Right to Join.** CTI independently has the right to join any legal proceeding brought by DFCI under this Section 6.4 and fund up to fifty percent of the cost of the legal proceeding from the date of joining. If CTI elects to join as a party plaintiff pursuant to this paragraph 6.4(b)(iii), CTI may jointly participate in the action with DFCI, but DFCI's counsel will be lead counsel.

(c) **Action by CTI.**

(i) **Procedure.** If DFCI notifies CTI within the first three-month period that it does not intend to prosecute the Substantial Infringement or, if DFCI fails to cause the Substantial Infringement to terminate or bring legal proceeding to compel termination within six (6) months of the date of its notice to CTI, then CTI may initiate legal proceedings against the alleged infringer, at CTI's expense according to the terms of this Section 6.4. Before CTI commences any legal proceeding with respect to the Substantial Infringement, CTI shall consider in good faith the views of DFCI, particularly as they relate to the potential effects on the public interest. CTI has the right to join DFCI as a party-plaintiff if required by law, at CTI's expense.

(ii) **DFCI's Right To Join.** DFCI independently has the right to join any legal proceeding brought by CTI under this Section 6.4 and fund up to fifty percent of the cost of the legal proceeding from the date of joining. If DFCI elects to join as a party plaintiff pursuant to this Section 6.4, DFCI may jointly participate in the action with CTI, but CTI's counsel will be lead counsel.

(iii) **Reduction of Royalties.** If CTI initiates legal proceedings under this Section 6.4 in any country and DFCI does not independently join the proceeding, License may deduct up to \* percent (\*%) of CTI's documented costs and expenses of the proceeding (including reasonable attorney fees) from running and minimum royalties payable to DFCI under Section 5.9(a) of this Agreement from sales of Licensed Products covered by the patent(s)-in suit. However, CTI may not reduce DFCI's royalty payments by more than \* percent of the amount otherwise due under Article V. If \* percent (\*%) of CTI's costs and expenses exceed the amount of royalties deducted by CTI for any calendar year, CTI may, to that extent, reduce the royalties due to DFCI in succeeding calendar quarters for so long as CTI is actively engaged in legal proceedings to terminate the Substantial Infringement. However, CTI may not reduce total royalties due to DFCI in a given calendar quarter by more than \* percent (\*%). CTI's right to reduce royalty payments to DFCI under this paragraph 6.4(c)(iii) applies only for so long as the Substantial Infringement continues.

(iv) **Settlement.** Regardless of whether DFCI is joined or joins any legal proceeding initiated by CTI, no settlement, consent judgment or other voluntary final disposition of the legal proceeding may be entered into without the consent of DFCI.

**6.5 Cooperation.** If one party initiates legal proceedings to enforce the DFCI Patents pursuant to this Article VI, the other party shall cooperate with and supply all assistance reasonably requested by the party initiating the proceedings, at the initiating party's request and expense.

**6.6 Distribution of Amounts Paid by Third Parties.** Any amounts recovered by the Party initiating an Action pursuant to this Section 6.6, whether by settlement or judgment, shall be allocated in the following order: to reimburse the Parties for all out-of-pocket costs and expenses incurred in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it will be shared pro-rata in proportion to the relative amount of such costs and expenses incurred by each Party. If after such reimbursement any funds remain from such damages, the remaining amount of such recovery shall be allocated CTI as follows: the portion thereof attributable to "lost sales" shall be retained by CTI and shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by CTI and CTI shall pay to DFCI a royalty on such portion based on the royalty rates set forth in Section 5.9(a), and the portion thereof not attributable to "lost sales" shall be allocated 50% to DFCI and 50% to CTI.

**6.7 Declaratory Judgment Actions.** In the event that any third party initiates a declaratory judgment action alleging the invalidity or unenforceability of the DFCI Patents, or if any third party brings an infringement action against CTI or its Affiliates or Sublicensees because of the exercise of the rights granted CTI under this Agreement, then CTI shall have the right to defend such action under its own control and at its own expense; provided, however, that the parties shall mutually agree that DFCI may assume control of such defense, at its own expense, if DFCI in good-faith believes that assuming control of such defense is beneficial to the Parties. CTI shall NOT enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 6.7 without the consent of the other party, which consent shall not be unreasonably withheld unless the settlement includes any express or implied admission of liability or wrongdoing on DFCI's part, in which case DFCI's right to grant or deny consent is absolute and at its sole discretion. Any recovery shall be first applied to reimburse each party pro rata for any out-of-pocket expenses it may have incurred with respect to defense of such action and the remainder shall be retained entirely by the party controlling the action; provided, however, that any recovery for infringement will be distributed as described in Section 6.6.

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\* Confidential material redacted and filed separately with the Commission.

**ARTICLE VII  
CONFIDENTIALITY**

**7.1 Definitions.** CTI and DFCI each recognizes that during the Term, it may be necessary for a Party (the **Disclosing Party**) to provide Confidential Information (as defined herein) to another Party (the **Receiving Party**) that is highly valuable, the disclosure of which would be highly prejudicial to such Party. The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither CTI nor DFCI shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all information (including information relating to the business, operations and products of a Party or any of its Affiliates) disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within 30 days after such oral disclosure, including but not limited to any technical information, Know-How, trade secrets, or inventions (whether patentable or not), that such Party discloses to another Party under this Agreement, or otherwise becomes known to another Party by virtue of or that relates to this Agreement. **Obligation.** DFCI and CTI agree that they will disclose the other Party's Confidential Information to its own (or its respective Affiliate's, or with respect to CTI, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, no Party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, shall return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, within 60 days after the request, except for one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

**7.2 Exceptions.** The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

- (a) at the time of disclosure is in the public domain;
- (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;
- (c) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or
- (d) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

**7.3 Third Party Information.** The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. CTI and DFCI agree not to disclose to the other any Confidential Information of a Third Party which is in the possession of such Party, unless the other has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

**7.4 Press Release Announcing the Execution of the License Agreement and Related Disclosures.** Either Party may make an initial press release announcing the execution of this Agreement, including any matter covered by this Agreement, and the Development or Commercialization of Licensed Products, but such Party shall provide the text of such planned disclosure to the other Party sufficiently in advance of the scheduled disclosure to afford such other Party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure, and shall consider all reasonable comments of the other Party regarding such disclosure. (Provided, that no Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by Law or required by the rules of an applicable US national securities exchange or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld.)

**ARTICLE VIII**  
**REPRESENTATIONS, WARRANTIES AND COVENANTS**

**8.1 Representations and Warranties.** (a) CTI represents and warrants to DFCI, and (b) DFCI represents to CTI, in each case as of the Effective Date:

- (a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;
- (b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;
- (c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- (d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles;
- (e) To the best of such party's knowledge, the execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;
- (f) To the best of such party's knowledge, all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not violate any Law of any Governmental Body having authority over such Party;
- (g) No person or entity has or will have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and
- (h) To the best of such party's knowledge, no agreement between it and any Third Party is in conflict with the rights granted to any other party pursuant to this Agreement.



**8.2 Additional Representations and Warranties of DFCI.** DFCI represents to CTI, to the best of its knowledge as of the Effective Date, that no consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by DFCI or the consummation by DFCI of the transactions contemplated hereby;

**8.3 Disclaimer.** Notwithstanding the representations and warranties set forth in this Article VIII, CTI acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Licensed Products can be successfully Developed or Commercialized.

**8 . 4 DFCI MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, NON-PUBLIC OR OTHER INFORMATION, DFCI MATERIALS, DFCI ANTIBODIES, KNOW-HOW, OR TANGIBLE RESEARCH PROPERTY, LICENSED OR OTHERWISE PROVIDED TO CTI HEREUNDER AND HEREBY DISCLAIMS THE SAME.**

**8.5 DFCI DOES NOT WARRANT THE VALIDITY OF THE DFCI PATENTS LICENSED HEREUNDER AND MAKES NO REPRESENTATION WHATSOEVER WITH REGARD TO THE SCOPE OF THE LICENSED DFCI PATENTS OR THAT SUCH DFCI PATENTS MAY BE EXPLOITED BY CTI, AFFILIATE OR SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS. DFCI MAKES NO REPRESENTATION THAT DFCI ANTIBODIES, DFCIMATERIALS OR THE METHODS USED IN MAKING OR USING SUCH DFCI MATERIALS OR DFCI ANTIBODIES ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT.**

## **ARTICLE IX INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE**

### **Indemnification and Defense.**

**9.1** CTI shall indemnify, defend and hold harmless DFCI and its trustees officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability ( including but not limited to action in the form of tort, warranty, strict liability) concerning any product, process or service relating to, or developed by CTI, its Affiliates or Sublicensees pursuant to (a) any right or license granted under this Agreement or (b) arising out of any other activities to be carried out by CTI pursuant to this agreement.

**9.2** CTI's indemnification under Section 9.1 does not apply to any liability, damage, loss or expense to the extent that it is attributable to (a) the grossly negligent activities of the Indemnitees, or (b) the intentional wrongdoing or intentional misconduct of the Indemnitees.

**9.3** CTI shall, at its own expense, provide attorneys reasonably acceptable to DFCI to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

**9.4** If any such action is commenced or claim made or threatened against DFCI or other Indemnitees as to which CTI is obligated to indemnify it (them) or hold it (them) harmless, DFCI or the other Indemnitees shall promptly notify CTI of such event. CTI shall assume the defense of, and may settle, that part of any such claim or action commenced or made against DFCI (or other Indemnitees) which relates to CTI 's indemnification and CTI may take such other steps as may be necessary to protect it. CTI will not be liable to DFCI or other Indemnitees on account of any settlement of any such claim or litigation affected without CTI 's consent. The right of CTI to assume the defense of any action is limited to that part of the action commenced against DFCI and/or Indemnitees that relates to CTI 's obligation of indemnification and holding harmless.

**9.5** CTI shall require any Affiliates or Sublicensee(s) to indemnify, hold harmless and defend DFCI under the same terms set forth in Sections 9.1 – 9.4.

**9.6** DFCI shall indemnify, defend and hold CTI and its Affiliates and each of their respective agents, employees, officers and directors (the “**CTI Indemnitees**”) harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys’ fees and expenses) to the extent arising out of any and all Claims related to (a) DFCI’s performance of its obligations or exercise (by it or its Affiliates) of its or their rights under this Agreement; or (b) breach by DFCI of its representations and warranties set forth in Article VIII or (c) resulting from the gross negligence or willful misconduct of any DFCI Indemnitee; provided, however, that DFCI’s obligations pursuant to this Section 9.6 shall not apply (x) to the extent that such claims or suits result from the gross negligence or willful misconduct of any of the CTI Indemnitees or (y) with respect to claims or suits arising out of a breach by CTI of this Agreement, including without limitation its representations and warranties set forth in Article VIII.

**Insurance.**

**9.7** At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by CTI or by a Sublicensee, Affiliate or agent of CTI, CTI shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than \$2,000,000 per incident and \$2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability insurance must provide (a) product liability coverage and (b) contractual liability coverage for CTI’s indemnification under Sections 9.1 through 9.5 of this Agreement. If CTI elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$250,000 annual aggregate), such self-insurance program must be acceptable to the DFCI and the DFCI’s associated Risk Management Foundation. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of CTI’s liability with respect to its indemnification obligation under Sections 9.1 through 9.5 of this Agreement.

**9.8** CTI shall provide DFCI with written evidence of such insurance upon request of DFCI. CTI shall provide DFCI with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if CTI does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, DFCI has the right to terminate this Agreement effective at the end of such fifteen (15) day period without any notice or additional waiting periods.

**9.9** CTI shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (a) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by CTI or by a Sublicensee, Affiliate or agent of CTI and (b) a reasonable period after the period referred to in 9.8 (a) above which in no event shall be less than fifteen (15) years.

**9.10** CTI shall require any Affiliates or Sublicensee(s) to maintain insurance in favor of DFCI and the Indemnitees under the same terms set forth in Sections 9.7 – 9.9.

## **ARTICLE X TERM AND TERMINATION**

**10.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. (The “**Term**” shall mean the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to- expire Royalty Term.) The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the DFCI Patents have expired or been invalidated.

**10.2 Termination by DFCI.** DFCI has the right to immediately terminate this Agreement and all licenses granted hereunder, or at DFCI’s option to convert the exclusive license granted in Article 2.1 to a non-exclusive license in accordance with Section 3.6, by providing CTI with written notice of such, upon the occurrence of any of the following events.

(a) CTI’s Board of Director’s has agreed that CTI will cease to carry on its business with respect to Licensed Products.

(b) CTI fails to pay when due any undisputed royalty or other undisputed payment that has become due and is payable under Article V of this Agreement and has not cured the default by making the required payment, together with interest due, within ninety days of receiving a written notice of default from DFCI requesting such payment.

(c) An officer of the CTI is convicted of a felony relating to the manufacture, use, sale or importation of Licensed Products.

(d) CTI materially breaches any other provision of this Agreement (including but not limited to due diligence obligations under Article III and insurance obligations under Section 9.7 – Section 9.10), unless CTI has cured the breach within ninety days of receiving written notice from DFCI specifying the nature of the breach; provided, however, that the due diligence obligations shall be determined on a Licensed Product by Licensed Product basis.

**10.3 Termination for insolvency.** DFCI or CTI may terminate this Agreement immediately upon written notice, with no further notice obligation or opportunity to cure, if DFCI or CTI shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it (which is not dismissed within 60 days of such filing).

**10.4** Notwithstanding Sections 10.2 and 10.3, in the event of a good-faith dispute as to whether any alleged breach, default, failure or any other act or omission gives rise to a right of termination under this Agreement, is in fact a breach, default, failure or other act or omission that gives rise to a right of termination under this Agreement, termination of this Agreement in respect of such alleged breach, default, failure or other act or omission shall not take effect unless and until (y) such dispute is resolved in accordance with Section 10.7 below in favor of the Party alleging such breach, default, failure or other act or omission or (z) the non-terminating Party's denial that the alleged breach, default, failure or other act or omissions is in fact a breach, default, failure or other act or omission giving rise to a right of termination hereunder ceases to be in good faith.

**10.5 Termination by CTI.** CTI has the right to terminate this Agreement without cause by giving DFCI one hundred and eighty days prior written notice in whole or on a Licensed Product by Licensed Product basis. Any milestones achieved by CTI during this one hundred and eight day period will be due and payable to DFCI.

**10.6 Effect of Termination**

( a ) **No release.** Upon termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any obligation that matured prior to the effective date of the termination.

( b ) **Survival.** The provisions of Section 6.1(a) (patent expenses) Article V (Financial Provisions), Section 3.1.2(Publicity –paragraph 10.6(c) (Inventory), Article IX (Indemnification), Sections 9.7 – 9.10 (Insurance), Article VIII (Representations and Warranties) and Section 10.7 (Dispute Resolution) survive termination or expiration of this Agreement.

( c ) **Inventory.** CTI, any Affiliate(s) and any Sublicensees whose sublicenses are not converted as provided in paragraph 10.6(d) below, may, after the effective date of termination, sell all Licensed Products that are in inventory as of the date of written notice of termination, and complete and sell Licensed Products which the licensed entity(ies) can reasonably demonstrate were in the process of manufacture as of the date of written notice of termination, provided that CTI shall pay to DFCI the royalties thereon as required by Article V and shall submit the reports required by Section 5.10 on the sales of Licensed Products.

(d) **Sublicenses.** Any sublicenses will terminate contemporaneously with this Agreement; provided, however, that any sublicenses that are not in default under the sublicense agreement shall, at DFCI's written approval, survive and remain in full force and effect so long as the sublicensee agrees to be bound by all of the provisions of this Agreement, if not otherwise already provided for in the sublicense agreement. Such approval by DFCI shall not be unreasonably withheld and shall not require the payment of additional consideration.

**10.7 Dispute Resolution.**

(a) **Negotiation between the Parties.** The parties shall first attempt to resolve any controversy that arises from this Agreement, or claim for breach of the Agreement, by good faith negotiations, first between their respective business development representatives and then, if necessary, between senior representatives for the parties, such as the Senior Vice- President for Research or President of DFCI and the CEO or President of CTI.

(b) **Non-Binding Mediation.** If the controversy or claim cannot be settled through good faith negotiation between the parties, the parties agree first to try in good faith to settle their dispute by non-binding mediation under the Mediation Rules of the American Arbitration Association, before resorting to arbitration, litigation or other dispute resolution procedure.

**ARTICLE XI  
MISCELLANEOUS PROVISIONS**

**11.1 Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

**11.2 Assignment.**

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) No assignment shall relieve the assigning Party of any of its responsibilities or obligations hereunder.

(c) CTI may not transfer or assign its rights or licenses or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of DFCI, which consent shall not be unreasonably withheld, conditioned or delayed; provided that, notwithstanding the foregoing, CTI may assign its rights or licenses and/or delegate its obligations under this Agreement to an Affiliate or in connection with a Sale Event. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to DFCI and signed by a duly authorized officer of the assignee (and in a form reasonably acceptable to DFCI) all of CTI's obligations under this Agreement, whether arising before, at or after the assignment.

**11.3 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**11.4 Force Majeure.** No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

**11.5 Entire Agreement of the Parties; Amendments.** This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

**11.6 Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.

**11.7 Notices and Deliveries.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by express courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party.

If to CTI, addressed to:

Checkpoint Therapeutics, Inc.  
3 Columbus Circle, 15th Floor  
New York, NY 10019  
Attention: Michael S. Weiss, Executive Chairman  
Email: msw@opuspointpartners.com

If to DFCI, addressed to:

Michelle Erin Johnson  
Dana-Farber Cancer Institute, Inc.  
450 Brookline Avenue, BP304E  
Boston, MA 02115  
Email: michelle.e.johnson@outlook.com  
Ref: \*

**11.8 Waiver.** No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

**11.9 Rights and Remedies are Cumulative.** Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

**11.10 Severability.** This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

**11.11 Third Party Beneficiaries.** Except for the rights of Indemnified Parties pursuant to Article IX hereof and the rights of Sublicensees set forth in Sections 2.3 and 10.6(d), the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of DFCI under this Agreement shall only be pursued by CTI or such Indemnified Party, and not Sublicensees (except as set forth in Sections 2.3 and 10.6(d)).

**11.12 No Implied License.** No right or license is granted to CTI hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by DFCI or its Affiliates, except by an express license granted hereunder. No right or license is granted to DFCI hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by CTI or its Affiliates, except by an express license granted hereunder.

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\* Confidential material redacted and filed separately with the Commission.

**11.13 No Right of Set-Off.** Except as expressly provided in Article 5 of this Agreement, CTI shall not have a right to set-off any royalties, milestones or other amount due to DFCI under this Agreement against any damages incurred by CTI for a breach by DFCI of this Agreement.

**11.14 Equitable Relief.** Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

**11.15 Interpretation.** The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

**11.16 Construction.** The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require.

**11.17 Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, will be deemed an original.

*[the remainder of this page has been left blank intentionally]*



IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: Executive Chairman

DANA -FARBER CANCER INSTITUTE, INC.

By: 

Name: O.Prem Das, Ph.D.  
Chief Research Business Development Officer

Title: Dana-Farber Cancer Institute

Schedule 1

DFCI Patents

CA-IX

Institution Number	Application Number	Type of Patent Filing	Application Date	Patent Issued Number	Patent Issued Date	Filing Country
*	*	*	*	*	*	*
*	*	*	*	*	*	*
IP1084.03	12/095,773	ORD	03-Nov-2008	8,466,263	18-Jun-2013	United States
*	*	*	*	*	*	*
*	*	*	*	*	*	*
*	*	*	*	*	*	*
*	*	*	*	*	*	*
*	*	*	*	*	*	*
*	*	*	*	*	*	*

PD-L1

Institution Number	Application Number	Type of Patent Filing	Application Date	Patent Issued Number	Patent Issued Date	Filing Country
*	*	*	*	*	*	*
*	*	*	*	*	*	*
*	*	*	*	*	*	*

GITR

Institution Number	Application Number	Type of Patent Filing	Application Date	Patent Issued Number	Patent Issued Date	Filing Country
*	*	*	*	*	*	*

\* Confidential material redacted and filed separately with the Commission.

**Schedule 2**

**DFCI Know-How**

- \*
- \*
- \*
- \*
- \*
- \*
- \*
- \*
- \*
- \*

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\* Confidential material redacted and filed separately with the Commission.

**Schedule 3 – DFCI Materials**

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**Schedule 4 – DFCI Antibodies**

Anti-CA-IX  
Anti-GITR  
Anti-PD-L1

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\* Confidential material redacted and filed separately with the Commission.

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

CONFIDENTIAL  
Execution Version

**LICENSE AGREEMENT FOR CEP-9722**

**THIS LICENSE AGREEMENT** (this “**Agreement**”) is dated as of December 18, 2015 (the “**Effective Date**”) by and between Fortress Biotech, Inc., a Delaware corporation organized having its place of business at 3 Columbus Circle, New York, NY 10019 (“**FBIO**”), and Cephalon, Inc. a Delaware corporation having its place of business at 41 Moores Road, Frazier, PA 19355 (“**Cephalon**”). FBIO, on the one hand, and Cephalon, on the other hand, shall each be referred to herein as a “**Party**” or, collectively, as the “**Parties**.”

**RECITALS:**

**WHEREAS**, Cephalon and its Affiliates have been engaged in the development of CEP-9722, an oral low nM PARP inhibitor, and controls certain patent rights and know-how with respect thereto; and

**WHEREAS**, FBIO is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and FBIO is interested in developing and commercializing Licensed Compounds and Licensed Products; and

**WHEREAS**, FBIO desires to obtain an exclusive license from Cephalon, and Cephalon wishes to license to FBIO, under the Cephalon Patents and Cephalon Know-How for FBIO to develop, manufacture and commercialize Licensed Compounds and Licensed Products, all of the terms set forth below.

**NOW, THEREFORE**, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

**ARTICLE I  
DEFINITIONS**

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

**1.1** “**A Rated**” means “therapeutically equivalent” as evaluated by FDA (or other Regulatory Authority standards, on a country-by-country basis), applying the definition of “therapeutically equivalent” set forth in the Preface to the current edition of the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), as such requirements may be amended in the future, or any enabling legislation thereof, or pursuant to any similar evaluation and approval process in any other country in the Territory.

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**1.2** “**Additional Ingredient**” means any active ingredient, in addition to any Licensed Compound, which is contained in a Licensed Product. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be “active ingredients”, except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. § 210.3(b)(7) (as amended).

**1.3** “**Additional Studies Clinical Data**” has the meaning set forth in Section 10.7(c)(viii).

**1.4** “**Affiliate**” of a Person means any other Person that (directly or indirectly) controls, is controlled by or is under common control with such Party, but only for so long as such control exists. For the purposes of this Section 1.4, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors, (b) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%), including ownership by trusts with substantially the same beneficial interest, of the equity interests with the power to direct the management and policies of such Person, provided that if local law restricts foreign ownership, control shall be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests, or (c) the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract or otherwise.

**1.5** “**Agreement**” has the meaning set forth in the Preamble.

**1.6** “**Alternative Product**” means any compound or product (other than any Licensed Compound or Licensed Product) that has a primary mode of action that targets PARP.

**1.7** “**ANDA**” means an abbreviated new drug application submitted pursuant to the requirements of the FDA under § 355(j) of the United States Federal Food, Drug, and Cosmetic Act (as amended or any replacement thereof), and any equivalent application submitted in any country pursuant to any similar abbreviated route of approval together, in each case, with all additions, deletions or supplements thereto.

**1.8** “**Annual Report**” has the meaning set forth in Section 5.11.

**1.9** “**API**” has the meaning set forth in Section 3.3(a).

**1.10** “**Calendar Quarter**” means each three (3) month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

**1.11** “**Calendar Year**” means the period beginning on the 1<sup>st</sup> of January and ending on the 31<sup>st</sup> of December of the same calendar year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**1.12** “**Cephalon**” has the meaning set forth in the Preamble.

**1.13** “**Cephalon Indemnitee**” has the meaning set forth in Section 9.1.

**1.14** “**Cephalon Know-How**” means any and all Know-How that either (a) is Controlled by Cephalon or any of its Affiliates as of the Effective Date, or (b) is created, conceived or developed by or on behalf Cephalon or any of its Affiliates pursuant to, and in accordance with the terms and conditions of, the Manufacturing and Supply Agreement, and, in each case for clauses (a) and (b), is necessary for FBIO to Develop, Manufacture, or Commercialize any Licensed Compound or Licensed Product.

**1.15** “**Cephalon Patents**” means (a) those issued patents and patent applications set forth on Schedule I hereto, (b) any additions, divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patents and patent applications mentioned in clause (a) above, and (c) all patents issuing from any of the patents and patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and inter partes review.

**1.16** “**Cephalon Technology**” means the Cephalon Patents and Cephalon Know-How.

**1.17** “**Change of Control**” means, with respect to a Party, (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving a Party as a result of which the stockholders of such Party immediately preceding such transaction hold less than fifty percent (50%) of the outstanding shares, or less than fifty percent (50%) of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of a Party or all or substantially all of a Party’s assets, either directly or through one or more subsidiaries), (b) the adoption of a plan relating to the liquidation or dissolution of a Party, other than in connection with a corporate reorganization (without limitation of clause (a), above); (c) the sale or disposition to a Third Party of all or substantially all the assets of a Party (determined on a consolidated basis); or (d) the sale or disposition to a Third Party of assets or businesses that constitute fifty percent (50%) or more of the total revenue or assets of a Party (determined on a consolidated basis).

**1.18** “**Claim**” has the meaning set forth in Section 9.1.

**1.19** “**Clinical Trials**” means any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase I Trial, Phase II Trial, Phase III Trial or Phase IV Trial.

**1.20** “**Combination Product**” means a product containing a Licensed Compound together with one or more other Additional Ingredients.

**1.21** “**Commercialization**” or “**Commercialize**” means any and all activities undertaken at any time for a particular Licensed Product and that relate to obtaining pricing and reimbursement approvals, carrying out Phase IV Trials, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.

**1.22** “**Commercially Reasonable Efforts**” means, with respect to any Licensed Compound and each Licensed Product, that level of effort and resources commonly dedicated in the pharmaceutical industry by a company of comparable activity to the Manufacture, Development or Commercialization, as the case may be, of a product of similar commercial potential at a similar stage in its lifecycle to the Licensed Compound or such Licensed Product, in each case taking into account the following considerations (the “**CRE Considerations**”): issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment and the likely timing of market entry, the regulatory environment and status of such Licensed Product, and other relevant scientific, technical and commercial factors, but without regard to any payments owed to Cephalon under this Agreement.

**1.23** “**Confidential Information**” has the meaning set forth in Section 7.1.

**1.24** “**Controlled**” means, with respect to any patent right, Know-How, or other intellectual property right, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access.

**1.25** “**CPA Representative**” has the meaning set forth in Section 5.12.

**1.26** “**CRE Considerations**” has the meaning set forth in Section 1.22.

**1.27** “**CREATE Act**” has the meaning set forth in Section 6.7.

**1.28** “**Development**” or “**Develop**” means, with respect to any Licensed Compound and each Licensed Product, the performance of non-clinical, preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product (and specifically excluding activities directed to obtaining pricing and reimbursement approvals).

**1.29** “**Development Plan**” means the plan setting forth the activities and timelines relating to the Development of any Licensed Compound and each Licensed Product in the Field in the Territory from the Effective Date for at least two (2) Indications. The initial Development Plan is set forth on Schedule 2.



**1.30** “**Disclosing Party**” has the meaning set forth in Section 7.1.

**1.31** “**Distributor**” means a Third Party bona fide wholesaler or distributor engaged by FBIO only to market, distribute and sell a Licensed Product in a particular jurisdiction (but, for clarity, not to Develop or Manufacture any Licensed Product in any way).

**1.32** “**Effective Date**” has the meaning set forth in the Preamble.

**1.33** “**EMA**” means the European Medicines Agency or any successor agency thereto.

**1.34** “**European Commission**” means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

**1.35** “**Existing Contracts**” has the meaning set forth in Section 2.4.

**1.36** “**FBIO**” has the meaning set forth in the Preamble.

**1.37** “**FBIO Indemnitee**” has the meaning set forth in Section 9.2.

**1.38** “**FDA**” means the United States Food and Drug Administration or any successor agency thereto.

**1.39** “**FDCA**” means the United States Federal Food, Drug and Cosmetic Act, as amended.

**1.40** “**Field**” means all uses in humans or animals.

**1.41** “**First Commercial Sale**” means, with respect to a Licensed Product in any country, the first sale of such Licensed Product in such country. Sales for purposes of testing the Licensed Product in a Clinical Trial shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale shall be determined on a Licensed Product-by-Licensed Product and country-by-country (or region-by-region) basis, as applicable.

**1.42** “**GAAP**” means United States generally accepted accounting principles consistently applied.

**1.43** “**Generic Product**” means any generic pharmaceutical product (i) that is marketed and sold for use by a Third Party (not licensed, supplied or otherwise permitted by a Party or its Affiliates or Sublicensees) in the applicable country as a generic product A Rated to a Licensed Product pursuant to an ANDA for which such Licensed Product is the Reference Listed Drug, (ii) that contains the applicable Licensed Compound as the same active ingredient, (iii) with the same route of administration, dosage form, strength and dosing or dosage regimen as such Licensed Product, and (iv) for the treatment of the same indications in the same dosage strengths as such Licensed Product, except where changes to the labeled indications have been approved by the FDA or other comparable Regulatory Authority. For the avoidance of doubt, a Generic Product will not necessarily infringe a Cephalon Patent.

**1.44** “**Good Clinical Practice**” means the then current standards for Clinical Trials for pharmaceuticals (including all applicable requirements relating to protection of human subjects), as set forth in the FDCA and applicable regulations promulgated thereunder (including, for example, 21 C.F.R. Parts 50, 54, and 56), as amended from time to time, and such standards of good clinical practice (including all applicable requirements relating to protection of human subjects) as are required by other organizations and Governmental Body in any other countries, including applicable regulations or guidelines from the ICH, in which a Licensed Product is intended to be sold, to the extent such standards are not less stringent than in the United States.

**1.45** “**Good Laboratory Practice**” means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDCA, the FDA’s Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Commission and other organizations and Governmental Authorities in countries in which a Licensed Product is intended to be sold, to the extent such standards are not less stringent than in the United States.

**1.46** “**Good Manufacturing Practice**” means the then current standards for the manufacture, processing, packaging, testing, transportation, handling and holding of pharmaceuticals, as set forth in the FDCA and applicable regulations and guidances promulgated thereunder, as amended from time to time, including and the standards that require that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. § 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16 (in each case as amended), and applicable United States, EU, Canadian and ICH Guidance or regulatory requirements for a Licensed Product.

**1.47** “**Governmental Body**” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

**1.48** “**Hatch-Waxman Time Period**” has the meaning set forth in Section 6.8(c)(i).

**1.49** “**IND**” means an Investigational New Drug Application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

**1.50** “**Indemnified Party**” has the meaning set forth in Section 9.3(a)

**1.51** “**Indemnifying Party**” has the meaning set forth in Section 9.3(a).

**1.52** “**Indication**” means each separate and distinct disease, disorder, illness, health condition, or interruption, cessation or disruption of a bodily function, system, tissue type or organ, for which Regulatory Approval is required. For the avoidance of doubt, subtypes of the same disease are different indications if (a) a separate pivotal trial for each disease subtype is required for Regulatory Approval for each disease subtype, and (b) a separate NDA or supplemental NDA is required for Regulatory Approval for each disease subtype.

**1.53** “**Initial Supply Term**” has the meaning set forth in Section 3.3(a).

**1.54** “**Invoicing Entity**” has the meaning set forth in Section 1.66(a).

**1.55** “**Know-How**” means know-how, trade secrets, chemical and biological materials, formulations, information, documents, studies, results, data and regulatory approvals, data, filings and correspondence (including Drug Master Files), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, whether or not patented or patentable.

**1.56** “**Law**” or “**Laws**” means any federal, state, provincial, local, international or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Body, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

**1.57** “**Licensed Compounds**” means (a) the compound known as CEP-9722, as further described on Schedule 3, which compound is an oral low nM PARP inhibitor, and (b) the compound known as CEP-8983, as further described on Schedule 3.

**1.58** “**Licensed Product**” means any pharmaceutical product containing any Licensed Compound (alone or with other active ingredients), in all forms, presentations, formulations and dosage forms. For clarification, Licensed Product shall include any Combination Product.

**1.59** “**MAA**” means (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure or (ii) a Regulatory Authority in any country of the EU if the centralized EMA filing procedure is not used, or (b) any other equivalent or related regulatory submission, in either case to gain approval to market a Licensed Product in any country in the European Union, in each case including, for clarity, amendments thereto and supplemental applications.

**1.60** “**Major European Country**” means any of the United Kingdom, France, Germany, Italy or Spain.

**1.61** “**Manufacture**” or “**Manufacturing**” means activities related to the manufacture, formulation and packaging of any compound or product, including any Licensed Compound and Licensed Products, including related quality control and quality assurance activities.

**1.62** “**Manufacturing and Supply Agreement**” has the meaning set forth in Section 3.3(a).

**1.63** “**Milestone Event**” has the meaning set forth in Section 5.2(a).

**1.64** “**Milestone Payment**” has the meaning set forth in Section 5.2(a).

**1.65** “**NDA**” means a New Drug Application submitted pursuant to the requirements of the FDA under §505(b)(1) of the United States Federal Food, Drug, and Cosmetic Act (as amended or any replacement thereof), as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

**1.66** “**Net Sales**” means, with respect to the Licensed Products:

( a ) the gross sales price invoiced for sales, leases or other transfers of Licensed Products by FBIO or its Affiliates or Sublicensees (the “**Invoicing Entity**”); or

(b) the fair market value of non-monetary consideration received in connection with such sales, leases or transfers;

after deduction of: \*, all calculated and determined in accordance with GAAP, as reflected in FBIO’s financial statements and measured in United States Dollars.

Sales of Licensed Products by an Invoicing Entity to an Affiliate or Sublicensee of such Invoicing Entity for resale by such Affiliate or Sublicensee shall not be deemed Net Sales and Net Sales shall be determined based on the total amount invoiced by such Affiliate or Sublicensee on resale.

Net Sales for any Combination Product shall be calculated on a country-by-country basis by multiplying actual Net Sales of such Combination Product by\*. If such Licensed Product is not sold separately in finished form in such country, the Parties shall determine Net Sales for such Licensed Product by mutual agreement based on the relative contribution of such Licensed Product and each such other active ingredients in such Combination Product in accordance with the above formula, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

**1.67** “**New York Courts**” has the meaning set forth in Section 11.6.

**1.68** “**PARP**” means Poly(ADP-ribose) polymerase.

**1.69** “**Party(ies)**” has the meaning set forth in the Preamble.

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\* Confidential material redacted and filed separately with the Commission.

**1.70** “**Patent Challenge**” means any challenge in a legal or administrative proceeding to the patentability, validity or enforceability of any of the Cephalon Patents (or any claim thereof), including by: (a) filing or pursuing a declaratory judgment action in which any of the Cephalon Patents is alleged to be invalid or unenforceable; (b) citing prior art against any of the Cephalon Patents (other than art required to be cited under a duty of candor to a patent office), filing a request for or pursuing a re-examination of any of the Cephalon Patents (other than with Cephalon’s written agreement), or becoming a party to or pursuing an interference; or (c) filing or pursuing any re-examination, opposition, cancellation, nullity or other like proceedings against any of the Cephalon Patents; but excluding any challenge raised as a defense against a claim, action or proceeding asserted by Cephalon or its Affiliates against FBIO or its Affiliates or Sublicensees.

**1.71** “**Patent Counsel**” has the meaning set forth in Section 6.2.

**1.72** “**Periodic Report**” has the meaning set forth in Section 5.7.

**1.73** “**Person**” means any natural person, sole proprietorship, corporation, firm, business trust, trust, joint venture, association, organization, company, partnership, limited partnership or other business entity, or any government or agency or political subdivision thereof.

**1.74** “**Phase I Trial**” means a human clinical trial of a Licensed Product, the principle purpose of which is a preliminary determination of safety, tolerability, pharmacological activity or pharmacokinetics in patients, as described in 21 C.F.R. 312.21(a) (as amended or any replacement thereof), or a similar clinical study prescribed by the Regulatory Authorities outside of the United States. For purposes of this Agreement, (a) a Phase I Trial shall specifically exclude a study in healthy volunteers, and (b) “commencement” of a Phase I Trial for any Licensed Product means the first dosing of such Licensed Product in a Phase I Trial for such Licensed Product.

**1.75** “**Phase II Trial**” means a human clinical trial of a Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authorities outside of the United States. For purposes of this Agreement, “commencement” of a Phase II Trial for any Licensed Product means the first dosing of such Licensed Product in a Phase II Trial for such Licensed Product.

**1.76** “**Phase III Trial**” means a clinical trial of a Licensed Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Licensed Product, as described in 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar clinical trial prescribed by the Regulatory Authorities outside of the United States. For purposes of this Agreement, “commencement” of a Phase III Trial for any Licensed Product means the first dosing of such Licensed Product in a Phase III Trial for such Licensed Product.

**1.77** “**Phase IV Trial**” means (a) a human clinical trial of a Licensed Product conducted following commencement of a pivotal clinical trial for such Licensed Product that is not required for receipt of Regulatory Approval (whether such clinical trial is conducted prior to or after receipt of such approval), but that may be useful in support of the post-approval exploitation of a Licensed Product; or (b) a human clinical trial of a Licensed Product conducted after Regulatory Approval of such Licensed Product has been obtained from an appropriate Regulatory Authority due to a request or requirement of such Regulatory Authority.

**1.78** “**Receiving Party**” has the meaning set forth in Section 7.1.

**1.79** “**Reference Listed Drug**” means a listed drug identified by FDA or other Regulatory Authority as a drug product upon which an applicant may rely in seeking approval of an ANDA.

**1.80** “**Regulatory Approval**” means, with respect to a country or region in the Territory, approvals, licenses, registrations or authorizations from the relevant Regulatory Authority necessary for the Development, Manufacture or Commercialization of a Licensed Product in such country or region. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Licensed Product in such country or region.

**1.81** “**Regulatory Authority**” means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body or other analogous government regulatory authority or agency involving in granting approvals (including any required pricing or reimbursement approvals) for the Development, Manufacture or Commercialization pharmaceutical or biotechnology products (including any Licensed Product) in any other jurisdiction anywhere in the world.

**1.82** “**Regulatory Filing**” means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to any compound or product (including any Licensed Compound or Licensed Product), or its use or potential use in humans, including any documents submitted to any Regulatory Authority and all supporting data, including INDs and NDAs, and all correspondence with any Regulatory Authority with respect to such compound or product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

**1.83** “**Reversion IP**” has the meaning set forth in Section 10.7(c)(ix).

**1.84** “**Reversion License**” has the meaning set forth in Section 10.7(c)(ix).

**1.85** “**Royalty Term**” means, on a Licensed Product-by-Licensed Product and country-by-country basis, until the latest to occur of: (a) the date of expiration of the last Valid Claim included in any of the Cephalon Patents claiming or covering the making, use, sale, offer for sale or importation of such Licensed Product in or for such country; (b) the end of any exclusivity for the Licensed Product granted by a Regulatory Authority or Governmental Body applicable to such country; or (c) ten (10) years from the date of First Commercial Sale of such Licensed Product in such country.

**1.86** “**Sublicense**” means any grant by FBIO to an Affiliate or a Third Party of any of the licenses or rights granted under this Agreement or any part thereof, including the right to Develop, Manufacture, or Commercialize any License Compound or Licensed Product, in accordance with Section 2.3.

**1.87** “**Sublicense Revenue**” means any payments or other consideration that FBIO or its Affiliates actually receives from a non-Affiliated Third Party Sublicensee as consideration for the grant of a Sublicense, or an option to obtain such Sublicense, including, without limitation, milestone payments, license fees, license option fees, license maintenance fees and equity. Sublicense Revenue excludes \*. In the event such consideration received from a non-Affiliated Third Party Sublicensee is not cash, Sublicense Revenue shall be calculated by FBIO based on the fair market value of such consideration, at the time of the transaction, assuming an arm’s length transaction made in the ordinary course of business.

**1.88** “**Sublicensee**” means any Affiliate of FBIO or Third Party to whom FBIO shall grant a Sublicense or option to obtain such Sublicense in accordance with Section 2.3. Sublicensee shall include any other Third Party to whom such rights shall be transferred, assigned, or who may assume control thereof by operation of law or otherwise.

**1.89** “**Tax**” or “**Taxes**” means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

**1.90** “**Term**” has the meaning set forth in Section 10.1.

**1.91** “**Territory**” means worldwide.

**1.92** “**Third Party**” means any Person other than Cephalon, FBIO or their respective Affiliates.

**1.93** “**Third Party Royalties**” means royalties calculated on any amount invoiced by FBIO or its Affiliate for the sale of a Licensed Product (excluding any Combination Product) that includes any Licensed Compound as the sole active ingredient for either or both of the first two (2) Indications and actually paid by FBIO or its Affiliate to a Third Party for the right to use or practice patents of such Third Party, without which right of use or practice FBIO or its Affiliate would not be entitled to Manufacture or Commercialize such Licensed Product, provided that the duty to pay the royalty to such Third Party has been established at arm’s-length and in good faith, and is set out in a written agreement.

**1.94** “**United States**” or “**US**” means the United States of America and its territories and possessions.

**1.95** “**Valid Claim**” means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing to be invalid or unenforceable or of a scope not Covering a particular product or service through reissue, disclaimer or otherwise, provided that if a particular claim has not issued within five (5) years of its initial filing, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued or granted Patent, notwithstanding the foregoing definition.

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**ARTICLE II**  
**LICENSES AND OTHER RIGHTS**

**2.1 Grant of Licenses to FBIO.**

(a) Subject to the terms and conditions of this Agreement and the reserved rights described in Section 2.2, Cephalon hereby grants to FBIO, and FBIO hereby accepts, an exclusive, worldwide, royalty-bearing, non-transferable (except in accordance with Section 11.2) license (with the right to grant Sublicenses as provided for in Section 2.3 only) under the Cephalon Technology to research, Develop, use, and Commercialize and have Commercialized the Licensed Compounds and Licensed Products in and for the Field and Territory.

(b) Subject to the terms and conditions of this Agreement and the reserved rights described in Section 2.2, Cephalon hereby grants to FBIO, and FBIO hereby accepts, a co-exclusive (with Cephalon and its Affiliates), worldwide, non-transferable (except in accordance with Section 11.2) license (with the right to grant Sublicenses as provided for in Section 2.3 only) under the Cephalon Technology to Manufacture and have Manufactured the Licensed Compounds and Licensed Products in and for the Field and Territory.

(c) In addition, subject to the terms and conditions of this Agreement, Cephalon hereby grants to FBIO a non-transferable (except in accordance with Section 11.2), right of reference (with the right to grant Sublicenses as provided for in Section 2.3 only) to any INDs and other Regulatory Filings Controlled by Cephalon or any of its Affiliates as of the Effective Date for the Licensed Compounds and Licensed Products.

**2.2 Reservation of Rights.**

( a ) Notwithstanding anything herein to the contrary, Cephalon and its Affiliates shall have the co-exclusive right to Manufacture and have Manufactured the Licensed Compounds and Licensed Products in the Territory to supply Licensed Compounds and Licensed Products to FBIO and its Affiliates and Sublicensees pursuant to the Manufacturing and Supply Agreement.

(b) Except as expressly set forth in this Agreement, no licenses or other rights are granted or created hereunder to use any patent right, Know-How or other intellectual property rights owned, Controlled or otherwise in-licensed by Cephalon or any of its Affiliates, and all licenses and other rights are or shall be granted only as expressly provided in this Agreement, and no other licenses or other rights is or shall be created or granted hereunder by implication, estoppel or otherwise. The licenses granted in Section 2.1 above shall not grant or create (by implication, estoppel or otherwise) any license or right under any Cephalon Patents or Cephalon Know-How to Develop, Manufacture or Commercialize any molecule that is not a Licensed Compound or Licensed Product.



### **2.3 Grant of Sublicenses by FBIO.**

(a) FBIO shall be entitled to grant Sublicenses of the rights granted by Cephalon hereunder:

(i) to any Affiliate of FBIO, provided such Sublicense only remains in effect for as long as such Sublicensee remains an Affiliate of FBIO;

(ii) to Third Parties that are clinical research organizations, contract manufacturers, contract laboratory organizations, Distributors, and other similar organizations that support the Development, Manufacture and Commercialization of any Licensed Compounds and Licensed Products on a fee-for-service basis as Sublicensees hereunder, provided that such Sublicenses include obligations of confidentiality and non-use of the Cephalon Technology and Cephalon Confidential Information substantially in accordance with the terms of this Agreement;

(iii) to other Third Parties as a Sublicensee hereunder with the prior written consent of Teva, such consent which shall not be unreasonably withheld, conditioned or delayed. Teva's right to consent under this Section 2.3(a)(iii) shall include the right to consent to the entity entering into such Sublicense as well as the terms of such Sublicense. As part of such approval process FBIO or its Affiliate shall provide to Teva a copy of the proposed Sublicense agreement which may be redacted to remove financial terms, but shall include at a minimum all confidentiality provisions, intellectual property rights provisions, and all sections containing obligations of FBIO or its Affiliate. All Sublicenses granted by FBIO (or any option to a Sublicense) must (i) be in writing, (ii) be subject and subordinate to, and consistent with, the terms and conditions of this Agreement and (iii) require the applicable Sublicensee to comply with all applicable terms of this Agreement (except for the payment obligations, for which FBIO shall remain responsible). FBIO shall provide a copy of each executed agreement containing a Sublicense to Cephalon within ten (10) days after its execution. No Sublicense shall diminish, reduce or eliminate any obligation of FBIO under this Agreement, and FBIO shall remain responsible for its obligations under this Agreement and shall be responsible for the performance of the relevant Sublicensee as if such Sublicensee were "FBIO" hereunder.

(b) Without limiting the foregoing, FBIO shall ensure that each Sublicense shall include material terms that bind the Sublicensee to observe the terms of this Agreement, the breach of which terms shall be a material breach resulting in the termination of the Sublicense. In such an event, FBIO undertakes to take all reasonable steps to enforce such terms upon the Sublicensee, including the termination of the Sublicense. In all cases, FBIO shall immediately notify Cephalon of any alleged or actual breach of the material terms of a Sublicense, and shall copy Cephalon on all correspondence with regard such breach.

### **2.4 Intentionally Omitted.**

**2.5 Transfer of Cephalon Know-How.** Cephalon shall provide or make available to FBIO one (1) copy (in a format determined by Cephalon) of all Cephalon Know-How in Cephalon's or its Affiliates' possession as of the Effective Date within ninety (90) days of the Effective Date of this Agreement.

**2.6 Existing Inventory.** Within thirty (30) days after the Effective Date, FBIO shall have the right, at its option, to purchase from Cephalon, and Cephalon shall sell to FBIO if requested in writing by FBIO, all of Cephalon's and its Affiliates' existing inventory of Licensed Compounds, \*, pursuant to, and in accordance with the terms and conditions set forth in, the Manufacturing and Supply Agreement. In addition, Cephalon shall provide to FBIO at no cost expired inventory of Licensed Compounds up to a maximum of \* of such expired inventory. The Parties will mutually agree upon the cost for any expired inventory of Licensed Compounds in excess of \* that FBIO desires to purchase.

**2 . 7 Alternative Products.** During the Term, neither FBIO nor any of its Affiliates or Sublicensees shall directly or indirectly Develop, Manufacture or Commercialize, nor collaborate with, enable or otherwise authorize, license or grant any right to any Third Party to Develop, Manufacture or Commercialize, any Alternative Product anywhere in the Territory.

### **ARTICLE III DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION**

#### **3.1 Development.**

( a ) FBIO shall use Commercially Reasonable Efforts to Develop the Licensed Products in the United States, Japan and each of the Major European Countries and the remainder of the Territory in at least two (2) Indications. The Parties acknowledge that FBIO may Develop Licensed Products that are a Combination Product. Without limiting the generality of the foregoing, FBIO shall use Commercially Reasonable Efforts to execute and perform, or cause to be performed, the initial Development Plan in the form attached hereto as Schedule 2, in accordance with the timelines set forth therein, and FBIO shall conduct its Development activities in good scientific manner and in compliance with applicable Law, including Laws regarding environmental, safety and industrial hygiene, and Good Laboratory Practice, Good Clinical Practice, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Without limiting or derogating from the foregoing, FBIO shall use Commercially Reasonable Efforts to (i) commence a \* for a Licensed Product by no later than the \* of the Effective Date, and (ii) commence at least \* for the Licensed Products in at least \* Indications.

(b) FBIO shall be responsible, at its sole cost and expense, for all Development activities under this Agreement and the Development Plan.

(c) With respect to any facility or site at which FBIO or its Affiliates conducts Development activities pursuant to this Agreement or the Development Plan, Cephalon shall have the right, at its expense, upon reasonable written notice to FBIO (and if applicable, such Affiliate), and during normal business hours, to inspect such site and facility and any records relating thereto once per Calendar Year, or more often with reasonable cause, to verify FBIO's compliance with the terms of this Agreement pertaining to Development of the Licensed Products pursuant to all applicable Laws, including Good Laboratory Practices, Good Clinical Practices and current standards for pharmacovigilance practice. Such inspection shall be subject to the confidentiality provisions set forth in Article VII.

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\* Confidential material redacted and filed separately with the Commission.

### 3.2 Commercialization.

(a) FBIO shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Territory in those countries and for those Indications for which Regulatory Approval and pricing and reimbursement approval has been obtained.

( b ) FBIO shall be responsible, at its sole cost and expense, for all Commercialization activities under this Agreement and shall keep Cephalon reasonably informed as to the progress of such activities.

### 3.3 Manufacturing.

(a) Within sixty (60) days after the Effective Date, Cephalon (or its designee) and FBIO shall negotiate in good faith to enter into a manufacturing and supply agreement (the “**Manufacturing and Supply Agreement**”), pursuant to which Cephalon shall, subject to the terms of the Manufacturing and Supply Agreement, (i) Manufacture and supply (or have Manufactured and supplied) to FBIO \*, active pharmaceutical ingredient (“**API**”) and drug product for Licensed Compounds or Licensed Products, and (ii) conduct the Manufacturing development activities for Licensed Compounds or Licensed Products, in each case (for clauses (i) and (ii)) as requested by FBIO and in the Territory for an initial period to be agreed to by the Parties, unless earlier terminated as provided therein (the “**Initial Supply Term**”). Notwithstanding the foregoing, the Manufacturing and Supply Agreement shall in no way restrict FBIO from contracting with Third Parties to Manufacture and supply (or have Manufactured and supplied) to FBIO API and drug product for Licensed Compounds or Licensed Products and conduct Manufacturing development activities for Licensed Compounds or Licensed Products.

(b) From and after the Initial Supply Term, (i) FBIO, at its own cost and expense, shall be responsible for all Manufacturing development, establishment of Manufacturing sources and supply chains, and Manufacture and supply of the Licensed Compounds and Licensed Products in the Field and in the Territory, subject to the provisions of this Section 3.3(b), (ii) FBIO shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed through its Affiliates and Sublicensees, the Manufacturing activities assigned to it in this Agreement and by Cephalon, and (iii) FBIO shall be solely responsible, at its cost and expense, for Manufacturing and supplying the worldwide requirements for the Development and Commercialization of the Licensed Compounds and Licensed Products in and for the Field and the Territory in accordance with Good Manufacturing Practice and all applicable Laws and standards.

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\* Confidential material redacted and filed separately with the Commission.

**3 . 4 Development, Regulatory and Commercialization Reports.** Every six (6) months during the Term, FBIO shall issue to Cephalon a report on the Development and regulatory activities FBIO has performed or caused to be performed for the Licensed Compounds and Licensed Products, including a summary of the work performed in relation to the goals of the Development Plan, a summary of progress against each Development and regulatory-related Milestone Event and an estimate of the timing of the achievement of the next Development and regulatory-related Milestone Event, and provide such other information as may be reasonably requested by Cephalon with respect to such Development and regulatory activities. In addition to the foregoing, upon Cephalon's reasonable request, FBIO shall participate in a telephone or video conference to discuss such report and other information as to convey a reasonably comprehensive understanding of the status of the applicable Development or regulatory activity. In addition to the foregoing, FBIO shall provide prompt written notice to Cephalon (and in any event such notice shall be provided within thirty (30) days) if FBIO elects to suspend or no longer proceed with Developing, Manufacturing or Commercializing any Licensed Compound, any Licensed Product or any Indication(s) for a period equal to or greater than nine (9) consecutive months. At least once each Calendar Year, FBIO shall provide to Cephalon a report summarizing the Commercialization activities performed by FBIO or any Affiliates or Sublicensees for the Licensed Compounds and Licensed Products during the preceding Calendar Year.

**3 . 5 Trademarks.** As between Cephalon and FBIO, FBIO shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks, and shall be responsible for the registration, filing, maintenance and enforcement thereof.

**3.6 Other Government Laws.** FBIO shall comply with, and ensure that its Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Licensed Compounds or Licensed Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

#### **ARTICLE IV REGULATORY MATTERS**

**4.1 Regulatory Responsibilities.** FBIO shall, at its sole cost and expense, use Commercially Reasonable Efforts to seek and obtain all Regulatory Approvals for the Licensed Products in the Field in the United States, Japan and each of the Major European Countries, in at least \* in accordance with the Development Plan. FBIO may decide, in its sole discretion, and at its sole cost and expense to seek and obtain Regulatory approvals for the Licensed Products in the Field in all other countries in the Territory (outside of the United States, Japan and the Major European Countries).

**4 . 2 Ownership of Regulatory Approvals.** As between FBIO and Cephalon, FBIO (or its applicable Affiliate) shall own and maintain all Regulatory Filings made after the Effective Date for Licensed Products and all Regulatory Approvals for Licensed Products. All such filings shall be in the name of FBIO, except where otherwise required by local law.

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\* Confidential material redacted and filed separately with the Commission.

**4.3 Regulatory Cooperation.** Without limiting Section 3.1, FBIO shall provide Cephalon with copies (and in any event such copies shall be provided within sixty (60) days) of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to any Regulatory Filing or Regulatory Approval for Licensed Products. For clarity, Cephalon shall have no obligation, responsibility or liability relating to any Regulatory Filing or Regulatory Approval for any Licensed Compound or Licensed Product, and Cephalon shall have no obligation, responsibility or liability to maintain, comment on, respond to or file any Regulatory Filings or Regulatory Approvals for any Licensed Compound or Licensed Product.

**4.4 Regulatory Audits.** To the extent that Cephalon's participation is requested by FBIO, the Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Trials or Manufacturing of Licensed Products in the Field are conducted pursuant to this Agreement, whether such site or facility is FBIO's or its Affiliate's or a permitted subcontractor's.

**4.5 Pricing and Reimbursement Standards.** FBIO shall be responsible for and have the exclusive right to seek and attempt to obtain pricing and reimbursement approvals for the Licensed Products in the Field in the Territory.

## **ARTICLE V FINANCIAL PROVISIONS**

**5.1 Upfront Payment.** FBIO shall pay to Cephalon within five (5) days after the Effective Date a one-time payment of five hundred thousand dollars (US\$500,000). Such payment shall be non-refundable and non-creditable and not subject to set-off.

### **5.2 Milestone Payments.**

(a) **Licensed Product-based Milestones.** As further consideration for Cephalon's grant of the rights and licenses to FBIO hereunder, FBIO shall pay to Cephalon the following one-time, product-based milestone payments (the "**Milestone Payments**") upon the achievement of each of the milestone events set forth in the table below (the "**Milestone Events**") with regard to each Licensed Product (as specifically set forth below). FBIO shall pay the relevant Milestone Payment within sixty (60) days of such achievement by FBIO, its Affiliates or Sublicensees. For the avoidance of doubt, each of the Milestone Payments shall become payable upon the occurrence of the associated Milestone Event, irrespective of the order in which the Milestone Events occur relative to each other. If a development Milestone Event (e.g., commencement of a Phase II Trial or Phase III Trial) for a Licensed Product is skipped, or if Regulatory Approval for such Licensed Product is granted without completing one or more of the development Milestone Events for such Licensed Product, then the skipped Milestone Event(s) for such Licensed Product will be deemed to have been met upon the achievement of the subsequent development milestone or upon Regulatory Approval for such Licensed Product, as applicable. Such payments shall be non-refundable and non-creditable and not subject to set-off.

<b>Milestone Events</b>	<b>Milestone Payment</b>
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
<b>Total Potential Licensed Product-based Milestones for each Licensed Product</b>	<b>\$ *</b>

(b) **Aggregate Net Sales Achievement Milestones:** As further consideration for Cephalon’s grant of the rights and licenses to FBIO hereunder, FBIO shall pay to Cephalon the following one-time Milestone Payments upon the first achievement of each of the corresponding Milestone Events. FBIO shall pay the relevant Milestone Payment within sixty (60) days of such achievement by FBIO, its Affiliates or Sublicensees. Such payments shall be non-refundable and non-creditable and not subject to set-off.

<b>Milestone Event</b>	<b>Milestone Payment</b>
*	\$ *
*	\$ *
*	\$ *
*	\$ *
*	\$ *
<b>Total Potential Aggregate Net Sales Achievement Milestones</b>	<b>\$ *</b>

\* Confidential material redacted and filed separately with the Commission.

**5.3 Royalties.**

(a) As further consideration for Cephalon's grant of the rights and licenses to FBIO hereunder, FBIO shall pay to Cephalon a royalty at the graduated royalty rates specified in the table below with respect to the aggregate annual worldwide Net Sales of all such Licensed Products by FBIO and its Affiliates and Sublicensees in the Territory in a Calendar Year:

<b>Aggregate Annual Worldwide Net Sales of All Licensed Products in a Calendar Year (US Dollars)</b>	<b>Royalty Rate</b>
For that portion of aggregate annual Net Sales of all Licensed Products up to and including \$ <sup>*</sup>	%
For that portion of aggregate annual Net Sales of all Licensed Products that is greater than \$ <sup>*</sup>	%

The applicable royalty rate shall be calculated as provided in this Section 5.3(a) by reference to the aggregate annual worldwide Net Sales of all Licensed Products in a Calendar Year. By way of example, in a given Calendar Year, if the aggregate annual worldwide Net Sales of all Products for which royalties are due under this Section 5.3(a) were US\$<sup>\*</sup>, the following Royalty payment would be payable under this Section 5.3(a): (% x US\$<sup>\*</sup>) + (% x US\$<sup>\*</sup>) = US\$<sup>\*</sup>.

(b) Royalties shall be payable from the First Commercial Sale of a Licensed Product until the expiration of the Royalty Term, on a country-by-country basis.

(c) Only one royalty shall be due with respect to the sale of the same unit of Licensed Product. Only one royalty shall be due hereunder on the sale of a Licensed Product even if the manufacture, use, sale, offer for sale or importation of such Licensed Product infringes more than one claim of the Cephalon Patents.

(d) On a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the rights and licenses granted to FBIO under Section 2.1 with respect to such Licensed Product in such country shall continue in effect but become fully paid-up, royalty-free, and perpetual.

<sup>\*</sup> Confidential material redacted and filed separately with the Commission.

#### 5.4 Reductions

(a) *Royalty Stacking.* If FBIO or its Affiliate pays Third Party Royalties, and FBIO provides Cephalon with reasonably satisfactory evidence of such Third Party Royalties payment, then FBIO shall be entitled to deduct \* percent (\*%) of such Third Party Royalties from the Net Sales of such Licensed Products in such country, provided that in no event shall such royalty rates set forth in Section 5.3(a) be reduced by more than \* (%)\* pursuant to this Section 5.4(a) in any Calendar Quarter (without any right to carry forward).

(b) *Expiration of U.S. Cephalon Patents.* If royalties are payable under Section 5.3 on Net Sales of a particular Licensed Product for use in the United States after the expiration of all Valid Claims included in the U.S. Cephalon Patents (including any applicable patent term extension) claiming the manufacture, use, sale, offer for sale and importation of such Licensed Product, then the royalties payable on Net Sales of such Licensed Product for use in the United States shall be calculated as set forth in Section 5.3, provided that the portion of the royalties payable on Net Sales of such Licensed Product for use in the United States shall be reduced by \* percent (\*%) after the date of expiration of all such U.S. Cephalon Patents. The royalty applicable to the Net Sales of such Licensed Product for use in the United States shall be applied pro rata on a Calendar Quarter-by-Calendar Quarter basis with reference to the aggregate annual worldwide Net Sales of all Licensed Products in the Territory. For clarity, there shall be no reduction under this Section 5.4(b) on royalties payable on Net Sales of Licensed Products for use in any country or region in the Territory other than in the United States, unless FBIO can show that such other country has adopted patent misuse concepts similar to those recognized in the U.S.

(c) *Generic Competition.* Notwithstanding the foregoing, on a country-by-country basis the applicable royalty rates for Net Sales of a Licensed Product set forth in Section 5.3 will be reduced (A) by \* percent (\*%) following a launch of a Generic Product, if the unit sales of all Generic Products in such country exceed \* percent (\*%) of the sum of unit sales of Licensed Products plus unit sales of all Generic Products in such country, or (B) by \* percent (\*%) following a launch of a Generic Product, if the unit sales of all Generic Products in such country exceed \* percent (\*%) of the sum of unit sales of Licensed Products plus unit sales of all Generic Products in such country. For clarity, such reduction will not apply for any Calendar Quarter in which the market share of Generic Products does not meet either threshold in the preceding sentence. Unless otherwise agreed by the Parties, the unit sales of each such Generic Product sold during a Calendar Quarter will be as reported by IMS America Ltd. of Plymouth Meeting, Pennsylvania (“IMS”) or any successor to IMS or any other independent sales auditing firm reasonably agreed upon by the Parties.

(d) *Maximum Deduction.* In no event shall the cumulative reductions under Sections 5.4(a), 5.4(b) and 5.4(c) reduce the royalties otherwise due to Cephalon by more than \* percent (\*%) in any Calendar Quarter.

(e) *No Obligation to Pay Third Party Royalties.* In no event shall Cephalon be required to contribute to FBIO’s payments to Third Parties from which it has received (sub)licenses to intellectual property that claims or covers any Licensed Compound or Licensed Product.

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\* Confidential material redacted and filed separately with the Commission.



(f) *No Other Deductions.* There shall be no deductions or other reductions to any royalties or other amounts payable to Cephalon hereunder, except to the extent provided by Sections 1.66, 5.4(a), 5.4(b) and 5.4(c). All royalty payments shall be non-refundable and non-creditable and not subject to set-off.

**5.5 Sublicense Revenue.** FBIO shall pay Cephalon an amount equal to the percentage of all Sublicense Revenue set forth in the table below. All such amounts shall be due to Cephalon within thirty (30) days after receipt of the applicable Sublicense Revenue. For any Sublicense Revenue that is achieved based upon a Milestone Event that is met by a Sublicensee, Cephalon shall receive \*. For the avoidance of doubt, where a Milestone Event is achieved by a Sublicensee, Cephalon shall not be entitled to both the Sublicense Revenue fee and the Milestone Payment.

<b>Sublicense Revenue (US Dollars)</b>	<b>Percentage Share</b>
*	*%
*	*%
*	*%
*	*%

**5 . 6 Notice.** FBIO shall give Cephalon written notice of any Sublicense Revenue received, First Commercial Sale of a Licensed Product, or Milestone achievement within thirty (30) days of the occurrence of each such event.

**5.7 Periodic Reports.** Within thirty (30) days after the end of each Calendar Quarter commencing from the earlier of (a) the First Commercial Sale of a Licensed Product; or (b) the grant of a Sublicense or receipt of Sublicense Revenue, FBIO shall furnish Cephalon with a quarterly report (“**Periodic Report**”) detailing, at a minimum, the following information for the applicable Calendar Quarter, each listed by Licensed Product and by country of sale: (i) the total number of units of Licensed Product sold by FBIO, its Affiliates and Sublicensees for which royalties are owed Cephalon hereunder, including a breakdown of the number and type of Licensed Products sold, (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified in Section 1.66, (iv) Net Sales, (v) royalties and Milestone Payments owed to Cephalon, listed by category, (vi) Sublicense Revenue received during the preceding Calendar Quarter and Sublicense fees due to Cephalon, (vii) the currency in which the sales were made, including the computations for any applicable currency conversions pursuant to Section 5.9, (viii) all other data enabling the Sublicense Revenue payable to be calculated accurately and (ix) a summary of progress against each commercial Milestone, and an estimate of the timing of the achievement of the next commercial Milestone. Once the events set forth in sub-section (a) or (b), above, have occurred, Periodic Reports shall be provided to Cephalon whether or not royalties, milestone payments or Sublicense fees are payable for a particular Calendar Quarter. In addition to the foregoing, upon Cephalon’s reasonable request, FBIO shall provide to Cephalon such other information as may be reasonably requested by Cephalon, and shall otherwise cooperate with Cephalon as reasonably necessary, to enable Cephalon to verify FBIO’s compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Cephalon under this Agreement and of all financial information provided or required to be provided in the Periodic Reports and Annual Reports.

\* Confidential material redacted and filed separately with the Commission.

**5.8 Payments.** Within thirty (30) days after the date prescribed for the submission of each Periodic Report, FBIO shall pay the royalties and Sublicense Revenue due to Cephalon for the reported period. All payments under this Agreement shall be computed and paid in United States Dollars. All Payments shall be made by wire transfer to such bank accounts as Cephalon may designate.

**5.9 Currency Exchange.** With respect to Net Sales invoiced in United States Dollars, the Net Sales and the amounts due to Cephalon hereunder shall be expressed in United States Dollars. With respect to Net Sales invoiced in a currency other than United States Dollars, the Net Sales shall be expressed in the domestic currency of the entity making the sale, together with the United States Dollars equivalent, calculated based on the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the Calendar Quarter for which remittance is made for Royalties. For purposes of calculating the Net Sales thresholds set forth in Section 5.3, the aggregate Net Sales with respect to each Calendar Quarter within a Calendar Year shall be calculated based on the currency exchange rates for the Calendar Quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

**5.10 VAT; Withholding and Similar Taxes.** All amounts to be paid to Cephalon pursuant to this Agreement are exclusive of Value Added Tax. FBIO shall add value added tax, as required by Law, to all such amounts. If applicable Laws require that taxes be withheld from any amounts due to Cephalon under this Agreement, FBIO shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) promptly deliver to Cephalon a statement including the amount of tax withheld and justification therefore, and such other information as may be necessary for tax credit purposes. FBIO shall cooperate with Cephalon in claiming exemptions from such deductions or a reduced withholding tax rate as allowable under any agreement or treaty from time to time in effect. Payment of Value Added Tax – or of any analogous foreign tax, charge or levy (if charged), applicable to the sale of Licensed Products shall be added to each payment in accordance with the statutory rate in force at such time.

**5.11 Records.** FBIO shall keep, and shall require its Affiliates and Sublicensees to keep, full and correct books of account in accordance with US GAAP enabling the royalties, Sublicense fees and Milestone Payments, and all corresponding deductions, to be calculated accurately. Starting from the first Calendar Year after the First Commercial Sale, or the first grant of a Sublicense, whichever occurs first, an annual report, authorized by the chief financial officer of FBIO, shall be submitted to Cephalon within sixty (60) days of the end of each Calendar Year, detailing Net Sales, Sublicense Revenues, royalties, Sublicense fees, and Milestone Payments both due and paid, including all other information included in the Periodic Report (the “**Annual Reports**”). FBIO shall, and shall require and cause its Affiliates and Sublicensees to, retain the such books of account for five (5) years after the end of each Calendar Year during the Term of this Agreement, and, if this Agreement is terminated for any reason whatsoever, for five (5) years after the end of the Calendar Year in which such termination becomes effective, and shall be kept at each of their principal place of business and shall be open for inspection and audit in accordance with Section 5.12 below.

**5.12 Audit.** Cephalon shall be entitled to appoint, at its sole expense, a certified public accountant or other professional as appropriate (the “CPA Representatives”) to inspect, not more than once a Calendar Year, during normal business hours FBIO’s and its Affiliates’ books and records contemplated by Section 5.11 above, including all books of account, records and other relevant documentation to the extent relevant or necessary for the sole purpose of verifying compliance with the payment and related obligations under this Agreement, the calculation of amounts due to Cephalon under this Agreement and of all financial information required to be provided in the Periodic Reports and Annual Reports, provided that Cephalon shall coordinate such inspection with FBIO or Affiliate (as the case may be) in advance. In addition, Cephalon may require that FBIO, through the CPA Representatives, inspect during normal business hours the books and records contemplated by Section 5.11 above, including all applicable books of account, records and other relevant documentation of any Sublicensees, not more than once a Calendar Year, to the extent relevant or necessary for the sole purpose of verifying the compliance with the payment obligations under this Agreement, the calculation of amounts due to Cephalon under this Agreement and of all financial information provided in the Periodic Reports, and FBIO shall use its best efforts to cause such inspection to be performed, provided that Cephalon shall coordinate such inspection with the Sublicensee in advance. The Parties shall reconcile any underpayment or overpayment within thirty (30) days after the CPA Representatives deliver the results of the audit to Cephalon and FBIO. The results of such inspection, if any, shall be binding on both Parties. Any underpayment shall be subject to interest in accordance with the terms of Section 5.14, below. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods during the Term, or if such overpayments are identified following the Term, then such overpayments shall be refunded within sixty (60) days of receipt of the corresponding audit results. In the event that any inspection as aforesaid reveals any underpayment by FBIO to Cephalon in respect of any Calendar Quarter of the Agreement in an amount exceeding five percent (5%) of the amount actually paid by FBIO to Cephalon in respect of such Calendar Quarter, then FBIO shall pay the cost of such inspection. Any underpayments or overpayments under this Section 5.12 shall be subject to the currency exchange provisions set forth in Section 5.9 as applied to the Calendar Quarter during which the payment obligations giving rise to such underpayment or overpayment were incurred by FBIO.

**5.13 Blocked Payments.** In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for FBIO to transfer, or have transferred on its behalf, payments owed Cephalon hereunder, FBIO shall promptly notify Cephalon of the conditions preventing such transfer and such payments shall be deposited in local currency in the relevant country to the credit of Cephalon in a recognized banking institution designated by Cephalon or, if none is designated by Cephalon within a period of thirty (30) days, in a recognized banking institution selected by FBIO, as the case may be, and identified in a written notice given to Cephalon.

**5.14 Interest Due.** Any sum of money due to Cephalon which is not duly paid on time shall bear interest from the due date of payment until the actual date of payment at the rate of LIBOR plus two percent (2%) per annum, or the maximum applicable legal rate, if less, computed for the actual number of days the payment was past due.

**5.15 Mutual Convenience.** The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Cephalon. FBIO hereby stipulates to the fairness and reasonableness of such royalty and other payments obligations and covenants not to allege or assert, nor to allow any of its Sublicensees or Affiliates to allege or assert, nor further to cause or support any other Third Parties to allege or assert, that any such royalty or other payments obligations are unenforceable or illegal in any way.

## **ARTICLE VI INTELLECTUAL PROPERTY**

### **6.1 Intellectual Property; Inventions.**

(a) The Parties acknowledge that the ownership rights set out in this Section 6.1 are subject to the terms and conditions of this Agreement (including the license grants and restrictions on licensing that are set forth in Article II).

(b) Cephalon shall own all right, title and interest in and to the Cephalon Patents and the Cephalon Know-How.

(c) The Parties agree that ownership of Know-How, patent rights or other intellectual property rights created or conceived through the performance of activities under this Agreement shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred).

(d) In furtherance of the foregoing, each Party shall, upon request by the other, promptly undertake and perform (and/or cause its Affiliates and its and their respective employees and/or agents to promptly undertake and perform) such further actions as are reasonably necessary for Cephalon and FBIO, as between the Parties, to each perfect its title in any such Know-How, patent rights or other intellectual property rights as set forth in the foregoing provisions of this Section 6.1, as applicable, including by causing the execution of any assignments or other legal documentation, and/or providing the other Party or its patent counsel with reasonable access to any employees or agents who may be inventors of such Know-How, patent rights or other intellectual property rights.

### **6.2 Patent Prosecution and Maintenance.**

( a ) **Cephalon Patents.** FBIO shall have the first right, and shall use Commercially Reasonable Efforts, to pursue the filing, prosecution, and maintenance of the Cephalon Patents. FBIO shall be solely responsible for all costs and expenses incurred by FBIO in filing, prosecuting and maintaining the Cephalon Patents in the Territory. FBIO and its chosen patent counsel, which shall be reasonably acceptable to Cephalon (“**Patent Counsel**”), shall take all actions reasonably requested by Cephalon and its patent counsel in connection with FBIO’s obligations under this Section 6.2(a) with respect to filing, prosecution, and maintenance, including without limitation, facilitating and permitting direct communication with Cephalon and its patent counsel.

(b) **New or Revised Applications.** FBIO shall, upon forming an intention to file or revise one or more patent applications which are Cephalon Patents subject to the license grants in Section 2.1, promptly inform Cephalon of such intention, and shall provide Cephalon with the opportunity to comment on the content of such FBIO patent application before so filing or revising. FBIO shall consider any such reasonable Cephalon comments in good faith.

(c) **Liaising.** FBIO shall provide Cephalon with a copy of all documents generated or received by FBIO or its attorneys in connection with the filing, prosecution and maintenance of the Cephalon Patents, including, but not limited to, briefs, office actions, examinations, correspondence, etc. FBIO shall keep Cephalon promptly and regularly informed of the course of the filing and prosecution of Cephalon Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and to reasonably take into consideration the advice and recommendations of Cephalon and its patent counsel, and FBIO shall authorize its Patent Counsel to speak directly with Cephalon and its patent counsel. In the course of providing comments as contemplated in this Section, if Cephalon expresses its reasonable disagreement with FBIO's proposed course of action, and Cephalon and FBIO are unable to reconcile their differences in an expeditious manner, the matter shall be resolved by a Third Party patent counsel mutually selected by the Parties who (and whose firm) is not, and was not at any time during the five (5) years prior to such dispute, an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party. Any decision by such Third Party patent counsel regarding any such dispute shall be made in a manner consistent, and not otherwise in conflict, with the terms of this Agreement. The Parties shall equally share in the costs and expenses of retaining such Third Party patent counsel for any such prosecution disputes.

(d) **Election Not to File/Prosecute/Maintain Cephalon Patents** Cephalon acknowledges and agrees that FBIO shall not be required to file, prosecute or maintain the Cephalon Patents. If FBIO provides Cephalon with written notification that it shall no longer support or pursue the filing, prosecution, or maintenance of a specified Cephalon Patent in a particular country, then (i) FBIO's responsibility for such filing, prosecution, or maintenance of such Cephalon Patent in such country, and the fees and costs related thereto, shall terminate on the date sixty (60) calendar days after Cephalon's receipt of such written notice from FBIO, and (ii) Cephalon shall have the right, but not the obligation, to assume control of, and responsibility for, the filing, prosecution, or maintenance of such Cephalon Patent in such country, at Cephalon's expense. In such event, such patent shall no longer be deemed a Cephalon Patent or subject to the licenses and rights set forth herein; provided, that if such patent is a composition of matter patent in such country, then all licenses and rights with respect to such country shall terminate as well.

**6 . 3 Listing of Patents.** FBIO shall have the sole right to determine which of the Cephalon Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication (known as the "Orange Book") pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, or any similar patent listing in any other country, in each case with respect to the Licensed Products. Cephalon shall co- operate with FBIO to list any of said Cephalon Patents with respect to the Licensed Products.

**6 . 4 Patent Term Extension.** If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country with respect to any Licensed Product becomes available, upon Regulatory Approval or otherwise, the Parties shall mutually agree on which issued patent to extend, and in any event, the Parties understand and agree that a Cephalon Patent shall be extended (including in the U.S. upon Regulatory Approval thereof), if possible, in lieu of any other patent right only if such Cephalon Patent would extend longer than such other patent right. In addition, the Parties shall seek the maximum patent term extension available for all Cephalon Patents in accordance with this Section 6.4. The prosecution activities related to the foregoing shall be governed by Section 6.1.

**6.5 Data Exclusivity.** With respect to data exclusivity periods (such as those periods listed in the Orange Book (including any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and all equivalents in any country), FBIO, in consultation with Cephalon, shall seek and maintain all such data exclusivity periods that may be available for any of the Licensed Products.

**6 . 6 Notification of Patent Certification.** Each Party shall notify and provide the other Party with copies of any allegations of alleged patent invalidity, unenforceability or non-infringement of a Cephalon Patent pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, an application under §505(b)(2) of the United States Federal Food, Drug, and Cosmetic Act (as amended or any replacement thereof), or any other similar patent certification by a Third Party, and any foreign equivalent thereof. Such notification and copies shall be provided to the other Party within five (5) days after such Party receives such certification, and shall be sent to the address set forth in Section 11.7.

**6 . 7 CREATE Act.** Notwithstanding anything to the contrary in this Agreement, each Party shall have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the “**CREATE Act**”) when exercising its rights under this Agreement, but only with the prior written consent of the other Party in its sole discretion. In the event that a Party intends to invoke the CREATE Act, once agreed to by the other Party as required by the preceding sentence, it shall notify the other Party and the other Party shall cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in the CREATE Act.

**6.8 Enforcement of Patents.**

(a) **Notice.** If either Cephalon or FBIO believes that a Cephalon Patent is being infringed by a Third Party with respect to compounds or products that target PARP (“**Competitive Infringement**”) or if a Third Party claims that any Cephalon Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement, misappropriation or claim that are known by such Party, together with any available written evidence of such alleged infringement, misappropriation or claim.

(b) **Action by FBIO.**

(i) FBIO shall have the first right, but not the obligation, in its own name and at its own expense to enforce the Cephalon Patents and prosecute apparent Third Party infringers when, in its judgment, such action may be reasonably necessary and justified with respect to Competitive Infringement.

(ii) FBIO has three (3) months from the date of receiving satisfactory written evidence from Cephalon of Competitive Infringement to decide whether to bring an action or proceeding to terminate the Competitive Infringement. FBIO shall give Cephalon written notice of its decision by the end of this three (3)-month period. If FBIO notifies Cephalon that it intends to prosecute the alleged infringer, then FBIO has three (3) months from the date of its notice to Cephalon to either (A) cause the Competitive Infringement to terminate or (B) initiate legal proceedings against the infringer. If any such suit is brought by FBIO in its own name, or jointly with Cephalon if required by law, it shall be at FBIO's sole cost and expense and on its own behalf. Cephalon shall reasonably assist FBIO in any action or proceeding being defended or prosecuted if so requested, and shall be named in or join such action or proceeding if requested by FBIO or if Cephalon so requests. FBIO shall bear all related and reasonable legal costs and expenses if Cephalon is required to be named in or joined in such action or proceeding or is joined in such action or proceeding at FBIO's request. Cephalon may participate in any such action or proceeding at its election and expense (other than as provided in the immediately preceding sentence), whether or not Cephalon is a named party to any such action or proceeding, and FBIO shall reasonably cooperate with Cephalon in such participation.

(c) **Action by Cephalon.**

(i) If FBIO notifies Cephalon within the first three (3)-month period that it does not intend to prosecute the Competitive Infringement or, if FBIO fails to cause the Competitive Infringement to terminate or bring legal action or proceeding to compel termination within three (3) months of the date of its notice to Cephalon (and in all events at least ten (10) days before the end of the applicable Hatch-Waxman Time Period, as defined below), then Cephalon may initiate legal actions or proceedings against the alleged Third Party infringer, in its own name and at its expense and entirely under its own direction and control, according to the terms of this Section 6.8(c). FBIO shall reasonably assist Cephalon in any action or proceeding being defended or prosecuted if so requested, and shall join such action or proceeding if requested by Cephalon. FBIO shall have the right to participate in any such action or proceeding with its own counsel at its own expense and without reimbursement. For purposes of this Agreement, "**Hatch-Waxman Time Period**" means the applicable period of time during which a patent holder or licensee has the right to file an infringement suit to maintain certain rights and privileges upon receipt of Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application or an application under § 505(b)(2) of the United States Food, Drug, and Cosmetic Act (as amended), or any other similar patent certification by a Third Party, or any foreign equivalent thereof.

(ii) Regardless of whether Cephalon is joined or joins any legal proceeding initiated by FBIO, no settlement, consent judgment or other voluntary final disposition of the legal action or proceeding may be entered into without the consent of Cephalon, which consent may not be unreasonably withheld or delayed.

**6.9 Cooperation.** If one party initiates legal actions or proceedings to enforce the Cephalon Patents against Competitive Infringement pursuant to this Article VI, the other party shall cooperate with and supply all assistance reasonably requested by the party initiating the actions or proceedings, at the initiating party's request and expense.

**6.10 Withdrawal.** If either Party brings an action or proceeding under Section 6.8 and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of Section 6.8.

**6.11 Damages.** In the event that either Party exercises the rights conferred in Section 6.8 and recovers any damages or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including attorney's fees), unless not reimbursable hereunder. If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party's costs shall be paid in full first before any of the other Party's costs. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be \*.

**6.12 Declaratory Judgment Actions.** In the event that any Third Party initiates a declaratory judgment action or other proceeding alleging the invalidity or unenforceability of any of the Cephalon Patents, or if any Third Party brings an infringement action or other proceeding against FBIO or its Affiliates or Sublicensees with respect to any Licensed Product, then FBIO shall have the right to defend such action or proceeding under its own control and at its own expense; provided, however, that the Parties shall mutually agree that Cephalon may assume control of such defense, at its own expense, if Cephalon in good faith believes that assuming control of such defense is beneficial to the Parties. Each Party shall notify the other immediately upon learning of any such action, proceeding, claim or demand. FBIO shall NOT enter into any settlement, consent judgment or other voluntary final disposition of any action or proceeding under this Section 6.12, including any action or proceeding which restricts the scope, or adversely affects the enforceability of any Cephalon Patents, without the prior written consent of Cephalon. Any recovery shall be first applied to reimburse each Party pro rata for any out-of-pocket expenses it may have incurred with respect to defense of such action and the remainder shall be retained entirely by the Party controlling the action; provided, however, that any recovery for infringement shall be distributed as described in Section 6.11.

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\* Confidential material redacted and filed separately with the Commission.



**6.13 Patent Marking.** FBIO shall mark, and shall cause all of its Affiliates and Sublicensees to mark, virtually or otherwise, all Licensed Products with all Cephalon Patents in accordance with applicable Law, which marking obligation shall continue for as long as required under applicable Law.

## ARTICLE VII CONFIDENTIALITY

**7.1 Definitions.** FBIO and Cephalon each recognizes that during the Term, a Party (the “**Disclosing Party**”) may disclose or provide Confidential Information (as defined herein) to the other Party (the “**Receiving Party**”). The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither FBIO nor Cephalon shall use the other’s Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, “**Confidential Information**” means all confidential or proprietary information (including information relating to the business, operations and products of a Party or any of its Affiliates), including Third Party information, disclosed or provided by the Disclosing Party to the Receiving Party or its Affiliates or Sublicensees, regardless of whether any of the foregoing are marked “confidential” or “proprietary” or communicated to the other by the disclosing Party or its Affiliates in oral, written, graphic, or electronic form.

**7.2 Obligation.** Each Receiving Party agrees that it shall disclose the Disclosing Party’s Confidential Information to its own (or its respective Affiliate’s, or with respect to FBIO, its Sublicensees’) officers, employees, consultants, representatives and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to and consistent with such responsibilities and rights hereunder. In addition, Receiving Party may disclose Confidential Information as follows (a) on a need-to-know basis to such party’s legal and financial advisors; (b) as reasonably necessary in connection with an actual or potential (i) permitted Sublicense of such Party’s rights hereunder, (ii) debt or equity financing of the Receiving Party, or (iii) acquisition, consolidation, share exchange or other similar transaction involving the Receiving Party and any Third Party; (c) to the extent the Receiving Party is FBIO, to any Third Party that is or may be engaged by FBIO to perform services in connection with the Development, Manufacture or Commercialization of License Products as necessary to enable such Third Party to perform such services; and (d) as reasonably necessary to make regulatory filings with respect to the Licensed Products or to respond to any inquiry made by a Regulatory Authority with respect to Licensed Products and to prosecute or maintain patent rights, or to file, prosecute or defend litigation related to patent rights. Except as set forth in the foregoing sentence, the Receiving Party shall not disclose Confidential Information of the Disclosing Party to any Third Party without the Disclosing Party’s prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Receiving Party shall use Confidential Information of the Disclosing Party except as expressly allowed by and for the purposes of this Agreement. Each Receiving Party shall take such action to preserve the confidentiality of the Disclosing Party’s Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Receiving Party, upon the Disclosing Party’s request, shall return or destroy (at Disclosing Party’s discretion) all the Confidential Information disclosed to the Receiving Party pursuant to this Agreement, including all copies and extracts of documents, within sixty (60) days after the request, except for one archival copy (and such electronic copies that exist as part of the Receiving Party’s computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

**7.3 Exceptions.** The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

- (a) at the time of disclosure is in the public domain;
- (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees (including any Affiliates or Sublicensees);
- (c) is made available to the Receiving Party by an independent Third Party without an obligation of confidentiality with respect to such information; or
- (d) is independently developed by the Receiving Party without access, use or reference to the Disclosing Party's information.

In addition, the Receiving Party may disclose Confidential Information that is required to be disclosed by Law, by a valid order of a court or by order or regulation of a governmental agency, including but not limited to, regulations of the SEC, FTC, or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

**7.4 Terms of this Agreement.** The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and may only be disclosed as permitted by this Article VII.

**7.5 Publicity; Publications.** The Parties, upon the execution of this Agreement, shall jointly issue a press release with respect to this Agreement and such press release shall be in substantially the form set forth as Exhibit A attached hereto with the final version subject to the mutual agreement of the Parties. Either Party may make subsequent public disclosure of the contents of such press release without further approval of the other Party. Subject to the foregoing, except as required by applicable Laws (including those relating to disclosure of material information to investors), neither Party shall issue a press or news release or make any similar public announcement (it being understood that publication in scientific journals, presentation at scientific conferences and meetings and the like are not subject to this Section 7.5) related to the terms or existence of this Agreement or the conduct of the Development program or the Commercialization of Licensed Products without the prior written consent of the other Party (a **“Required Disclosure”**). For all such Required Disclosures the Party making the Required Disclosure shall use best efforts to (a) provide the other Party with notice and a copy of such proposed disclosure as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, and (b) provide the other Party a reasonable opportunity to request confidential treatment or review and comment on such communications. Notwithstanding anything to the contrary herein, if a Party seeking to make a disclosure required by applicable Law as set forth in this Section 7.5, and the other Party provides comments, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith (i) consider incorporating such comments and (ii) use reasonable efforts to incorporate such comments, limit disclosure or obtain confidential treatment to the extent reasonably requested by the other Party. Once any press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. Neither Party shall use the name of the other Party or its Affiliates in relation to this transaction in any public announcement, press release, publication or other public document without the prior written consent of such other Party; provided, however, that either Party may use the name of the other Party in any document filed with any Governmental Body or as otherwise permitted under this Agreement, including in this Article VII; provided further that FBIO may use the name and any logo of Cephalon to identify Cephalon as a partner of FBIO on any website of FBIO in a manner agreed to in writing in advance of such use by Cephalon. Without limiting the foregoing, FBIO shall use reasonable efforts to provide Cephalon with a copy (to the attention of “Alliance Management” pursuant to Section 11.7) of each abstract, presentation, manuscript and similar materials intended to be published or presented by FBIO or its Affiliates or Sublicensees in any medium or forum within ten (10) Business Days of publishing or presenting such materials.

**7.6 Survival.** The provisions of this Article VII shall survive expiry or termination of this Agreement for a period of ten (10) years thereafter.

## **ARTICLE VIII REPRESENTATIONS, WARRANTIES AND COVENANTS**

**8 . 1 Representations and Warranties.** (a) FBIO represents and warrants to Cephalon, and (b) Cephalon represents to FBIO, in each case as of the Effective Date:

- (a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;
- (b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;
- (c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this

Agreement;

(d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles;

(e) To the best of such Party's knowledge, the execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;

(f) To the best of such Party's knowledge, all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not violate any Law of any Governmental Body having authority over such Party;

(g) No person or entity has or shall have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and

(h) To the best of such Party's knowledge, no agreement between it and any Third Party is in conflict with the rights granted to any other Party pursuant to this Agreement.

**8.2 Additional Representations and Warranties of Cephalon.** Cephalon represents and warrants to FBIO as of the Effective Date that:

(a) No consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Cephalon or the consummation by Cephalon of the transactions contemplated hereby;

(b) Cephalon or its Affiliates exclusively own all right, title and interest in and to the Cephalon Patents. Schedule 1 attached hereto contains a true and complete list of patents and patent applications Controlled by Cephalon and its Affiliates as of the Effective Date that exclusively relate to the Licensed Compound;

(c) Cephalon has full right and authority to grant the licenses set forth in Section 2.1 and it has not granted or conferred upon or undertaken to grant to or confer upon any person, with or without consideration, and there are no outstanding options, licenses, rights or agreements of any kind which grant any rights relating to the Cephalon Technology, and has not undertaken to grant any Third Party with any rights in any of the above, in each case, that would conflict with or limit the scope of any of the rights or licenses granted to FBIO hereunder.

(d) To Cephalon's knowledge, there is no Third Party that is infringing or misappropriating the Cephalon Technology.

(e) No action, claim, proceeding or inquiry or investigation is pending or, to the knowledge of Cephalon, threatened by any Third Party with respect to the patentability or validity of any claims of any of the Cephalon Patents.

(f) To Cephalon's knowledge, the Development and Commercialization of the Licensed Compounds do not infringe any patent rights of a Third Party that may have rights which conflict or interfere with the grant to, or exercise of the licenses set forth in Section 2.1 by, FBIO as envisaged herein.

(g) \*.

**8 . 3 Disclaimer.** Notwithstanding the representations and warranties set forth in this Article VIII, FBIO acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Licensed Compounds or Licensed Products can be successfully Developed or Commercialized.

**8 . 4 EXCEPT AS EXPRESSLY SET FORTH HEREIN, CEPHALON DOES NOT MAKE ANY REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY CEPHALON PATENT OR CEPHALON KNOW-HOW, ANY LICENSED COMPOUND, OR ANY LICENSED PRODUCTS, INCLUDING ANY WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE OR NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.**

#### ARTICLE IX INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

**9 . 1 Indemnification by FBIO.** FBIO shall indemnify, defend and hold Cephalon and its Affiliates and each of their respective employees, officers, directors and agents (each a "**Cephalon Indemnitee**") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any Third Party claim, demand, action or other proceeding (each, a "**Claim**") arising out of or resulting from (a) the Development, Manufacture, Commercialization (including testing, handling, storage, transportation, sale or use or other disposition) of any Licensed Compound or Licensed Product; (b) FBIO's or its Affiliates' and Sublicensees' use or practice of the Cephalon Technology; (c) breach by FBIO of any of its representations, warranties, covenants or obligations set forth in this Agreement, or (d) FBIO's or its Affiliates' and Sublicensees' gross negligence, recklessness or willful misconduct; provided, however, that FBIO's obligations pursuant to this Section 9.1 shall not apply to the extent such Claims are subject to Cephalon's indemnification obligations set forth in Section 9.2.

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\* Confidential material redacted and filed separately with the Commission.

**9.2 Indemnification by Cephalon.** Cephalon shall indemnify, defend and hold FBIO and its Affiliates and each of their respective agents, employees, officers and directors (each a “**FBIO Indemnitee**”) harmless from and against any and all Claims arising out of or resulting from (a) breach by Cephalon of its representations, warranties, covenants or obligations set forth in this Agreement, or (b) Cephalon’s or its Affiliates’ and Sublicensees’ gross negligence, recklessness or willful misconduct; provided, however, that Cephalon’s obligations pursuant to this Section 9.2 shall not apply to the extent such Claims are subject to Cephalon’s indemnification obligations set forth in Section 9.1.

**9.3 Procedure.**

( a ) The Party or other Person intending to claim indemnification under this Article IX (an “**Indemnified Party**”) shall promptly notify the opposed Party (the “**Indemnifying Party**”) of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party shall relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. For clarity, in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.

(b) If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

(c) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the rights of any person by an Indemnified Party, no requirement that the Indemnified Party admit negligence, fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

( d ) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

(e) Regardless of who controls the defense, each Party hereto shall reasonably cooperate in the defense as may be requested.

**9.4 Expenses.** As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Article IX shall also be reimbursed by the Indemnifying Party...

**9.5 Limitation of Liability.** IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES ARISING OUT OF A BREACH OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 9.1 AND 9.2, A PARTY'S OR ITS AFFILIATES' DIRECT OR INDIRECT VIOLATION OF THE SCOPE OF EXCLUSIVE RIGHTS GRANTED TO FBIO HEREUNDER OR EITHER PARTY'S LIABILITY FOR A BREACH OF Article VII.

**9.6 Insurance.** During the Term and for at least two (2) years thereafter, FBIO shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such insurance shall insure against all liability, including but not limited to, bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of any Licensed Compounds or Licensed Products. Such insurance shall include commercial general liability insurance, including product liability insurance, which coverage shall have limits of liability which are commercially reasonable for a U.S. pharmaceutical company of comparable activity. The coverage limits set forth herein will not create any limitation on FBIO's liability to Cephalon under this Agreement.

## **ARTICLE X TERM AND TERMINATION**

**10.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. The "Term" means the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term. The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Cephalon Patents have expired or been invalidated.

**10.2 Termination upon Material Breach.** If a Party breaches any of its material obligations under this Agreement, the Party not in breach may give to the breaching Party a written notice specifying the nature of the breach, requiring it to cure such breach, and, if desired, stating its intention to terminate this Agreement if such breach is not cured. If such breach is not capable of being cured, or is capable of being cured but nonetheless has not within ninety (90) days after the receipt of such notice been cured, then the Party not in breach shall (in addition to and not in lieu of all other available rights and remedies) be entitled to at its option either (a) terminate this Agreement immediately by written notice to the other Party, or (b) continue this Agreement in full force and effect and seek any legal or equitable remedies that the non-breaching Party may have. Notwithstanding the foregoing provisions, in the event of a good-faith dispute as to whether any alleged breach is in fact a material breach, termination under this Section 10.2 in respect of such alleged breach shall not take effect unless and until such dispute is finally resolved (by the final unappealable decision of a court or arbitrator or otherwise) in favor of the Party alleging the breach. In case of a breach of an obligation to pay money, which obligation to pay is not disputed in good faith, the cure period shall be sixty (60) days instead of ninety (90) days.

**10.3 Termination by Cephalon for Cause.** Cephalon may terminate this Agreement by delivering written notice to FBIO, such termination to be effective upon ninety (90) days following the date of such notice, in the event of any of the following:

- (a) FBIO fails to commence a \* for a Licensed Product prior to the \* of the Effective Date; or
- (b) FBIO fails to commence at least \* for the Licensed Products in at least \* Indications.

**10.4 Termination by Cephalon for Patent Challenge.**

( a ) Cephalon will have the right to terminate this Agreement in full upon written notice to FBIO in the event that FBIO or any of its Affiliates or Sublicensees directly or indirectly asserts a Patent Challenge; provided, that with respect to any such Patent Challenge by any non-Affiliate Sublicensee, Cephalon will not have the right to terminate this Agreement under this Section 10.4(a) if FBIO (i) causes such Patent Challenge to be terminated or dismissed or (ii) terminates such Sublicensee's Sublicense to the Cephalon Patents being challenged by the Sublicensee, in each case within sixty (60) days of Cephalon's notice to FBIO under this Section 10.4(a). In the event FBIO or any of its Affiliates intends to assert a Patent Challenge in any forum, not less than sixty (60) days prior to making any such assertion, FBIO will provide to Cephalon a complete written disclosure of each basis known to FBIO and its Affiliates for such assertion.

(b) FBIO acknowledges and agrees that this Section 10.4 is reasonable, valid and necessary for the adequate protection of Cephalon's interest in and to the Cephalon Patents, and that Cephalon would not have granted to FBIO the licenses under the Cephalon Patents, without this Section 10.4. Cephalon will have the right, at any time in its sole discretion, to strike this Section 10.4 (or any portion thereof) from this Agreement, and Cephalon will have no liability whatsoever as a result of the presence or absence of this Section 10.4 (or any struck portion thereof).

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\* Confidential material redacted and filed separately with the Commission.



**10.5 Termination for Bankruptcy.** Cephalon may terminate this Agreement immediately upon written notice to FBIO in the event that FBIO has a petition in bankruptcy filed against it that is not dismissed within sixty (60) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. FBIO may terminate this Agreement immediately upon written notice to Cephalon in the event that Cephalon has a petition in bankruptcy filed against it that is not dismissed within sixty (60) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.

**10.6 Termination by FBIO.** FBIO may terminate this Agreement in its entirety without cause at any time upon at least one-hundred eighty (180) days prior written notice to Cephalon, provided that FBIO has paid to Cephalon all amounts due and payable up to the effective date of termination.

**10.7 Effect of Termination.**

(a) **No release.** Upon expiration or termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any liability or obligation that accrued or matured prior to the effective date of the expiration or termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

(b) **Survival.** The provisions of 5.8 (with respect to payments which accrued prior to the effective date of termination), 5.9, 5.10, 5.11, 5.12, 5.13, 5.14 and 10.7 and Articles 7, 9 and 11 shall survive termination or expiration of this Agreement.

(c) **Consequences.** In the event of termination pursuant to Sections 10.2, 10.3, 10.4, 10.5 or 10.6:

(i) **Wind-down.** Except as may otherwise be agreed in writing by the Parties, FBIO will be responsible at its own expense for an orderly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, of any then on-going clinical trials hereunder for which it has responsibility.

(ii) **Inventory.** At Cephalon's election, either (A) FBIO or its Affiliate(s) or Sublicensees will sell to Cephalon all inventory of Licensed Compounds or Licensed Products in FBIO's (or its Affiliate's or Sublicensees') possession, and in connection therewith, Cephalon shall pay to FBIO \*, or (B) FBIO, any Affiliate(s) and any Sublicensees may, after the effective date of termination, for a period of six (6) months sell all Licensed Products that are in inventory as of the date of written notice of termination, provided that FBIO shall pay to Cephalon \*. From and after the date of any notice of termination until the effective date of termination, FBIO shall not participate in any activity of the type sometimes referred to as "channel stuffing" or that would result in an increase, temporary or otherwise, in the demand for any Licensed Product in the Field in the Territory prior to such date.

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(iii) *Licenses.* All licenses and other rights granted by Cephalon to FBIO hereunder will terminate and such licenses and other rights will revert to Cephalon, and FBIO and its Affiliates and Sublicensees will have no further rights to use any Cephalon Technology (except as expressly set forth in Sections 10.7(c)(i), 10.7(c)(ii) and 10.7(c)(iv)). Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party's Confidential Information and any materials, Cephalon Technology, Licensed Compounds and Licensed Products provided by or on behalf of such other Party hereunder that are in such Party's (or its Affiliates' or in the case of FBIO's Sublicensees') possession or control, save that such Party will have the right to retain (A) one (1) copy of intangible Confidential Information of such other Party for legal purposes, and (B) any of the foregoing that such Party retains any license or other right hereunder. FBIO and its Affiliates and Sublicensees will cease to Develop, Manufacture or Commercialize any Licensed Compounds and Licensed Products and cease all use and practice of the Cephalon Technology.

(iv) *Sublicenses.* Upon termination of this Agreement by FBIO pursuant to Sections 10.2 or 10.6, or by Cephalon pursuant to Sections 10.2, 10.3, 10.4 or 10.5, and FBIO or an Affiliate has granted a Sublicense that is in effect as of such termination and provided that such Sublicensee is not in material breach of such Sublicense as of such termination, then \*.

(v) *Regulatory.* At Cephalon's election, all Regulatory Approvals, Regulatory Filings, regulatory documents and regulatory communications owned (in whole or in part) or otherwise controlled by FBIO and its Affiliates and Sublicensees concerning any Licensed Compounds or Licensed Products will be assigned to Cephalon, and FBIO will provide to Cephalon one (1) copy of the foregoing and all documents contained in or referenced in any such items, together with the raw and summarized data for any clinical trials (and where reasonably available, electronic copies thereof). In the event of failure to obtain assignment, FBIO hereby consents and grants to Cephalon the right to access and reference (without any further action required on the part of FBIO, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item. During the three (3) month period following the effective date of any such termination, FBIO shall cooperate with Cephalon in order to ensure the orderly transfer of such Regulatory Approvals, Regulatory Filings, regulatory documents, regulatory communications and data to Cephalon's personnel.

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(vi) *Transition Assistance.* At Cephalon's election, FBIO and its Affiliates and Sublicensees shall reasonably cooperate with Cephalon and its designees to facilitate a smooth, orderly and prompt transition to Cephalon or its designees of its activities with respect to Licensed Compounds and Licensed Products, including any ongoing Development, Manufacturing and Commercialization of Licensed Compounds and Licensed Products, and including any litigation described in Sections 6.8 or 6.12, for a period agreed to by the Parties (not to exceed twelve (12) months after the Term); provided that the transition of any litigation described in Sections 6.8 or 6.12 may be transitioned from FBIO to Cephalon, upon Cephalon's written request, prior to the effective date of termination upon the mutual agreement of the Parties, such agreement not to be unreasonably withheld, conditioned or delayed. During the pendency of any transition, FBIO will cooperate in good faith with Cephalon regarding any litigation under Sections 6.8 or 6.12 and will not take any action in such actions that would reasonably be expected to have a material adverse effect on any Licensed Product. In connection with the transfer of activities under this Section 10.7(c) (vi), the Parties will develop and agree upon a written plan to effect such transition. For a period agreed to by the Parties (not to exceed six (6) months after the Term), in the event that FBIO or its Affiliates or Sublicensees has a manufacturing site for the Licensed Products and only if an assignment under Section 10.7(vii) is not possible or successful, FBIO or its Affiliates or Sublicensees shall manufacture and supply Licensed Products to Cephalon at FBIO's fully-burdened manufacturing cost.

(vii) *Manufacturing.* At Cephalon's election, FBIO will use reasonable efforts to assign to Cephalon or its designee all then-existing Manufacturing contracts with Third Party contract manufacturers in connection with the Manufacture of any Licensed Compounds and Licensed Products. After such assignment, Cephalon will be solely responsible for the performance of the obligations under such Manufacturing contracts.

(viii) *Additional Studies Clinical Data.* At Cephalon's election, promptly after the effective date of termination, FBIO shall transfer a true and complete copy of all clinical data, results and reports that (a) are owned or controlled by FBIO as of the effective date of termination, and (ii) was created by or on behalf of FBIO and its Affiliates or Sublicensees following the Effective Date but prior to the effective date of termination as a result of any clinical trials in the Territory and under and pursuant to this Agreement, and (iii) are necessary or reasonably useful for Cephalon and its Affiliates to develop, manufacture and commercialize Licensed Compounds or Licensed Products in the Territory following the effective date of termination ("**Additional Studies Clinical Data**"). Effective from and after the effective date of termination, FBIO and its Affiliates hereby grant to Cephalon and its Affiliates worldwide, perpetual and irrevocable, nontransferable (except in connection with a permitted assignment of this Agreement in accordance with Section 11.2), exclusive license, with the right to grant sublicenses through multiple tiers, under the Additional Studies Clinical Data solely to develop, manufacture and commercialize such Licensed Compounds or Licensed Products in the Field in the Territory after the effective date of termination.

(ix) *Reversion IP.* At Cephalon's election, FBIO hereby grants (without any further action required on the part of Cephalon), and agrees to grant to Cephalon and its Affiliates a worldwide, perpetual and irrevocable, nontransferable (except in connection with a permitted assignment of this Agreement in accordance with Section 11.2) license (the "**Reversion License**"), with the right to grant sublicenses through multiple tiers, in the Territory, under all Reversion IP that (A) is Controlled by FBIO (or any of its Affiliates or Sublicensees) as of the date of notice of termination, (B) is actually used or incorporated in any Licensed Compounds or Licensed Products as of the date of notice of termination, and (C) only to the extent necessary to Develop, Manufacture and Commercialize, and for the sole purpose of Developing, Manufacturing, and Commercializing, in each case, any Licensed Compounds or Licensed Products; in all cases in the Territory and in the Field. It is understood and agreed that with respect to any Reversion IP that is in-licensed by FBIO or any of its Affiliates or Sublicensees, Cephalon will be responsible for any payments due to a Third Party with respect thereto and Cephalon's rights will be subject to the terms of the applicable Third Party agreement. The Reversion License will be exclusive (even as to FBIO) with respect to Reversion IP that is first created, conceived or made by or on behalf of FBIO or any of its Affiliates or Sublicensees during the conduct of the Development, Manufacture or Commercialization of any Licensed Compounds or Licensed Products under this Agreement, and will be otherwise non-exclusive, but in all cases is limited solely to the Development, Manufacture and Commercialization of any Licensed Compounds or Licensed Products, as provided in the immediately preceding sentences. At Cephalon's written request, the Parties will enter into commercially reasonable prosecution, maintenance, enforcement and defense terms for the exclusively licensed Reversion IP, and Cephalon will bear the costs of such prosecution, maintenance, enforcement and defense activities to the extent controlled by Cephalon. For purposes hereof, "**Reversion IP**" means any patent rights or Know-How Controlled by FBIO or any its Affiliates or Sublicensees that claim or cover any Licensed Compounds or Licensed Products (subject to the last sentence of this Section 10.7(c)(ix)), or their method of manufacture or use, as such patent rights or Know-How exist as of the date of notice of termination (including any other patent right that claims priority, directly or indirectly, to any such patent right, no matter when any such other patent right is filed or issued). Notwithstanding anything to the contrary herein, in no event will any product owned or Controlled by FBIO or its Affiliates or Sublicensees (other than, for clarity, any Licensed Compounds or Licensed Products (i.e., excluding Combination Products)) be included or subject to the license set forth in this Section 10.7(c)(ix).

(x) *Royalty to FBIO.* In the event of termination of this Agreement by FBIO pursuant to Sections 10.2, or 10.6, after \*, then upon Cephalon's election of the rights set forth in Section 10.7(v), Section 10.7(viii) or Section 10.7(ix), Cephalon shall pay to FBIO a royalty of \* percent (\*%) on aggregate annual worldwide net sales of all Licensed Products sold by Cephalon and its Affiliates in the Territory in a Calendar Year for a period of five (5) years after the First Commercial Sale of a Licensed Product, subject to a maximum royalty payment equal to (A) if such termination is effective prior to receipt of FDA or EMA approval of an NDA for a Licensed Product for the treatment of the first Indication, \* percent (\*%) \* incurred by FBIO of such Licensed Products prior to the effective date of such termination, or (B) if such termination is effective after receipt of FDA or EMA approval of an NDA for a Licensed Product for the treatment of the first Indication, \* percent (\*%) \* incurred by FBIO of such Licensed Products prior to the effective date of such termination. As it relates to the royalty due FBIO, Cephalon (and its Affiliates) shall comply with the same royalty reporting and audit requirements as detailed in this Agreement. For clarity, no royalty shall be owed by Cephalon in the event of (A) any termination of this Agreement by Cephalon pursuant to Sections 10.2, 10.3, 10.4, or 10.5 or by FBIO pursuant to Section 10.5, or (B) any termination of this Agreement \*, and in each case (clauses (A) or (B)), the rights set forth in Section 10.7(v), Section 10.7(viii) and Section 10.7(ix) shall be royalty-free and fully paid-up.

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\* Confidential material redacted and filed separately with the Commission.

(xi) *Third Party Agreements.* At Cephalon's election, FBIO agrees to discuss in good faith and reasonably cooperate with Cephalon with respect to the assignment and transfer to Cephalon of FBIO's and its Affiliates' right, title and interest in and to any agreements between FBIO or any of its Affiliates and Third Parties that relate solely to the Development, Manufacture or Commercialization of any Cephalon Technology or Licensed Compounds or Licensed Products (including any Third Party licenses or sublicenses) and for any such agreement that does not relate solely to the Development, Manufacture or Commercialization of Cephalon Technology or Licensed Compounds or Licensed Products, the assignment (or license, if applicable) to Cephalon of only such portions of such agreements relating thereto. After such assignment, Cephalon will be solely responsible for the performance of the obligations under such contracts.

(xii) *Trademarks.* At Cephalon's election, FBIO will assign (or, if applicable, will cause its Affiliates or Sublicensees to assign) to Cephalon all of FBIO's (and such Affiliates' or Sublicensees') worldwide right, title and interest in and to any registered or unregistered trademarks or internet domain names that are specific to and solely used for any Licensed Products (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of FBIO or any of its Affiliates or Sublicensees).

**10.8 Bankruptcy Code.** All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of applicable law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code or analogous provisions of applicable law outside the United States, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Cephalon Technology or Reversion IP and all embodiments of such Cephalon Technology or Reversion IP (as applicable), which, if not already in such Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the other Party's written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of such Party upon written request therefor by the other Party. Any agreements supplemental hereto shall be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

**ARTICLE XI  
MISCELLANEOUS PROVISIONS**

**11.1 Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

**11.2 Assignment.**

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) FBIO may not delegate, transfer or assign its rights or obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of Cephalon, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, FBIO may assign its rights or licenses and/or delegate its obligations in whole or in part under this Agreement to an Affiliate or in connection with a Change of Control. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to Cephalon and signed by a duly authorized officer of the assignee (and in a form reasonably acceptable to Cephalon) all of FBIO's obligations under this Agreement, whether arising before, at or after the assignment.

(c) Cephalon may delegate, sell, transfer or assign its rights or obligations under this Agreement, in whole or part, to an Affiliate, any Third Party or in connection with a Change of Control. Further, Cephalon may sell, transfer or assign its rights to any Third Party to receive payments under Article V, and Cephalon may disclose Confidential Information of FBIO to one or more Third Parties in connection with any such assignment to enable the Third Parties to evaluate and monitor any such purchase, provided that such Third Parties are subject to confidentiality obligations consistent with those set forth in Article VII.

(d) Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall be binding on the Parties and their successors and permitted assigns.

**11.3 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**11.4 Force Majeure.** No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

**11.5 Entire Agreement of the Parties; Amendments.** This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized representative of each Party.

**11.6 Governing Law; Consent to Jurisdiction.** All disputes, claims or controversies arising out of this Agreement, or the negotiation, validity or performance of this Agreement, or the transactions contemplated hereby shall be governed by and construed in accordance with the laws of the State of New York without regard to its rules of conflict of laws. Each of the parties hereto hereby irrevocably and unconditionally consents to submit to the sole and exclusive jurisdiction of the courts of the State of New York and of the United States of America located in the State of New York (the "**New York Courts**") for any litigation among the parties hereto arising out of or relating to this Agreement, or the negotiation, validity or performance of this Agreement, waives any objection to the laying of venue of any such litigation in the New York Courts and agrees not to plead or claim in any New York Court that such litigation brought therein has been brought in any inconvenient forum or that there are indispensable parties to such litigation that are not subject to the jurisdiction of the New York Courts. To the extent that it may otherwise be applicable, the Parties hereby expressly agree to exclude from the operation of this Agreement the United Nations Convention on Contracts for the International Sale of Goods, concluded at Vienna, on 11 April 1980, as amended and as may be amended further from time to time.

**11.7 Notices and Deliveries.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, or by express or overnight courier service to the Party to which it is directed at its physical address shown below or such other physical address as such Party shall have last given by such written notice to the other Party.

If to FBIO, addressed to:

Fortress Biotech, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019  
Attention: Michael S. Weiss, Executive Chairman  
Email: msw@opuspointpartners.com

With a copy to:           Foley & Lardner LLP  
3000 K Street, NW, Suite 600  
Washington, DC 20007  
Attention: Gilberto M. Villacorta

If to Cephalon, addressed to:

Cephalon, Inc.  
41 Moores Road, Frazer, PA 19355  
Attention: Head of Alliance Management

With a copy to:           Teva Pharmaceuticals  
425 Privet Road, Horsham, PA 19044  
Attention: General Counsel

and

Goodwin Procter LLP  
53 State Street, Boston, MA 02109  
Attention: Robert M. Crawford

**11.8 Waiver.** No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized representative of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

**11.9 Rights and Remedies are Cumulative.** Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

**11.10 Severability.** This Agreement is severable. When possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.



**11.11 Third Party Beneficiaries** Except for the rights of Indemnified Parties pursuant to Article IX hereof, the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other Person.

**11.12 No Implied License.** No right or license is granted to FBIO hereunder by implication, estoppel, or otherwise to any Know-How, patent or other intellectual property right owned or controlled by Cephalon or its Affiliates, except by an express license granted hereunder. No right or license is granted to Cephalon hereunder by implication, estoppel, or otherwise to any Know-How, patent or other intellectual property right owned or controlled by FBIO or its Affiliates, except by an express license granted hereunder.

**11.13 Equitable Relief.** Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which shall be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

**11.14 Interpretation.** The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

**11.15 Construction.** The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein will be construed as referring to such Laws as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person's permitted successors and assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (e) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided, will be construed to refer to Articles, Sections, and Schedules of this Agreement.

**11.16 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, shall be deemed an original.

*[the remainder of this page has been left blank intentionally]*

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed and delivered by their respective duly authorized representatives as of the day and year first above written.

**FORTRESS BIOTECH, INC.**

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: Executive Vice Chairman

**CEPHALON, INC.**

By: /s/ Ivana Magovcevic-Liebisch

Name: Ivana Magovcevic-Liebisch

Title: SVP, Global Business Development

By: /s/ Michele Holcomb

Name: Michele Holcomb

Title: SVP, COO Global R&D

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Signature Page

**EXHIBIT A**

Joint Press Release

*See Attached*

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Schedule 1

Cephalon Patents

Teva Ref.	Country	Title	Status	Appl. No.	Appl. Date	Publ. No.	Publ. Date	Grant No.	Grant Date	Expected Expiry Date	Notes
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\* Confidential material redacted and filed separately with the Commission.

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\* Confidential material redacted and filed separately with the Commission.

**Schedule 2**

**Initial Development Plan**

Phase 1:

Duration: \*

\*

Phase 2:

Duration: \*

\* Tentatively, the key features of the planned Phase 2 study would be as follows:

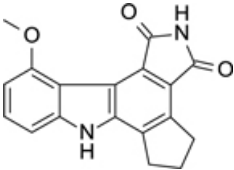
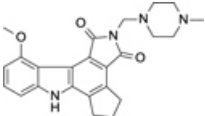
Study design	*
Clinical sites	*
Principal Investigators	*
Patient populations	*
Treatment arms	*
Number of patients	*
* dose level	*
Primary endpoints	1. *
	2. *
	3. *
	4. *
	5. *

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\* Confidential material redacted and filed separately with the Commission.

Schedule 3

Licensed Compounds

Structure	CEP #	Name (From CAS Scifinder)
	CEP-8983	11-methoxy-4,5,6,7-tetrahydro-1H-cyclopenta[a]pyrrolo[3,4-c]carbazole-1,3(2H)-dione
	CEP-9722	4,5,6,7-tetrahydro-11-methoxy-2-[(4-methyl-1-piperazinyl)methyl]-1H-cyclopenta[a]pyrrolo[3,4-c]carbazole-1,3(2H)-dione

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

OPTION AGREEMENT

This Option Agreement (the "Agreement") dated as of March 17, 2015 (the "Effective Date"), is entered into by and between Fortress Biotech, Inc. ("Fortress"), a Delaware Corporation having a place of business at 3 Columbus Circle, 15<sup>th</sup> Floor, New York, NY 10019, and TG Therapeutics, Inc. ("TG"), a Delaware Corporation having a place of business at 3 Columbus Circle, 15<sup>th</sup> Floor, New York, NY 10019, with respect to the following:

**WHEREAS**, Fortress entered into a license agreement (the "License Agreement") with NeuPharma, Inc. ("NeuPharma") dated as of March 17, 2015, pursuant to which Fortress licensed certain intellectual property rights with respect to Compounds and owns or controls certain know-how, technology, documentation, data, and other materials relating thereto; Capitalized terms used herein but not otherwise defined herein shall have the meanings ascribed to such terms in the License Agreement;

**WHEREAS**, Fortress wishes to grant, and TG wishes to receive, an option to enter into a global collaboration in the Territory for such intellectual property rights with respect to the Compounds and the know-how, technology, documentation, data, and other materials relating thereto, all on the terms and subject to the conditions set forth in this Agreement;

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

1. Definitions.

For purposes of this Agreement, the following terms shall have the following meanings:

- 1.1. "Confidential Information" shall mean, with respect to a party, all information (and all tangible and intangible embodiments thereof), which is owned or controlled by such party, and is disclosed by such party to the other party in connection with this Agreement (whether prior to or following the Effective Date). Notwithstanding the foregoing, Confidential Information of a party shall not include information which, and only to the extent that, the receiving party (the "Recipient") can demonstrate that (a) the disclosed information was public knowledge at the time of such disclosure to the Recipient, or thereafter became public knowledge, other than as a result of actions of the Recipient in violation hereof; (b) the disclosed information was rightfully known by the Recipient (as shown by its written records) prior to the date of disclosure to the Recipient by the other party without a duty of confidentiality to any party; (c) the disclosed information was disclosed to the Recipient on an unrestricted basis from a source unrelated to any party to this Agreement and not under a duty of confidentiality to the other party; or (d) the disclosed information was independently developed by the Recipient without use of the Confidential Information disclosed by the other party.
-

- 1.2. “Collaboration Agreement” shall mean a definitive global collaboration agreement between the parties, in a form mutually acceptable to the parties and incorporating the terms and conditions set forth in Exhibit A.
- 1.3. “Field” all prophylactic, palliative, therapeutic or diagnostic uses in humans or animals for the prevention, diagnosis and treatment of hematological malignancies, including, without limitation, all Leukemia’s, Lymphoma’s, Multiple Myeloma and Waldentroms Macroglobulemia. Additionally, the Field shall include the prevention, diagnosis and treatment of Autoimmune Diseases, which shall mean any disease which results from a loss of immune tolerance to self-antigens, including without limitation multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, sjogren syndrome, celiac disease, Graves’ disease, myasthenia gravis, Type I diabetes, idiopathic thrombocytopenic purpura, pemphigus vulgaris, among others, including any presentation or manifestation thereof.
- 1.4. “Option” shall mean the exclusive option set forth in Section 3.2.
- 1.5. “Option Period” shall mean the period ending on the date that is 180 days following the Effective Date; subject to a 3-month extension upon prior written consent of Fortress, not to be unreasonably withheld.

2. Representations and Warranties.

- 2.1. Mutual Representations and Warranties. Each party hereby represents and warrants to the other party as follows:
  - 2.1.1. Existence. Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.
  - 2.1.2. Authorization and Enforcement of Obligations. Such party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary actions on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation enforceable against such party in accordance with its terms.
  - 2.1.3. No Conflict. The execution and delivery of this Agreement and the performance of such party’s obligations hereunder (a) do not conflict or violate any requirements of applicable laws or regulations, and (b) do not conflict with, or constitute default under, any contractual obligations of such party.

- 2.2. Products. Fortress represents and warrants to TG that, as of the Effective Date, Fortress owns or has rights to the Compounds.
3. Option.
- 3.1. Option Consideration. Upon the execution of this Agreement, TG shall pay to Fortress \$25,000 as consideration for granting the Option (the "Option Fee").
- 3.2. Grant of Option. In consideration of the Option Fee, Fortress hereby grants to TG an exclusive (as defined below in this Section 3.2) option to enter into a collaboration for the Compounds in the Field and Territory (the "Collaboration Option") on the terms described in Exhibit A. For purposes of this Section 3.2, "exclusive" means that during the Option Period, Fortress will not grant a third party a license or enter into a collaboration to make, use or sell Compounds in the Territory and Field.
- 3.3. Exercise of Option. During the Option Period, TG shall have the right, but not the obligation, within its sole discretion, to exercise the Option by delivering written notice of such exercise (the "Exercise Notice") to Fortress. Upon exercise of the Option, Fortress and TG shall negotiate the Collaboration Agreement in good faith and upon agreement to the terms therefore, will execute the Collaboration Agreement.
- 3.4. TG agrees that it shall not, except as set forth in the Option Agreement, exercise any rights to the Compounds. In the event the parties do not execute the Collaboration Agreement prior to the expiration of the Option Period, the Option shall expire and (i) Fortress shall be free to grant a third party a license to make, use or sell Compounds in the Territory and Field and (ii) TG shall not exercise any rights under to the Compounds. This Section 3.4 shall survive the expiration or termination of this Agreement.
4. Confidentiality.
- 4.1. Confidential Information. During the term of this Agreement, and for a period of five (5) years following the termination hereof, each party shall maintain in confidence the Confidential Information of the other party, and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, affiliates employees, permitted licensees, permitted assignees and agents, consultants, clinical investigators or contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to such disclosure, each party hereto shall obtain agreement of any such person to hold in confidence and not make sure of the Confidential information for any purpose other than those permitted by this Agreement. Each party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the other party's Confidential information.

- 4.2. Permitted Disclosures. The confidentiality obligations contained in this Section 4 shall not apply to the extent that Recipient is required (a) to disclose information by law, regulation, or order of a governmental agency or a court of competent jurisdiction, or (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that the Recipient shall provide written notice hereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment hereof.
5. Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY IN ANY MANNER, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), INDEMNITY, BREACH OF WARRANTY, OR OTHER THEORY, FOR ANY INDIRECT, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, PUNITIVE, STATUTORY OR SPECIAL DAMAGES, INCLUDING LOST PROFITS AND LOSS OF DATA, REGARDLESS OF WHETHER SUCH PARTY WAS ADVISED OF OR WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.
6. Term: Termination.
- 6.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 6.2, shall terminate upon expiration of the Option Period.
- 6.2. Termination.
- 6.2.1. If a party has materially breached any of its obligations hereunder, and such material breach shall continue for thirty (30) days after written notice of such breach was provided to the breaching party, the nonbreaching party shall have the right, at its option, to terminate this Agreement effective at the end of such thirty (30) day period.
- 6.2.2. TG may terminate this Agreement for its convenience by providing thirty (30) days advanced written notice to Fortress.
- 6.3. Effect of Expiration or Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination and the provisions of Sections 4, 5, 6.3, and 7 shall survive the expiration or termination of this Agreement.
7. Miscellaneous.
- 7.1. Entire Agreement. This Agreement and all exhibits and schedules hereto embody the entire agreement between the parties and supersedes any prior representations, understandings, and agreements between the parties regarding the subject matter hereof. There are no representations, understandings, or agreements, oral or written, between the parties regarding the subject matter hereof that are not fully expressed herein.



- 7.2. Severability. Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof, and without affecting the validity or enforceability of any of the terms of this Agreement in any other jurisdiction.
- 7.3. Notices. Any consent, notice, or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee. Notice shall be addressed as followed:
- To TG: TG Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019 USA  
Attn. Michael S. Weiss
- To Fortress: Fortress Biotech, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019  
Attn. Lindsay Rosenwald
- 7.4. Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party, provided however, that each party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 7.5. Headings. The section headings are for convenience only and are not a part of this Agreement.
- 7.6. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 7.7. Waiver. The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.

7.8. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law principles thereof.

In Witness Whereof, the parties have executed this Agreement effective as of the Effective Date.

TG Therapeutics, Inc.

/s/ Michael S. Weiss

By: Michael S. Weiss

Title: Chief Executive Officer

Fortress Biotech, Inc.

/s/ Michael S. Weiss

By: Michael S. Weiss

Title: Executive Vice Chairman

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

EXHIBIT A - TERM SHEET

**COMPOUNDS**

As defined in the License Agreement

**FORTRESS KNOW-HOW**

As defined as "Know-How" in the License Agreement

**FORTRESS Patents**

As defined as "Licensor Patents" in the License Agreement

**TERRITORY**

As defined in the License Agreement.

**FIELD OF USE**

As defined in the Option Agreement; provided that any BTK inhibitors discovered under the Sponsored Research Agreement with NeuPharma funded by TGTX, the Field of Use shall not be restricted and shall include all uses under the License Agreement.

**DIRECT SALES ROYALTIES**

\*% royalties on Net sales > \$\*

\*% royalties on Net sales > \$\* but < \$\*

\*% royalties on Net Sales > \$\*

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\* Confidential material redacted and filed separately with the Commission.

**MILESTONE PAYMENTS**

**TO FORTRESS**

The following amounts within 20 days of the following milestones:

Upon Exercise of Option: \$\*

1: \$\* - \*

2: \$\* - \*

3: \$\* - \*

4: \$\* on \*

5: \$\* on \*

6: \$\* on \*

7: \$\* on \*

8: \$\* on \*

9: \$\* on \*

Milestones 2-7 above shall be payable one time for any Product (including RX518) primarily targeting EGFR. For any Product primarily targeting BTK, Milestones 2-7 shall be payable for each of the first three Indications for which Product achieves the respective Product Milestone Event.

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\* Confidential material redacted and filed separately with the Commission.

**RESPONSIBILITIES OF THE PARTIES**

The parties shall share the costs of all IND-Enabling work 50/50. IND-Enabling costs shall include, without limitation, all pre-clinical toxicology, pharmacology, CMC, and other work required for the filing of an IND. These costs shall include only external costs incurred and each party shall be responsible for internal costs (personnel, overhead, etc.) incurred in connection with the IND filing. Each party shall pay the costs of filing their own IND and thereafter, TG shall be responsible for 100% of the clinical development, drug supply, and commercialization costs and expenses of developing the Compounds in the Field. Parties shall share CMC and formulation development costs.

TG shall pay individually for any specific experiments that relate solely to the BTK properties of the Compounds. Any Compounds that target BTK and are derived from the sponsored research by TG, TG shall be responsible for the full costs of development and commercialization and will have full worldwide rights to these Compounds under the License Agreement.

**GOVERNING LAW**

The Collaboration Agreement shall be governed by the laws of the State of New York without regard to principals of conflicts of law thereof.

**Other Provisions**

The Agreement would also contain additional customary terms and conditions agreed by the Parties.

**EFFECT OF TERM SHEET**

The terms and conditions set forth in this Exhibit A shall not be binding on either party until such time as the parties enter into the Collaboration Agreement.



September 11, 2015

Dr. Lindsay Rosenwald  
Fortress Biotech, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

Mr. Michael Weiss  
Checkpoint Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

#### EXTENSION OF OPTION AGREEMENT

Gentlemen:

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.

1. Parties. Effective March 17, 2015, Fortress and the 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. As such, the Parties agree to extend the Option Period for 3 months, with an expiration date of December 17, 2015.
3. Terms. The Amendment 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.

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**TG Therapeutics, Inc.**  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

---

Sincerely,  
TG Therapeutics, Inc.

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

Agreed and Accepted by:  
Fortress Biotech, Inc.

/s/ Lindsay Rosenwald  
By: Dr. Lindsay Rosenwald  
Title: Chief Executive Officer

Agreed and Accepted by:  
Checkpoint Therapeutics, Inc.

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

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December 15, 2015

Mr. James Oliviero  
Checkpoint Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

**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.

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 for an additional 30 days, with an expiration date of January 17, 2016.

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.

---

**TG Therapeutics, Inc.**  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

---



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

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January 11, 2016

Mr. James Oliviero  
Checkpoint Therapeutics, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

**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 and December 15, 2015.

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 for an additional 180 days, with an expiration date of July 17, 2016.

3 . Terms. This Extension of Option Agreement shall be governed under all of the same terms as the Option Agreement. The parties hereby acknowledge and agree that, under the Option Agreement, TG shall pay individually for any specific experiments that relate solely to the BTK properties of the Compounds. Accordingly, all costs associated with the Research Agreement dated September 15, 2015 between Checkpoint and NeuPharma shall be borne by TG Therapeutics, with such obligation for this Research Agreement surviving the expiration or earlier termination of 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.

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**TG Therapeutics, Inc.**  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019

---

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

---

**RESEARCH AGREEMENT**

THIS RESEARCH AGREEMENT (this "Agreement"), dated as of September 15th, 2015 (the "Effective Date"), between Fortress Biotech, Inc. (f/k/a Coronado Biosciences, Inc.), a Delaware Corporation (the "Company") having an address 3 Columbus Circle, 15<sup>th</sup> Floor, New York, NY 10019, and NeuPharma, Inc., a Delaware corporation ("NeuPharma") having an address of 1175 Chess Drive, Ste 206, Foster City, CA 94404.

**PRELIMINARY STATEMENT**

On March 17, 2015, NeuPharma and the Company entered into a license agreement pursuant to which, *inter alia*, NeuPharma granted the Company an exclusive royalty-bearing right and license under the Licensor Technology to research, Develop, have Developed, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products (the "License Agreement").

Pursuant to the License Agreement, the Parties contemplated the possibility entering into a sponsored research agreement to identify additional inhibitors of EGFR and/or BTK, with differing kinase profile from the current lead Licensed Products.

Accordingly, the Parties have agreed as to the terms and conditions on which NeuPharma shall conduct the research required to identify additional Compounds and Licensed Products as follows:

**TERMS AND CONDITIONS**

In consideration of their mutual covenants set forth in this Agreement, Company and NeuPharma agree as set forth herein.

**1. DEFINITIONS**

The following initially capitalized terms have the meanings set forth herein, unless otherwise expressly provided. Each meaning shall apply to both singular and plural forms of such capitalized terms as the context may require. Capitalized terms used herein but not defined herein shall have the meaning ascribed to such term in the License Agreement.

"Force Majeure" means, as to any person, any act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining energy or other utilities, labor disputes of whatever nature or any other reason beyond the reasonable control of the person in question.

"Party" means NeuPharma or Company, and "Parties" means NeuPharma and Company.

"Research" means the work to be performed by NeuPharma pursuant to this Research Agreement as set forth in one or more Research Work Orders.

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“Research Work Order” means any plan of work to be conducted by NeuPharma pursuant to this Agreement executed by the Parties and attached hereto a form as Exhibit A, as amended from time to time by the Parties.

“Results” has the meaning provided in Section 5.4.

“Subject Inventions” shall mean patentable inventions or discoveries conceived and reduced to practice in the course of the Research by one or more employees or agents of NeuPharma, or by one or more employees or agents of Company, or jointly by one or more employees or agents of NeuPharma and one or more employees or agents of Company, including all intellectual property rights therein and thereto.

“Term” has the meaning provided in Section 11.1 below.

## 2. CONDUCT OF THE RESEARCH

2 . 1 Research: Additional Research Work Orders. Commencing on the Effective Date, NeuPharma shall use reasonable efforts to conduct the Research in a professional manner, consistent with the applicable Research Work Orders. Company shall identify a designated representative in the Research Work Order (“Designated Representative”) to be Company’s contact person with respect to the conduct of the Research. NeuPharma shall consider in good faith the advice and guidance of the Designated Representative with respect to the conduct of the Research. Any disputes as to the conduct of the Research shall be settled by agreement of the CEO’s of each of the Parties. At the request of the Company, NeuPharma shall prepare a proposal for additional Research Work Orders. Additionally, if during the conduct of the Research, either Party believes a modification to Research Work Order is necessary, the Parties shall discuss in good faith any modifications to a Research Plan that may be proposed by Company or NeuPharma. Such proposed modifications shall not become effective until agreed to in writing by Company and NeuPharma; provided, however, that for items in the budget that require discussion among the parties, NeuPharma will not move forward without the agreement of the Designated Representative. NeuPharma shall have the right to subcontract any of its obligations under this Agreement, provided that NeuPharma shall be responsible for the activities of its subcontractors performing NeuPharma’s obligations under this Agreement.

2 . 2 Cooperation. To the extent reasonably required to perform the Research, NeuPharma shall permit personnel of Company, upon reasonable prior notice to NeuPharma and conditioned upon appropriate assurances of confidentiality and compliance with NeuPharma restrictions applicable to such facilities, to visit the NeuPharma facilities where the Research is being conducted.

## 3. NEUPHARMA AND COMPANY RESOURCES

3 . 1 Personnel. Following the Effective Date as it relates to the initial Research Work Order and once additional Research Work Orders are finalized, NeuPharma will take reasonable steps to make available suitably qualified personnel for the conduct of the Research. NeuPharma shall be responsible for all compensation, fringe benefits, reimbursement of expenses and withholding of governmental taxes and charges with respect to its personnel, and NeuPharma shall have the right to terminate or replace any of its personnel involved in the Research in its discretion.

3.2 Equipment and Facilities. All equipment and facilities necessary to perform the Research shall be the responsibility of NeuPharma.

#### 4. PAYMENT

4.1 Payments. Company shall not be obligated to pay any amount for Research other than as specifically stated in a Research Work Order. Except as set forth in a Research Work Order, this Agreement or the License Agreement, including with respect to prosecution of any Licensor Patents, NeuPharma shall be responsible for all costs and expenses it incurs in connection with this Agreement. Company shall make the payments to NeuPharma for the Research as set forth in each Research Work Order. All such payments shall be made by bank wire transfer in accordance with the instructions agreed to by the Parties.

#### 5. RECORDS; REPORTS; OWNERSHIP OF DATA AND DOCUMENTS; INTELLECTUAL PROPERTY

5 . 1 Records. NeuPharma will maintain complete and accurate records of the conduct, status and progress of the Research in compliance with its standard internal practices as in effect during the term of the Agreement and make such records available to Company during mutually convenient times during normal business hours upon reasonable advanced written notice.

5 . 2 Reports. On quarterly basis following the Effective Date, NeuPharma will provide a written report to Company with respect to the Research. Such reports will be prepared in the standard format of NeuPharma, and will summarize the work performed on the Research during the prior quarter and results obtained to date. Additionally, between quarterly reports NeuPharma shall communicate with the Designated Representative on a regular basis, including weekly or bi-monthly calls, or other agreed upon frequency of calls as the Parties may agree, to review the Research and troubleshoot any issues and/or suggest modifications. A final written report shall be delivered by NeuPharma to Company within 30 days after the completion of the Research or the termination of this Agreement, whichever is earlier. Company shall, upon NeuPharma's request, provide a written report of any Results prepared or generated by Company, conducted in connection with the Research.

5.3 Personnel. Each Party shall obtain, or shall have obtained, from each of its personnel involved in the Research an agreement by which each of them assigns to such Party all of his or her right, title and interest in and to (a) any invention or discovery conceived or reduced to practice in the performance of the Research, and (b) all rights, including copyright rights, in and to any original work of authorship prepared in connection with the Research.

5 . 4 Ownership of Data and Documents. All reports, findings, data and supporting documentation, in whatever form (*e.g.*, laboratory notebooks, original data, slides, photographs or computer records), that are prepared or generated by NeuPharma or Company pursuant to this Agreement and that do not constitute Subject Inventions (collectively, the "Results") shall be the property of the preparing or generating Party. Results prepared or generated by NeuPharma that pertain directly to SRA Compounds shall be deemed to be included in Licensor Know-How licensed to Company under the License Agreement. Results prepared or generated by Company that pertain directly to SRA Compounds shall be deemed to be included in Company Technology licensed to NeuPharma under the License Agreement.

5.5 Subject Inventions. Each Party shall promptly report to the other Party any Subject Invention, which report shall be accompanied by an invention disclosure that describes in reasonable detail the substance of the discovery or invention (a "Disclosure Report"). All rights to Subject Inventions conceived solely by employees, contractors, representatives or agents of NeuPharma will belong solely to NeuPharma ("NeuPharma Inventions"). All rights to Subject Inventions conceived solely by employees, contractors, representatives or agents of Company will belong solely to Company ("Company Inventions"). All rights to Subject Inventions conceived jointly by employees, contractors, representatives or agents of NeuPharma and employees or agents of Company will belong jointly to NeuPharma and Company ("Joint Inventions"). All NeuPharma Inventions Covering SRA Compounds shall be deemed included in Licensor Patents licensed to Company under the License Agreement. All Company Inventions outside the Territory Covering SRA Compounds shall be deemed included in Coronado Technology licensed to NeuPharma under the License Agreement. Except as expressly provided in this Agreement, it is understood that neither Party shall have any obligation to account to the other for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit such jointly owned inventions or intellectual property, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such approval or accounting.

5 . 6 Compounds. Any inhibitor(s) primarily targeting EGFR or BTK that are discovered in performance of the Research at any time during the term of this Agreement ("SRA Compounds") shall be deemed Compounds under the License Agreement. To the extent that NeuPharma provides company with any information or materials pertaining to inhibitors that are not SRA Compounds, Company agrees to use such information and materials only for the purpose of internal evaluation of the structure-activity relationships of SRA Compounds by Company and for no other purposes.

## 6. NOTICES

All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to this Agreement shall be sent to:

**If to NeuPharma:**

Address:

NeuPharma, Inc.  
1175 Chess Dr., Ste 206  
Foster City, CA 94404  
Attention: Shawn Qian

**If to the Company:**

Fortress Biotech, Inc.  
3 Columbus Circle, 15<sup>th</sup> Floor  
New York, NY 10019  
Attention: Leonid Gorelik

7. REPRESENTATIONS AND WARRANTIES

7 . 1 Company. Company hereby represents and warrants that: (a) it has full power and authority to enter into this Agreement, and (b) it is bound by this Agreement in accordance with its terms.

7 . 2 NeuPharma. NeuPharma hereby represents and warrants that it (a) has full power and authority to enter into this Agreement, and (b) is bound by this Agreement in accordance with its terms.

8. DISCLAIMERS AND LIMITATION OF LIABILITY

8 . 1 Warranties Disclaimed. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES PROVIDED IN SECTION 7, EACH PARTY DISCLAIMS ALL WARRANTIES OF WHATEVER NATURE, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR AS TO THE SUCCESS OR LIKELIHOOD OF SUCCESS OF THE RESEARCH, DEVELOPMENT OR COMMERCIALIZATION OF A COMPOUND, INCLUDING ANY SRA COMPOUND.

8.2 Indemnification.

(a) Company shall indemnify, defend and hold harmless NeuPharma and its officers, directors, medical and professional staff, employees, affiliates and representatives and their respective successors, heirs and assigns (the "NeuPharma Indemnitees"), against any liability, damage, loss or expense incurred by or imposed upon them in connection with any claims, suits, actions, demands or judgments ("Claim") by a third party arising out of the manufacture, use or sale of any material or product by or on behalf of Company as a result of the Research and/or embodying Subject Inventions and/or based on any theory of product liability (including, but not limited to, actions in the form of tort, warranty, or strict liability) concerning any process or service made, used or sold by Company pursuant to any right or license granted under this Agreement. Company shall not have any obligations under this paragraph with respect to Claims arising out of the negligence or intentional misconduct of the NeuPharma Indemnitees.

(b) NeuPharma shall indemnify, defend and hold harmless the Company and its officers, directors, medical and professional staff, employees, affiliates and representatives and their respective successors, heirs and assigns ("Company Indemnitees"), against any liability, damage, loss or expense incurred by or imposed upon them in connection with any Claim by a third party arising out of NeuPharma's negligence, bad faith, willful misconduct or material breach of this Agreement. NeuPharma shall not have any obligation under this paragraph with respect to Claims arising out of the negligence or intentional misconduct of the Company Indemnitees.



(c) The procedure and expenses for a Party or other Person intending to claim indemnification under this Section 8.2 shall be as set forth in Sections 9.3 and 9.4 of the License Agreement, *mutatis mutandis*.

## 9. CONFIDENTIALITY

9.1 Mutual Confidentiality. Neither Party shall disclose the other Party's Confidential Information to any person other than its employees, officers, directors, affiliates, agents and representatives who are bound by obligations of confidentiality and who have a need to know such information in order to perform their obligations in connection with the Research. Each Party may only use the other Party's Confidential Information as permitted to perform its respective obligations under this Agreement. "Confidential Information" means any information disclosed by a Party to the other Party that is reasonably expected to be treated in a confidential manner under the circumstances of disclosure under this Agreement or by the nature of the information itself.

9.2 Exceptions. The obligations of confidentiality applicable to Confidential Information of the other Party shall not apply to any information that is (a) known publicly or becomes known publicly through no fault of the recipient; (b) learned by the recipient on a non-confidential basis from a third party entitled to disclose it without obligation of confidentiality; (c) developed by the recipient independently of and without use of or reference to Confidential Information of the other Party as evidenced by prior written records of the recipient; (d) already known to the recipient without obligations of confidentiality before receipt from the disclosing party, as shown by its prior written records; or (e) is disclosed to the public to the extent required by law, regulation or the order of a judicial or administrative authority, provided that the recipient notifies the disclosing party promptly upon receipt at any such order or becoming aware of any such law or regulation. If a Party becomes legally compelled to disclose any Confidential Information of the other Party, such Party will (1) provide the other Party prompt written notice, if legally permissible, and will use its best efforts to assist such other Party in seeking a protective order or another appropriate remedy and (2) furnish only that portion of the Confidential Information that is legally required to be disclosed. Any Confidential Information legally compelled to be disclosed shall maintain its confidentiality protection for all purposes other than such legally compelled disclosure.

9.3 Publicity. Neither Party may issue a press releases or otherwise disclose the existence or terms of this Agreement without the prior written consent of the other Party; provided, however, that once the existence or any terms or conditions of this Agreement has been publicly disclosed in a manner mutually and reasonably agreed-to by the Parties, either Party may republish the facts previously disclosed without the prior consent of the other Party.

## 10. TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date, and, unless terminated earlier as provided herein, shall expire on the earlier of (i) the completion of the Research or (ii) the second anniversary of the Effective Date.

10.2 Right to Terminate. Company shall have the right to terminate this Agreement at any time upon thirty (30) days written notice to NeuPharma. Either Company or NeuPharma may terminate this Agreement effective upon notice to the other:

(a) the other Party commits a material breach of this Agreement and the breach is not remedied within 30 days after the receipt of notice identifying the breach, requiring its remedy and stating the intent of the Party giving notice to terminate in the absence of remedy, or

(b) the other Party (i) becomes unable to pay its debts as they become due, (ii) suspends payment of its debts, (iii) enters into or becomes subject to corporate rehabilitation or bankruptcy proceedings or liquidation or dissolution that is not dismissed within 60 days of filing, (iv) makes an assignment for the benefit of its creditors or (v) seeks relief under any similar laws for debtor's relief.

10.3 Effect of Expiration or Termination. Upon the termination of this Agreement, NeuPharma shall cease all Research. Within 30 days following the expiration or termination of this Agreement, each Party shall promptly deliver to the other party all of its Confidential Information (save one copy for purposes of determining compliance with its obligations of confidentiality hereunder). This Section 10.3 and Sections 1, 5.4, 5.5, 5.6, 6, 8, 9 and 11 shall survive expiration or termination of this Agreement. Termination or expiration of this Agreement shall not relieve the Parties of any liability that accrued hereunder before the effective date of such termination or expiration. In addition, termination or expiration of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

## 11. MISCELLANEOUS

(a) Neither this Agreement nor any right or obligation hereunder shall be assignable in whole or in part, whether by operation of law, or otherwise by one party without the other prior written permission. Notwithstanding the foregoing, either Party may assign or transfer all of its rights and obligations under this Agreement without the consent of the other Party to an Affiliate of such assigning Party or a person that succeeds to all or substantially all of that Party's business or assets to which this Agreement pertains whether by sale, merger, operation of law or otherwise. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and permitted assignees. Any transfer or assignment of this Agreement in violation of this Section 11(a) shall be null and void.

(b) This Agreement and the License Agreement contains the entire agreement between the Parties relating to the subject matter hereof, and all prior understandings, representations and warranties between the Parties are superseded by this Agreement and the License Agreement.

(c) Changes and additional provisions to this Agreement shall be binding on the Parties only if agreed upon in writing and signed by the Parties.

(d) This Agreement shall be construed and interpreted in accordance with the laws of the State of New York and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law. Any dispute arising under or with respect to this Agreement may be brought and maintained solely in the state or federal courts located in New York, NY, and the Parties expressly consent to the exclusive jurisdiction of such courts for such purpose.

(e) The Parties do not intend to violate any public policy or statutory common law. However, if any sentence, paragraph, clause or combination of this Agreement is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of this Agreement shall remain binding, provided that such deletion does not alter the basic purpose and structure of this Agreement.

(f) Nothing herein shall create any association, partnership, joint venture, fiduciary duty or the relation of principal and agent between the Parties hereto, it being understood that each Party is acting as an independent contractor, and neither Party shall have the authority to bind the other or the other's representatives in any way.

(g) No delay on the part of either Party hereto in exercising any power or right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any power or right hereunder preclude other or further exercise thereof or the exercise of any other power or right. No waiver of this Agreement or any provision hereof shall be enforceable against any Party hereto unless in writing, signed by the Party against whom such waiver is claimed, and shall be limited solely to the one event.

(h) This Agreement has been prepared jointly and no rule of strict construction shall be applied against either Party. In this Agreement, the singular shall include the plural and vice versa and the word "including" shall be deemed to be followed by the phrase "without limitation." The section headings contained in this Agreement are inserted for convenience only and shall not affect in any way the meaning or interpretation of this Agreement.

(i) This Agreement may be executed in counterparts, each of which together shall constitute one and the same Agreement. For purposes of executing this agreement, a facsimile copy of this Agreement, including the signature pages, will be deemed an original.

**[The remainder of this page intentionally left blank.]**

IN WITNESS WHEREOF, Company and NeuPharma have caused this Agreement to be executed and delivered as of the date hereof.

FORTRESS BIOTECH, INC.

NEUPHARMA, INC.

By /s/ Michael Weiss

By /s/ Shawn Qian

Name: Michael Weiss

Name: Shawn Qian

Title: Executive Vice Chairman

Title: President & CEO

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EXHIBIT A

Research Work Order #1

Scope of Research to be Conducted: Identify selective compounds with more potent BTK inhibition: BTK  $IC_{50} < 10$  nM;  $IC_{50}$  wtEGFR/BTK  $> 10$ ; selectivity against majority of the kinome.

Company's Designated Representative Leonid Gorelik

Budget/Payment Obligations: The projected 12-month budget is totaled \$1,300,000 to \$1,533,000.

The non-refundable down payment of \$260,000 is due within 7 days after the agreement is signed.

NeuPharma shall raise quarterly invoices to Company for the work conducted and expenses incurred for that particular quarter. Payment by Company on any invoice issued by NeuPharma shall be due within thirty (30) days of the receipt date of such invoice.

If NeuPharma does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Company from the due date until the date of payment at a rate equal to the lesser of (a) US dollar one-month LIBOR plus 500 basis points, or (b) the maximum rate permissible under applicable Law.

Projected Start Date: October 1, 2015

Projected End Date: October 1, 2016

## ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT ("**Assignment and Assumption Agreement**") is effective as of September 15 2015, by and between by and between Fortress Biotech., Inc., a Delaware corporation ("**Fortress**") and Checkpoint Therapeutics, Inc., a Delaware corporation ("**Checkpoint**").

**RECITALS**

WHEREAS, Fortress and NeuPharma ("**NeuPharma**") are parties to that certain Research Agreement (the "**NeuPharma Agreement**");

WHEREAS, pursuant to the NeuPharma Agreement, Fortress may assign the NeuPharma Agreement to an Affiliate (as defined in the NeuPharma Agreement) of Fortress without NeuPharma's prior written consent; and

WHEREAS, Checkpoint is an Affiliate of Fortress; and

WHEREAS, Fortress wishes to assign the NeuPharma Agreement to Checkpoint and, in connection therewith, Checkpoint has agreed to accept such assignment and assume the obligations thereunder.

**AGREEMENTS**

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is hereby agreed that:

**1 . Assignment.** Fortress hereby sells, assigns, conveys, transfers and delivers to Checkpoint all of Fortress's right, title and interest in and to the NeuPharma Agreement.

**2 . Assumption.** Checkpoint hereby accepts the foregoing assignment, and in connection therewith, Checkpoint hereby agrees to assume all liabilities arising thereunder from and after the Effective Date.

**4. Effective Time.** The effective time of this Assignment and Assumption Agreement is 11:59 p.m. EST on the date hereof.

**5 . Counterparts; Electronic Delivery.** This Assignment and Assumption Agreement may be executed in any number of counterparts with the same effect as if each of the parties hereto had signed the same document. All counterparts shall be construed together and shall constitute one Assignment and Assumption Agreement. This Assignment and Assumption Agreement, to the extent signed and delivered by means of a facsimile machine or via e-mail, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

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IN WITNESS WHEREOF, the parties have executed this Assignment and Assumption Agreement as of the date first above written.

**FORTRESS BIOTECH, INC.**

By: /s/ Lindsay Rosenwald

Name: Lindsay Rosenwald

Title: CEO

**CHECKPOINT THERAPEUTICS, INC.**

By: /s/ Michael Weiss

Name: Michael Weiss

Title: Interim President and CEO

[Signature Page to Assignment and Assumption Agreement]

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**ASSIGNMENT AND ASSUMPTION AGREEMENT**

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT ("**Assignment and Assumption Agreement**") is effective December 18, 2015 (the "**Effective Date**"), by and between Fortress Biotech, Inc. ("**Fortress**"), a Delaware corporation, and Checkpoint Therapeutics, Inc. ("**Checkpoint**"), a Delaware corporation.

**RECITALS**

WHEREAS, Fortress and Cephalon, Inc. ("**Cephalon**") are parties to that certain License Agreement, dated December 18, 2015 (the "**License Agreement**");

WHEREAS, pursuant to Section 11.2 of the License Agreement, Fortress may assign the License Agreement to an Affiliate (as defined in the License Agreement) of Fortress without Cephalon's prior written consent;

WHEREAS, Checkpoint is an Affiliate of Fortress; and

WHEREAS, Fortress wishes to assign the License Agreement to Checkpoint and, in connection therewith, Checkpoint has agreed to accept such assignment and assume the obligations thereunder.

**AGREEMENTS**

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is hereby agreed that:

1. **Assignment.** Fortress hereby sells, assigns, conveys, transfers and delivers to Checkpoint all of Fortress' right, title, and interest in and to the License Agreement.
  2. **Assumption.** Checkpoint hereby accepts the foregoing assignment, and in connection therewith, Checkpoint hereby agrees to assume all of Fortress' obligations under the License Agreement, whether arising before, at or after the Effective Date.
  3. **Effective Time.** The effective time of this Assignment and Assumption Agreement is 11:59pm EST on the date hereof.
  4. **Counterparts; Electronic Delivery.** This Assignment and Assumption Agreement may be executed in any number of counterparts with the same effect as if each of the parties hereto had signed the same document. All counterparts shall be construed together and shall constitute one Assignment and Assumption Agreement. This Assignment and Assumption Agreement, to the extent signed and delivered by means of facsimile machine or via e-mail, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.
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IN WITNESS WHEREOF, the parties have executed this Assignment and Assumption Agreement as of the date first above written.

**FORTRESS BIOTECH, INC.**

By: /s/ Lindsay Rosenwald

Name: Lindsay Rosenwald

Title: CEO

**CHECKPOINT THERAPEUTICS, INC.**

By: /s/ James Oliviero

Name: James Oliviero

Title: President & CEO

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