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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2018
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from_____ to _____.

Commission File Number 001-38128

CHECKPOINT THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

(Title of Class)	**(Name of exchange on which registered)**
Common Stock, par value $0.0001 per share	**NASDAQ Capital Market**

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of June 29, 2018, the last business day of the registrant's mostly recently completed second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the registrant was $58,374,725 based upon the closing sale price of our common stock of $2.98 on that date. Common stock held by each officer and director and by each person known to own in excess of 5% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

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

Class of Common Stock	**Outstanding Shares as of March 12, 2019**
Class A Common Stock, $0.0001 par value	7,000,000
Common Stock, $0.0001 par value	28,856,662

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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ANNUAL REPORT ON FORM 10-K
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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

PART I

Item 1. Business

OVERVIEW

We are a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. We are currently evaluating our lead small-molecule, targeted anti-cancer agent, CK-101, in a Phase 1/2 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer ("NSCLC"). In addition, we are currently evaluating our lead antibody product candidate, CK-301, an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more Biologics License Application ("BLA") submissions.

We have also entered into various collaboration agreements with TG Therapeutics, Inc. ("TGTX"), a related party, to develop and commercialize certain assets in connection with our licenses in the field of hematological malignancies, while we retain the right to develop and commercialize these assets in solid tumors.

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, we have an accumulated deficit of $95.4 million.

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

CORPORATE INFORMATION

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

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

PRODUCTS UNDER DEVELOPMENT

Targeted Anti-Cancer Agents

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

We are developing CK-101 as an oral, third-generation, irreversible kinase inhibitor against selective mutations of EGFR. Activating mutations in the tyrosine kinase domain of EGFR such as L858R and exon 19 deletion are found in approximately 20% of patients with advanced NSCLC. Compared to chemotherapy, first-generation EGFR inhibitors significantly improved overall response rate ("ORR") and progression-free survival in previously untreated NSCLC patients carrying EGFR mutations. However, tumor progression could develop due to resistance mutations, often within months of treatment with first-generation EGFR inhibitors.

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

Third-generation EGFR inhibitors are designed to be highly selective against the EGFR T790M mutation while sparing wild-type EGFR, thereby improving tolerability and safety profiles. In November 2015, Tagrisso ® (osimertinib), a third-generation EGFR tyrosine kinase inhibitor ("TKI") developed by AstraZeneca that specifically targets the EGFR activating and T790M resistance mutations, received accelerated Food and Drug Administration ("FDA") approval for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC who have progressed on or after EGFR TKI therapy. Tagrisso received full approval from the FDA in 2017 based on data from a randomized, Phase 3 trial, in which Tagrisso significantly improved progression-free survival ("PFS") versus platinum-based doublet chemotherapy, providing 10.1 months of median PFS compared to 4.4 months from chemotherapy.

In addition, third-generation inhibitors may also be active against activating EGFR mutations seen in first-line NSCLC patients and have shown efficacy in monotherapy studies. In April 2018, Tagrisso received FDA approval for the first-line treatment of NSCLC patients with EGFR mutations based on data from a randomized, Phase 3 trial, in which Tagrisso significantly improved PFS versus first-generation EGFR inhibitors, providing 18.9 months of median PFS compared to 10.2 months.

We are developing CK-101 for the treatment of NSCLC patients carrying the susceptible EGFR mutations. These include EGFR L858R and exon 19 deletion mutations in first-line NSCLC patients as well as the EGFR T790M mutation in second-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. Existing preclinical and clinical data from other programs support the potential combination of third-generation EGFR inhibitors with checkpoint inhibitors (anti-PD-1 or anti-PD-L1).

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma, Inc. ("NeuPharma"), which agreement was assigned to us by Fortress on the same date, to develop and commercialize novel covalent third-generation EGFR inhibitors on a worldwide basis outside of certain Asian countries. In August 2016, the FDA accepted our IND application and we initiated a Phase 1/2 clinical study in September 2016. The study is evaluating the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and the safety and efficacy of CK-101 in patients with EGFR mutation-positive NSCLC. In September 2018, we announced preliminary interim safety and efficacy data from our ongoing clinical trial of CK-101. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer ("IASLC") 19th World Conference on Lung Cancer in Toronto. Enrollment in the trial is ongoing to identify the optimal dose with a new softgel capsule formulation to maximize therapeutic effect, following which a Phase 3 trial is planned to initiate in 2019 in treatment-naïve EGFR mutation-positive NSCLC patients.

CK-103 BET Inhibitor Program

We are developing CK-103, a novel, selective and potent small molecule inhibitor of BET bromodomains. CK-103 binds to the first and second bromodomains (BD1, BD2) of the BET protein family, BRD2, BRD3, BRD4, and BRDT. A bromodomain is an amino acid protein domain that recognizes acetylated-lysine. The binding of the drug prevents interaction between BET proteins and both acetylated histones and transcription factors. Therefore, BET proteins, such as BRD4, are considered potential therapeutic targets in cancer, as they may play a pivotal role in regulating the transcription of key regulators of cancer cell growth and survival, including the c-Myc oncogene. BRD4 is often required for expression of c-Myc. Scientific literature has shown that small molecule inhibition of BET bromodomains may lead to selective killing of tumor cells across a broad range of hematologic malignancies and certain targeted solid tumors. We plan to develop CK-103 for the treatment of various advanced and metastatic solid tumor cancers, including, but not limited to, those associated with elevated c-Myc expression.

In May 2016, we entered into an exclusive license agreement with Jubilant Biosys Limited ("Jubilant") to develop and commercialize novel compounds that inhibit BET bromodomains on a worldwide basis. Also in May 2016, we entered into a Sublicense Agreement with TGTX to develop and commercialize CK-103 in the field of hematological malignancies. We retain the right to develop and commercialize CK-103 in solid tumors. In 2018, we completed the required CMC, pharmacology and toxicology activities to support a potential IND application filing.

Anti-CAIX Research Program

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

In 2015, preclinical data were published in the peer-reviewed journal, Molecular Cancer, that demonstrated that our anti-CAIX antibodies could 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 potentially other anti-tumor immune response potentiating compounds and/or targeted therapies.

We licensed the exclusive worldwide rights to certain anti-CAIX antibodies from Dana-Farber in March 2015. Currently, we are in preclinical development for this program. We will need to identify and optimize a lead anti-CAIX antibody to select as a clinical candidate, following which we plan to commence CMC development, pharmacology and toxicology activities in order to potentially submit an IND application in the future.

Immuno-Oncology Agents

CK-301 (Anti-PD-L1) Program

CK-301 is a fully-human monoclonal antibody of IgG1 subtype that directly binds to Programmed Death Ligand-1 ("PD-L1") and blocks the PD-L1 interaction with the Programmed Death Receptor-1 ("PD-1") and B7.1 receptors. PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, and is utilized by tumor cells as an immune escape mechanism. CK-301's primary mechanism of action is based on the inhibition of the interaction between PD-L1 and its receptors PD-1 and B7.1, which removes the suppressive effects of PD-L1 on anti-tumor CD8+ T-cells to restore the cytotoxic T cell 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 ORR in the labels for the FDA approved PD-1 and PD-L1 blocking antibodies was cited in the 20-45% range based on clinical trials in patients with metastatic melanoma and NSCLC. Potent therapeutic anti-tumor responses due to blocking of PD-1/PD-L1 interaction has been demonstrated by these approved products in patients with various solid tumors including, but not limited to, NSCLC, melanoma, RCC, head and neck cancer, cutaneous squamous cell carcinoma ("cSCC") and urothelial carcinoma.

We are developing CK-301 in solid tumor oncology indications where studies of other PD-1/PD-L1 antibodies have shown to be effective. We licensed the exclusive worldwide rights to certain anti-PD-L1 antibodies from Dana-Farber in March 2015. Also in March 2015, we entered into a Global Collaboration Agreement with TGTX, a related party, to develop and commercialize anti-PD-L1 antibodies in the field of hematological malignancies. We retain the right to develop and commercialize our anti-PD-L1 antibodies in solid tumors. We believe that CK-301 has the potential to be effective in many oncological indications as a monotherapy or in combination with other anti-tumor immune response potentiating compounds and targeted therapies.

We commenced a Phase 1 multi-center clinical study for CK-301 in October 2017. The study is evaluating the safety and tolerability of ascending doses of CK-301 in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Following completion of dose escalation in March 2018, multiple dose expansion cohorts were initiated. In January 2019, we announced the expansion of the ongoing study to enroll patients in three cohorts intended to support requests for accelerated approval and BLA submissions to the FDA. These cohorts include:

- Microsatellite instability-high ("MSI-H") endometrial cancer that has progressed following one or two prior anti-cancer therapies;
- Microsatellite stable ("MSS") endometrial cancer that has progressed following one or two prior anti-cancer therapies; and
- MSI-H or mismatch repair deficient ("dMMR") colorectal cancer that has progressed on or after, or been intolerant of, previous treatments, including a fluoropyrimidine- and oxaliplatin- and irinotecan-based chemotherapy.

The primary endpoint for each cohort is ORR, and secondary endpoints include duration of response, PFS, and overall survival. The ongoing trial is also enrolling cohorts of patients with NSCLC and cSCC.

CK-302 (Anti-GITR) Program

Our anti-GITR monoclonal antibody, CK-302, is a fully human agonistic antibody that is designed to bind and trigger signaling in GITR expressing cells. Scientific literature indicates that GITR is a co-stimulatory molecule of the TNF receptor family and is expressed on activated T cells, B cells, natural killer ("NK") and regulatory T-cells ("Treg"). As a co-stimulatory molecule, GITR engagement increases proliferation, activation, and cytokine production of CD4+ and CD8+ T-cells**.** We believe our anti-GITR monoclonal antibody abrogates immunosuppressive activity of natural Treg on expansion of T-effector cells. GITR-specific agonistic monoclonal antibodies under development by third parties have been shown to induce tumor regression in vivo through the activation of CD4+ T-cells, CD8+ T-cells and NK cells in a number of tumor models.

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

Currently, we are in preclinical development for this program. In late 2016, we commenced CMC development activities, which include the construction and testing of a production cell line, the development of a manufacturing process for production of the antibody, as well as the development of suitable analytical methods to characterize the antibody. We plan to develop control mechanisms to satisfy GMP requirements and scale-up manufacturing in order to conduct the required pharmacology and toxicology studies to support a potential IND application.

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 key product candidates. For a description of the risk factors that could significantly affect our ability to meet these cost and time estimates, see Item 1A of this report.

Product Candidate	Target Indication(s)	Development Status	Estimated Completion of Phase	Estimated Cost to Complete Phase
CK-101	EGFR mutation-positive NSCLC	Phase 1	2019	$4 to $6 million
CK-301	MSI-H and MSS endometrial cancer; MSI-H/dMMR colorectal cancer	Phase 1	2020*	$8 to $10 million

*Completion of phase for this study indicates completion of portion of study, which, if successful, would support an accelerated approval application.

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

INTELLECTUAL PROPERTY AND PATENTS

General

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

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

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

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, the continued patent eligibility of certain subject matter, 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 or derivation proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or inventorship, 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 and, in any case, is limited to a maximum of five additional years of patent term.

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

In March 2015, we licensed intellectual property related to certain antibodies from Dana-Farber. The intellectual property includes issued patents in a number of countries, including the United States and Europe, as well as pending patent applications in several countries elsewhere. The issued patents and pending patent applications relate generally to compositions and methods of treatment involving antibodies against CAIX, PD-L1 and GITR. Regarding CAIX antibodies, the in-licensed IP portfolio includes one granted US patent (U.S. Patent Nos. 8,466,263) and one pending US application (US Appl. No. 15/590,678). The '263 patent is directed to isolated human monoclonal antibodies and scFv antibodies that bind to CAIX (G250) protein, and compositions and kits comprising such antibodies. The term of the '263 patent runs to July 9, 2029. The '678 application is directed to methods of treating cancer with anti-CAIX antibodies. The '263 patent and any patent issuing from the '678 application may be entitled to any patent term restorations that might become available under the provisions of US patent laws, based on regulatory delays associated with obtaining marketing approval. The European counterpart is in force in Switzerland, Liechtenstein, Germany, France and the United Kingdom. A Canadian counterpart patent has also been issued. Both the European and Canadian counterpart patents, as well as any pending applications outside the United States, are scheduled to expire no sooner than December 2026. The PD-L1 segment of the portfolio includes a granted US patent (US Patent No. 9,828,434) directed to antibodies that bind to PD-L1 and a pending US application (U.S. Appl. No. 15/821.087) directed to methods of augmenting a patient's immune response by administering an anti-PD-L1 antibody. The '434 patent is scheduled to expire October 4, 2033, not including any patent term restorations, which might become available under the provisions of US patent laws, based on regulatory delays associated with obtaining marketing approval. International counterpart applications are pending in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, and Mexico. 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. National stage applications claiming priority to are PCT/US2015/054010 pending in the US (US Appl. No. 15/516,272), Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, and Mexico. Any of these national stage applications that issue or grant as patents (including U.S. Application No. 15/516,272), would expire no earlier than October 2035.

In June 2016, we filed a US provisional application (US 62/356,105) directed to antibodies and functional fragments thereof that bind to human PD-L1, and methods of inhibiting tumor cell proliferation in patients using such antibodies or functional fragments. The provisional application was converted into a PCT application (PCT/US2017/039810) in June 2017, and a US non-provisional application (US Appl. No. 15/636,610) was filed at the same time. Additional national stage applications have since been filed in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and Thailand. Any patents maturing from these pending applications will expire no sooner than June 2037.

In March 2015, Fortress in-licensed intellectual property from NeuPharma, assigned to us by Fortress on the same date, which is directed to technology involving small molecules that are inhibitors of EGFR and kinase mutants, including the compound CK-101. EGFR is a receptor tyrosine kinase of the ErbB family and is also known as "Her1" and "ErbB1." The in-licensed patent estate includes two granted US patents and a granted European patent. US Patent No. 9,559,770 is directed to a generic formula of small molecules, as well as a specific claim directed to the compound, CK-101. The granted claims also cover pharmaceutically acceptable salts, pharmaceutical compositions, particular dosage forms and packaged goods. US Patent No. 9,849,139 is directed to methods of inhibiting EGFR or an EGFR mutant in a subject in need thereof, comprising administering a therapeutically effective amount of the compounds of the '770 patent, including the compound, CK-101. European Patent No. 3035936 specifically covers the compound, CK-101, and a broad range of related compounds, salts, pharmaceutical compositions, including various dosage forms of such pharmaceutical compositions and certain uses of such compounds or salts thereof in treating cancer, a disorder mediated by EGFR, or NSCLC, either alone or in combination with an additional anti-cancer and/or cytotoxic agent. The term of granted US and European patents runs to August 22, 2034, not including any patent term restorations in the US, which might become available under the provisions of US patent laws, based on regulatory delays associated with obtaining marketing approval. A continuation application remains pending before the US Patent and Trademark Office, and counterpart applications exist in selected jurisdictions around the world, including, but not limited to, Canada and Europe. Any patents maturing from these pending applications would be scheduled to expire no sooner than August 2034.

In May 2016, we in-licensed intellectual property from Jubilant. Under the terms of the license agreement, Jubilant granted us exclusive, worldwide rights under Jubilant's patents and know-how covering small molecule inhibitors of BET, specifically targeting BRD4, a member of the BET family which is often required for the expression of c-Myc. The in-licensed patent estate includes two international (PCT) applications filed in March 2016 (PCT/IN2016/050098) and September 2016 (PCT/IN2016/050300), respectively, claiming the benefit of two earlier-filed Indian provisional applications. Any patents maturing from this patent estate are expected to expire no sooner than March 2036.

Other Intellectual Property Rights

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

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, to provide market exclusivity for certain of our product candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan-drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In September 2017, we received FDA Orphan Drug Designation for CK-101 for the treatment of EGFR mutation-positive NSCLC.

LICENSING AGREEMENTS AND COLLABORATIONS

Dana-Farber Cancer Institute, Inc.

In March 2015, we entered into a license agreement with Dana-Farber, which license was amended effective on October 5, 2015, April 12, 2016, and October 24, 2016, whereby we obtained an exclusive, worldwide license to Dana-Farber's patents for a portfolio of fully human immuno-oncology targeted 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 receives 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. 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 $2.2 million of upfront licensing and milestone payments under this license agreement.

In connection with the 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. Under the terms of the Global Collaboration Agreement, TGTX paid us $0.5 million, representing an upfront licensing fee, and we are eligible to receive substantive potential milestone payments up to an aggregate of approximately $21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. In addition, we are eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, we receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to us. TGTX also pays us for our out-of-pocket costs of material used by TGTX for its development activities. 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. For the years ended December 31, 2018 and 2017, we recognized approximately $3.0 million and $0.1 million respectively, in revenue from our collaboration agreement with TGTX in the Statements of Operations.

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized CK-301, our anti-PD-L1 antibody which we originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to us, and we entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive payments up to an aggregate of approximately $7.1 million upon our successful achievement of certain clinical development and regulatory milestones, of which $4.8 million are due upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments based on a tiered low single digit percentage of net sales. The license will terminate on a country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this agreement shall expire in its entirety with respect to such licensed product in such country. The royalty term, on a product-by-product and country-by-country basis, begins on the first commercial sale of a product in a country and ends on the later of (a) expiry of the last-to-expire licensor patent containing a valid claim to the compound in such country; or (b) twelve years after the first commercial sale of such licensed product in such country. To date, we have not incurred any costs under our collaboration agreement with Adimab. We previously incurred $1.3 million in option and milestone payments under Fortress' collaboration agreement with Adimab.

NeuPharma, Inc.

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma, which agreement was assigned to us by Fortress on the same date, and amended on February 21, 2017, whereby we obtained an exclusive, worldwide license, other than certain Asian countries, to NeuPharma's patents to a library of EGFR inhibitors, including CK-101. Under the terms of the agreement, we paid NeuPharma an up-front licensing fee of $1.0 million, and NeuPharma is eligible to receive payments of up to an aggregate of approximately $40.0 million upon our successful achievement of certain clinical development and regulatory milestones in up to three indications, of which $22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of $40.0 million upon our successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales. The license will terminate on a country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. Royalty term means, on a licensed product-by-licensed product and country-by-country basis, the period from the first commercial sale of a given licensed product in such country until the later of (a) expiry of the last-to-expire licensor patent containing a valid claim to the compound in such country; or (b) the 10^{th} anniversary of the first commercial sale of such licensed product in such country. In a country where no licensor patent containing a valid claim with respect to the compound has ever existed nor ever exists, the royalty term means on a product-by-product and country-by-country basis, the period from the first commercial sale of such product in such country until the 10^{th} anniversary of such first commercial sale of such product in such country. To date, we have incurred $2.0 million of upfront licensing and milestone payments under the license agreement.

In connection with the license agreement with NeuPharma, in March 2015, Fortress entered into an Option Agreement with TGTX, a related party, 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. The Option Agreement expired on December 31, 2018.

Also in connection with the license agreement with NeuPharma, we entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid us for all amounts we paid NeuPharma previously. This assumption of costs by TGTX survives any termination or expiration of the option agreement. For the years ended December 31, 2018 and 2017, we recognized approximately $35,000 and $0.6 million, respectively, in revenue related to the Sponsored Research Agreement in the 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 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, a PARP inhibitor, which we refer to as CK-102. Under the terms of the agreement, we paid Cephalon an up-front licensing fee of $0.5 million. In August 2018, the Company gave notice to Cephalon of its intention to terminate the license agreement, which became effective in February 2019. To date, we have incurred $0.5 million of upfront licensing and milestone payments under the license agreement.

Jubilant Biosys Limited

In May 2016, we entered into a license agreement with Jubilant, whereby we obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103. Under the terms of the agreement, we paid Jubilant an up-front licensing fee of $2.0 million, and Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon our successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 million upon our successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. The license will terminate on a country-by-country and product-by-product basis until the royalty term in such country with respect to such product expires, at which time this agreement shall expire in its entirety with respect to such licensed product in such country. The royalty term, on a product-by-product and country-by-country basis, begins on the first commercial sale of a product in a country and ends on the expiration of the last-to-expire Jubilant patent containing a valid claim to the product in such country. To date, we have incurred $2.4 million of upfront licensing and milestone payments under the license agreement.

In connection with the license agreement with Jubilant, we entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while we retain the right to develop and commercialize these compounds in the field of solid tumors. Under the terms of the sublicense agreement, TGTX paid us $1.0 million, representing an upfront licensing fee, and we are eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.2 million upon TGTX's successful achievement of preclinical, clinical development, and regulatory milestones. This is comprised of up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, we are eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of three sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays us for 50% of IND enabling costs and patent expenses. For the years ended December 31, 2018 and 2017, we recognized approximately $0.4 million and $1.0 million, respectively, in revenue related to the sublicense agreement in the Statements of Operations.

COMPETITION

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

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

In the targeted anti-cancer agent area, there are several companies with marketing approvals or in development with EGFR inhibitors that are targeting mutations similar to our programs. There are also a number of early stage programs developing BET inhibitors which could overlap with our upcoming programs.

In the EGFR inhibitor space, Tarceva®, Iressa®, Gilotrif®, Tagrisso ® and Vizimpro® are currently approved drugs for the treatment of first-line EGFR-mutant NSCLC. AstraZeneca's Tagrisso ® is also 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, Novartis' EGF816, Janssen's lazertinib and Acea Bio (Hangzhou)'s avitinib.

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

In the Immuno-Oncology area, almost every major pharmaceutical company has a PD-1 and/or PD-L1 antibody in clinical development or on the market, including, without limitation, Merck & Co. (approved drug PD-1 with the brand name Keytruda ®), Bristol-Myers Squibb (approved PD-1 with the brand name Opdivo ®), Roche (approved PD-L1 with the brand name Tecentriq ®), AstraZeneca (approved PD-L1 with the brand name Imfinzi ®), Pfizer/Merck KGA (approved PD-L1 with the brand name Bavencio ®) and Regeneron (approved PD-1 with the brand name Libtayo ®). We are aware of several anti-GITR antibody development programs in preclinical or early clinical studies, including, without limitation, by Merck & Co., Leap Therapeutics, Inc. and Astellas Pharma Inc., and an anti-CAIX antibody in clinical studies by Telix Pharmaceuticals.

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

EMPLOYEES

As of December 31, 2018, we had seven full and part-time employees. None of our employees are represented by a labor union and we consider our employee relations to be good.

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 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, if not prior, and to the extent possible and commercially practicable, we would seek to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current GMP ("cGMP") regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

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

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

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

GOVERNMENT AND INDUSTRY REGULATIONS

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

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a product candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA, or comparable filing outside the U.S., 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 may 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 a NDA or BLA 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 a NDA or BLA for filing if certain content criteria are not met and, even after accepting a NDA or BLA, 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 or BLA. 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 or BLA. Certain changes to an approved NDA or BLA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

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

Other Healthcare Laws and Compliance Requirements

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

International Regulation

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

Item 1A. Risk Factors

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

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

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, or ethics committee, as applicable, approval at each site;
- recruiting suitable and sufficient number of 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;
- obtaining resolution for any clinical holds that arise;
- 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 or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency ("EMA") and similar regulatory authorities outside the United States. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations and other third-party vendors 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 by severity of disease, patient group, or include contraindications, interactions, or warnings, 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. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

In all interactions with regulatory authorities, the company is exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

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 and customer confidence in our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

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

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

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

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

If one or more of our product candidates or any future product candidate are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause serious side effects that prevented further development of the compound. In the event that our clinical trials reveal a high or 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, and requirements regarding company presentations and interactions with health care professionals.

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

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

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

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

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

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

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

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

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

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

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

Regulatory approval for any approved product is limited by the FDA, and any similar regulatory authorities outside the United States, to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

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

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

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

In the US and some foreign jurisdictions, there have been a number of proposed and enacted legislative and regulatory 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 US 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 US, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA 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;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal 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 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 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug 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;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; 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.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

Most recently, the Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applies to biosimilars beginning in 2019.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

We expect that the ACA, 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 proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been raised in Congress, but have been met with opposition and have not been enacted so far.

The administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has in the past proposed to test alternative payment methodologies for drugs covered under the Part B program and currently is proposing to pay hospitals less for Part B-covered drugs purchased through the 340B Drug Pricing Program.

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 US 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 number of clinical trials sponsored by other companies for the same patient population;
- 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.

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 may 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 of our own candidates 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, it may impact the market acceptance of our products and we may be unable to achieve or sustain profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a NDA or BLA 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 or the manufacture of drug product. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The U.S. DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for one or more of our product candidates.

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

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

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

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and may 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 are any disputes between us and any of our licensors regarding our rights under our license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under any of our license agreements could result in our loss of exclusive rights to one or more of our product candidates 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, bribery, 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, as well as civil and criminal liability. 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 civil and/or criminal 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;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our product candidates or any future product candidate that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. 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 in the market they are being used or developed.

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 methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, 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, and we may fail to seek or obtain patent protection in all major markets. 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, or in some cases not 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 or any of our respective licensors' 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 instance 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.

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, 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 changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. 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 pre-issuance 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. 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 US patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

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

We depend on our licensors to protect the proprietary rights covering our antibody and certain of our small molecule product candidates and we have limited, if any, control over the amount or timing of resources that they devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage. Moreover, we have limited, if any, control over the strategies and arguments employed in the maintenance of patent rights and the prosecution of patent applications to our advantage.

Our licensors, depending on the patent or application, are responsible for maintaining issued patents and prosecuting patent applications for our antibody and certain of our small molecule product candidates. We cannot be sure that they will perform as required. Should they decide they no longer want to maintain any of the patents licensed to us, they are required to afford us the opportunity to do so at our expense. If our licensors do not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, and possibly unbeknownst to us, 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 and to inform us of the status of those protections and efforts thereto.

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, in addition to being costly and time consuming to undertake. 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 scope of our issued patents may not extend to competitive products developed or produced by others;
- 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
- intellectual property rights 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 invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute inter partes review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. 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 pending patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Furthermore, adverse results on US patents may affect related patents in our global portfolio.

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

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

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

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;

- substantial damages for past infringement which we may have to pay if a court decides that our product infringes a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds, time, and may result in an inferior or less-desirable process or product.

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

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Even if frivolous or unsubstantiated in nature, 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 and the implicated employee(s).

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 $95.4 million as of December 31, 2018. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

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

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

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

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

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

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

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

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. We currently anticipate that our cash and cash equivalents balances at December 31, 2018 are sufficient to fund our anticipated operating cash requirements for approximately the next 12 to 15 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, preclinical 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 or BLA for any of our product candidates or any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;

- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and

- the success of the commercialization of one or more of our product candidates.

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

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

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

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

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

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

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

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

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

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

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as that term is used in the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our common stock, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our outstanding common stock that are held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report on Form 10-K;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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 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 adopt the new or revised standard. This may make comparison of our financial statements with another public company which has opted into using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

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

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

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

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

Fortress controls a voting majority of our common stock.

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

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

Under the terms of the Founders Agreement, Fortress has the right to receive an annual grant of shares of our common stock equal to 2.5% of the fully-diluted outstanding equity at the time of issuance, on the anniversary of the date of the Founders Agreement, which became effective as of March 17, 2015 and was amended and restated on July 11, 2016. This annual issuance of shares to Fortress will dilute your holdings in our common stock and, if the value of Checkpoint has not grown over the prior year, would result in a reduction in the value of your shares.

In October 2017, the Founder's Agreement was amended to change the issuance date of the annual grant of shares from the anniversary date of the Agreement to January 1 of each year beginning in 2018. The annual grant of shares payable on January 1, 2018 was prorated such that it was only payable for the portion of 2017 between March 17, 2017 and December 31, 2017.

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

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

The Chairman of our Board of Directors is also the Executive Chairman, President and Chief Executive Officer of TG Therapeutics, Inc. ("TGTX"), with whom we have a collaboration agreement and a sublicense agreement, and as a result during the term of these agreements certain conflicts of interest may arise which will require the attention of our officers and independent directors who are unaffiliated with TGTX.

In connection with our license agreement with Dana-Farber, we entered into a collaboration agreement with TGTX to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs, including CK-301, in the field of hematological malignancies. Michael S. Weiss, our Chairman of the Board of Directors, is also the Executive Chairman, President and Chief Executive Officer of TGTX. As such, as the collaboration agreement proceeds, certain conflicts of interest may arise between us and TGTX. Those conflicts will have to be resolved by our officers and directors who are unaffiliated with TGTX, and also by officers and directors of TGTX who are unaffiliated with us. This may lead to less than desirable complications and costs to both companies, which could harm our results of operations.

In connection with our license agreement with Jubilant, we entered into a sublicense agreement with TGTX to develop and commercialize the Jubilant family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103, in the field of hematological malignancies. As such, as the sublicense agreement proceeds, certain conflicts of interest may arise between us and TGTX. Those conflicts will have to be resolved by our officers and directors who are unaffiliated with TGTX, and also by officers and directors of TGTX who are unaffiliated with us. This may lead to less than desirable complications and costs to both companies, which could harm our results of operations.

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable

PART II

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

Market information

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol "CKPT." We commenced trading on the NASDAQ Capital Market on June 26, 2017. Prior to this, but only since December 19, 2016, our common stock was quoted on the OTCQX market. Prior to December 19, 2016 there was no public market for our common stock.

Equity Compensation Plans

On March 21, 2017 and November 9, 2017, we filed registration statements on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our Amended and Restated 2015 Incentive Plan ("2015 Plan"). The registration statements became effective immediately upon filing, and shares covered by the registration statements are 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 12, 2019, there were approximately 75 holders of record for our common stock and 1 holder of record for our Class A common stock. The number of beneficial holders of our common stock does not reflect shareholders who hold shares in street name through brokerage accounts or other nominees.

Dividends

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

Securities Authorized for Issuance under Equity Compensation Plans

Subject to adjustment as provided in the 2015 Plan, the total aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 5,000,000, of which 2,345,457 shares remain available for future issuance as of December 31, 2018.

Item 6. Selected Financial Data

Not applicable.

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

Forward-Looking Statements

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

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

Overview

We are a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. We are currently evaluating our lead small-molecule, targeted anti-cancer agent, CK-101, in a Phase 1/2 clinical trial for the treatment of patients with EGFR mutation-positive NSCLC. In addition, we are currently evaluating our lead antibody product candidate, CK-301, an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts intended to support one or more BLA submissions.

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

In September 2018, we announced preliminary interim safety and efficacy data from our ongoing Phase 1/2 clinical trial of CK-101. The data were presented in an oral presentation at the IASLC 19th World Conference on Lung Cancer in Toronto. Enrollment in the trial is ongoing to identify the optimal dose with a new softgel capsule formulation to maximize therapeutic effect, following which a Phase 3 trial is planned to initiate in 2019 in treatment-naïve EGFR mutation-positive NSCLC patients.

To date, we have not received approval for the sale of any product candidate in any market and, therefore, have not generated any product sales from any product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, we have an accumulated deficit of $95.4 million.

We are a majority-controlled subsidiary of Fortress.

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

Critical Accounting Policies and Use of Estimates

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

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

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Revenue

For the year ended December 31, 2018, revenue was approximately $3.5 million compared to approximately $1.7 million for the year ended December 31, 2017, an increase of approximately $1.8 million. Revenue for the current period primarily consisted of 3.0 million from TGTX for the purchase of clinical material of CK-301 in connection with the collaboration agreement and $0.4 million from TGTX related to the sublicense agreement for CK-103. Revenue for the year ended December 31, 2017 primarily consisted of $1.0 million from TGTX related to the sublicense agreement for CK-103, including $0.2 million due upon the successful completion of toxicology studies, and approximately $0.6 million from TGTX in connection with the Sponsored Research Agreement with NeuPharma. A small portion of revenue was also generated in connection with the collaboration agreement with TGTX.

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, 2018, research and development expenses were approximately $33.7 million, compared to approximately $19.1 million for the year ended December 31, 2017, an increase of $14.6 million. The current period research and development expenses primarily consisted of $23.2 million related to manufacturing costs of our product candidates, $0.7 million related to preclinical development activities for our product candidates, $5.6 million related to clinical costs for our product candidates, $1.0 million related to a non-refundable milestone payment upon the twelfth patient dosed in a Phase 1 clinical study of CK-301, $1.7 million related to the non-cash annual equity fee in connection with the Founders' Agreement, and $0.1 million related to stock compensation expense. The year ended December 31, 2017 research and development expenses primarily consisted of $7.3 million related to manufacturing costs of our product candidates, $2.0 million related to preclinical and product development activities for our product candidates, $3.4 million related to clinical costs for our product candidates, $2.3 million related to the non-cash annual equity fee in connection with the Founders' Agreement, $1.2 million related to stock compensation expense, $0.7 million for salary expenses due to the hiring of research and development employees, and $0.4 million milestone payment to Jubilant upon the successful completion of toxicology studies under the terms of the license agreement with Jubilant.

We expect our research and development activities to decrease in 2019 due to lower manufacturing costs of CK-301 due to sufficient clinical supply from batches produced in 2018. This decrease will be partially offset by higher costs associated with non-clinical and clinical activities for our product candidates.

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, 2018, general and administrative expenses were approximately $6.6 million, compared to approximately $5.4 million for the year ended December 31, 2017, an increase of $1.2 million. The current period general and administrative expenses primarily consisted of stock compensation expense of $1.9 million, $0.8 million related to our issuance of shares to Fortress in connection with our March and September 2018 common stock offerings pursuant to the Founders Agreement, $1.1 million related to salary expenses, $0.8 million related to legal and accounting fees and $0.6 million related to investor relation fees. The prior year general and administrative expenses primarily consisted of stock compensation expense of $1.9 million, $1.2 million related to legal and accounting fees, $0.9 million related to salary expenses, and $0.4 million related to consulting and outside services expenses.

We anticipate general and administrative expenses in 2019 to remain relatively consistent as compared to 2018.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, we had an accumulated deficit of $95.4 million.

In March 2018, we completed an underwritten public offering, in which we sold 5,290,000 shares of our common stock at a price of $4.35 per share for gross proceeds of approximately $23.0 million. Total net proceeds from the offering were approximately $20.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million, including approximately $1.8 million paid to National Securities Corporation, a related party at the time of the offering. The shares were sold under a Registration Statement (No. 333-221493) on Form S-3, filed with the Securities and Exchange Commission ("SEC").

During the year ended December 31, 2018, we sold a total of 1,841,774 shares of common stock under an At-the-Market Issuance Sales Agreement ("ATM") for aggregate total gross proceeds of approximately $8.0 million at an average selling price of $4.33 per share, resulting in net proceeds of approximately $7.7 million after deducting commissions and other transactions costs.

Our major sources of cash have been proceeds from the sale of equity securities. We expect to use these proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. We currently anticipate that our cash and cash equivalents balances at December 31, 2018, are sufficient to fund our anticipated operating cash requirements for at least one year from the date of this Annual Report on Form 10-K.

We will be required to expend significant funds in order to advance the development of our product candidates. Our estimate as to how long we expect our existing cash to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Accordingly, we will be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources. Further financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy and we may be forced to curtail or cease operations.

Cash Flows for the Years Ended December 31, 2018 and 2017

Operating Activities

Net cash used in operating activities was $25.8 million for the year ended December 31, 2018, compared to $15.5 million for the year ended December 31, 2017. The increase in net cash used in operating activities was due primarily to increased expenditures associated with manufacturing and other product development activities for our product candidates.

Investing Activities

There were no investing activities for the year ended December 31, 2018. Net cash used in investing activities was $0.4 million for the year ended December 31, 2017 and related to the purchase of research and development licenses.

Financing Activities

Net cash provided by financing activities was $28.6 million for the year ended December 31, 2018. All the cash provided by financing activities related to net proceeds of $20.8 million from the issuance of common stock as part of our underwritten public offering in March 2018 and net proceeds of $7.7 million from the issuance of common stock as part of our ATM offerings in September 2018. There were no financing activities for the year ended December 31, 2017.

Recently Issued Accounting Standards

See Note 2 to our Financial Statements

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of December 31, 2018, our portfolio of financial instruments consists of cash equivalents, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2018, management carried out, under the supervision and with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on these criteria.

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

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements.

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

(b) Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.2.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 7, 2018 (File No. 001-38128) and incorporated herein by reference.
3.3	Bylaws of Checkpoint Therapeutics, Inc., filed as Exhibit 3.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.1	Specimen certificate evidencing shares of common stock, filed as Exhibit 4.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.2	Form of warrant agreement, filed as Exhibit 4.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.1	Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.2	Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated July 11, 2016 and effective as of March 17, 2015, filed as Exhibit 10.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.2.1	Amendment 1 to Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc., dated October 5, 2017 filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 3, 2017 (File No. 000-55506) and incorporated herein by reference.
10.3	Management Services Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.4	Promissory Note to NSC Biotech Venture Fund I, LLC dated February 27, 2015, filed as Exhibit 10.4 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.5	Common Stock Warrant issued by Checkpoint Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC dated July 30, 2015, filed as Exhibit 10.5 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.6	License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc. dated March 2, 2015, filed as Exhibit 10.6 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.7	Amendment 1 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 5, 2015, filed as Exhibit 10.7 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.8	Amendment 2 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated April 12, 2016, filed as Exhibit 10.8 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.9	Amendment 3 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 24, 2016, filed as Exhibit 10.9 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.

10.10	License Agreement by and between NeuPharma Inc. and Coronado Biosciences, Inc. (Fortress' predecessor) dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015), filed as Exhibit 10.8 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.11	Amendment 1 to License Agreement by and between NeuPharma Inc. and Checkpoint Therapeutics, Inc. dated February 21, 2017, filed as Exhibit 10.11 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.12	Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated March 3, 2015, filed as Exhibit 10.9 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.13	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.10 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.13.1	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 9, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.14	Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated October 13, 2015, filed as Exhibit 10.11 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.15	Amendment to Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated September 27, 2016, filed as Exhibit 10.1 to Form 8-K filed on October 3, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.16	Amendment No. 2, dated December 15, 2016, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.16 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.16.1	Amendment No. 3, dated January 30, 2018, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.21 to Annual Report on Form 10-K filed on March 16, 2018 (File No. 001-38128) and incorporated herein by reference. #
10.17	License Agreement by and between Cephalon, Inc. and Fortress Biotech, Inc. dated December 18, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated December 18, 2015), filed as Exhibit 10.12 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.18	Non-Employee Directors Compensation Plan, filed as Exhibit 10.13 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.18.1	Amended and Restated Non-Employee Directors Compensation Plan, filed as Exhibit 10.2 to Quarterly Report on Form 10-Q filed on August 9, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.19	Board Advisory Services Agreement by and between Caribe BioAdvisors, LLC and Checkpoint Therapeutics, Inc. dated January 1, 2017, filed as Exhibit 10.19 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.20	Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015); extended as of September 11, 2015; extended as of December 15, 2015; extended as of January 11, 2016; extended as of July 8, 2016, filed as Exhibit 10.14 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.21	Extension dated December 30, 2016, to Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015), filed as Exhibit 10.21 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.21.1	Extension dated December 29, 2017, to Option Agreement by and between Fortress Biotech, Inc. and TG Therapeutics, Inc., dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015), filed as Exhibit 10.21 to Annual Report on Form 10-K filed on March 16, 2018 (File No. 001-38128) and incorporated herein by reference.
10.22	Research Agreement by and between Fortress Biotech, Inc. and NeuPharma, Inc., dated September 15, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015), filed as Exhibit 10.15 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.23	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated September 15, 2015, filed as Exhibit 10.16 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.24	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated December 18, 2015, filed as Exhibit 10.17 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.

10.25	License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.18 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.26	Amendment 1 to License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc. dated December 13, 2016, filed as Exhibit 10.26 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.26.1	Amendment 2 to License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc. dated March 31, 2017, filed as Exhibit 10.2 to Quarterly Report on Form 10-Q filed on May 10, 2017 (File No. 000-55506) and incorporated herein by reference.
10.27	Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.19 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference. *
10.28	Amendment 1 to Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc. dated December 13, 2016, filed as Exhibit 10.28 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.28.1	Amendment 2 to Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2017, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on May 10, 2017 (File No. 000-55506) and incorporated herein by reference.
10.29	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.20 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference.
10.30	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.21 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference.
10.31	Collaboration Agreement by and between Adimab, LLC and Checkpoint Therapeutics, Inc., dated January 22, 2019. *
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP.
24.1	Power of Attorney (included on signature page).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from the Company's Quarterly Report on Form 10-K for the period ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statement of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

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

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Checkpoint Therapeutics, Inc.
New York, NY

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Checkpoint Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

New York, NY
March 15, 2019

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

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 21,995	$ 19,225
Prepaid expenses and other assets	1,372	1,857
Other receivables - related party	1,532	331
Total current assets	24,899	21,413
Total Assets	**$ 24,899**	**$ 21,413**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,317	$ 5,762
Accounts payable and accrued expenses - related party	776	610
Total current liabilities	13,093	6,372
Total Liabilities	**13,093**	**6,372**
Commitments and Contingencies		
Stockholders' Equity		
Common Stock ($0.0001 par value), 60,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2018 and December 31, 2017	1	1
Common shares, 27,076,154 and 18,512,429 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	3	2
Common stock issuable, 960,428 and 591,836 shares as of December 31, 2018 and December 31, 2017, respectively	1,748	2,296
Additional paid-in capital	105,451	71,772
Accumulated deficit	(95,397)	(59,030)
Total Stockholders' Equity	11,806	15,041
Total Liabilities and Stockholders' Equity	**$ 24,899**	**$ 21,413**

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

CHECKPOINT THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	For the year ended December 31,	
	2018	**2017**
Revenue - related party	$ 3,506	$ 1,725
Operating expenses:		
Research and development	33,654	19,081
General and administrative	6,592	5,419
Total operating expenses	40,246	24,500
Loss from operations	(36,740)	(22,775)
Other income		
Interest income	148	98
Other income	225	-
Total other income	373	98
Net Loss	**$ (36,367)**	**$ (22,677)**
Loss per Share:		
Basic and diluted net loss per common share outstanding	$ (1.27)	$ (1.00)
Basic and diluted weighted average number of common shares outstanding	28,553,711	22,618,931

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

CHECKPOINT THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Class A Common Shares		Common Shares		Common Shares	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Equity
Balances at December 31, 2016	**7,000,000**	**$ 1**	**17,426,876**	**$ 2**	**$ 3,919**	**$ 64,736**	**$ (36,353)**	**$ 32,305**
Stock-based compensation expense	-	-	359,303	-	-	3,117	-	3,117
Issuance of common shares - Founders Agreement	-	-	721,699	-	(3,919)	3,919	-	-
Common shares issuable - Founders Agreement	-	-	-	-	2,296	-	-	2,296
Exercise of warrants	-	-	4,551	-	-	-	-	-
Net loss	-	-	-	-	-	-	(22,677)	(22,677)
Balances at December 31, 2017	**7,000,000**	**$ 1**	**18,512,429**	**$ 2**	**$ 2,296**	**$ 71,772**	**$ (59,030)**	**$ 15,041**
Issuance of common shares, net of offering costs - Public offering	-	-	5,290,000	1	-	20,827	-	20,828
Issuance of common shares, net of offering costs - At-the-market offering	-	-	1,841,774	-	-	7,747	-	7,747
Stock-based compensation expense	-	-	616,240	-	-	1,994	-	1,994
Issuance of common shares - Founders Agreement	-	-	770,128	-	(2,296)	3,111	-	815
Common shares issuable - Founders Agreement	-	-	-	-	1,748	-	-	1,748
Exercise of warrants	-	-	45,583	-	-	-	-	-
Net loss	-	-	-	-	-	-	(36,367)	(36,367)
Balances at December 31, 2018	**7,000,000**	**$ 1**	**27,076,154**	**$ 3**	**$ 1,748**	**$ 105,451**	**$ (95,397)**	**$ 11,806**

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

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

	For the year ended December 31,	
	2018	**2017**
Cash Flows from Operating Activities:		
Net loss	$ (36,367)	$ (22,677)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,994	3,117
Issuance of common shares - Founders Agreement	815	-
Common shares issuable - Founders Agreement	1,748	2,296
Research and development-licenses acquired, expensed	-	400
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	485	(1,786)
Other receivables - related party	(1,201)	490
Accounts payable and accrued expenses	6,721	2,699
Net cash used in operating activities	(25,805)	(15,461)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	-	(400)
Net cash used in investing activities	-	(400)
Cash Flows from Financing Activities:		
Issuance of common shares - Public offering	23,012	-
Offering costs for the issuance of common shares - Public offering	(2,184)	-
Issuance of common shares - At-the-market offering	7,981	-
Offering costs for the issuance of common shares - At-the-market offering	(234)	-
Net cash provided by (used in) financing activities	28,575	-
Net increase (decrease) in cash and cash equivalents	2,770	(15,861)
Cash and cash equivalents at beginning of period	19,225	35,086
Cash and cash equivalents at end of period	**$ 21,995**	**$ 19,225**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 2,296	$ 3,919

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. Checkpoint is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. The Company may acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. The Company may also enter into collaboration agreements with third and related parties including sponsored research agreements to develop these technologies for liquid tumors while retaining the rights in solid tumors.

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

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "CKPT."

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, 2018, the Company had an accumulated deficit of $95.4 million.

In March 2018, the Company completed an underwritten public offering, whereby it sold 5,290,000 shares of its common stock at a price of $4.35 per share for gross proceeds of approximately $23.0 million. Total net proceeds from the offering were approximately $20.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million, including approximately $1.8 million to National Securities Corporation, a related party at the time of the offering (see Note 4 and Note 6). The shares were sold under a Registration Statement (No. 333-221493) on Form S-3, filed by the Company with the Securities and Exchange Commission ("SEC").

During the year ended December 31, 2018, the Company sold a total of 1,841,774 shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $8.0 million at an average selling price of $4.33 per share, resulting in net proceeds of approximately $7.7 million after deducting commissions and other transactions costs.

The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, which may include financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at December 31, 2018 are sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Annual Report on Form 10-K.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company's estimate as to how long it expects its existing cash to be able to continue to fund its operations is based on assumptions that may prove to be wrong, and it could use its available capital resources sooner than it currently expects. Further, changing circumstances, some of which may be beyond its control, could cause the Company to consume capital faster than it currently anticipates, and it may need to seek additional funds sooner than planned. Accordingly, the Company will be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources. Further financing may not be available to it on acceptable terms, or at all. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategy and may be forced to curtail or cease operations.

Note 2 - Significant Accounting Policies

Basis of Presentation

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

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents.

Other Receivables - Related Party

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

Research and Development Costs

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

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

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1,*Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use.

Annual Equity Fee

Under the Founder's Agreement with Checkpoint dated March 17, 2015, and amended and restated on July 11, 2016, Fortress is entitled to an annual equity fee on each anniversary of the Agreement equal to 2.5% of fully diluted outstanding equity, payable in Checkpoint common shares ("Annual Equity Fee"). The Annual Equity Fee was part of the consideration payable for formation of the Company, identification of certain assets, including the license contributed to Checkpoint by Fortress (see Note 4).

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

In October 2017, the Founder's Agreement was amended to change the issuance date of the Annual Equity Fee from the anniversary date of the Agreement to January 1 of each year beginning in 2018. Because the issuance of shares on January 1, 2018 occurred prior to the issuance of the December 31, 2017 financial statements, the Company recorded approximately $2.3 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2017. The number of shares issued on January 1, 2018 were prorated to include only the portion of 2017 between March 17, 2017 and December 31, 2017.

Pursuant to the Founders Agreement, the Company issued 960,428 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2019. Because the issuance of shares on January 1, 2019 occurred prior to the issuance of the December 31, 2018 financial statements, the Company recorded approximately $1.7 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2018.

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. The Company accounts for forfeitures as they occur. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as stock-based compensation expense in the period of change.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying individual's role at the Company.

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 from Contracts with Customers

The Company recognizes revenue under ASC 606, Revenue from Contracts with Customers. The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. When determining the transaction price, an entity must consider the effects of all of the following:

- Variable consideration
- Constraining estimates of variable consideration
- The existence of a significant financing component in the contract
- Noncash consideration
- Consideration payable to a customer

Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

Revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property is recognized only when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.

b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Incremental contract costs are expensed when incurred when the amortization period of the asset that would have been recognized is one year or less; otherwise, incremental contract costs are recognized as an asset and amortized over time as services are provided to a customer.

Income Taxes

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

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The following table summarizes potentially dilutive securities outstanding at December 31, 2018 and 2017 that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	December 31,	
	2018	**2017**
Warrants (Note 6)	4,280,972	4,326,555
Stock options (Note 6)	60,000	60,000
Unvested restricted stock (Note 6)	2,932,106	2,611,116
Total	7,273,078	6,997,671

Recently Issued Accounting Standards

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, "*Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*," which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its financial statements.

Recently Adopted Accounting Standards

In May 2017, the FASB issued an ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The new standard was effective on January 1, 2018; however, early adoption is permitted. The Company adopted ASU No. 2017-09 as of January 1, 2018. The adoption of this update did not impact the Company's financial statements.

In January 2017, the FASB issued an ASU 2017-01, "*Business Combinations (Topic 805) Clarifying the Definition of a Business*". The amendments in this ASU clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of this update did not impact the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-08, "*Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*". 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 adopted the new standard effective January 1, 2018, using the modified retrospective approach applied to all of its contracts. The adoption of this update did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *"Improvements to Nonemployee Share-Based Payment Accounting"*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. The adoption of this update did not have a material impact on the Company's financial statements.

In November 2018, the FASB issued ASU No. 2018-18, "*Collaboration Arrangements: Clarifying the Interaction between Topic 808 and Topic 606*". The issuance of ASC 606 raised questions about the interaction between the guidance on collaborative arrangements and revenue recognition. ASU 2018-18 addresses this uncertainty by (1) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaboration arrangement participant is a customer, (2) adding unit of account guidance to assess whether the collaboration arrangement or a part of the arrangement is with a customer and (3) precluding a company from presenting transactions with collaboration arrangement participants that are not directly related to sales to third parties together with revenue from contracts with customers. The new standard is effective on January 1, 2020 with early adoption permitted. The Company elected to adopt ASU 2018-18 in December 2018. The adoption of this update did not have a material impact on the Company's financial statements.

Note 3 - License Agreements

Dana-Farber Cancer Institute

In March 2015, the Company entered into an exclusive license agreement with Dana-Farber Cancer Institute ("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 and, on May 11, 2015, granted Dana-Farber 500,000 shares, valued at $32,500 or $0.065 per share. The agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that the Company raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, the Company granted to Dana-Farber an additional 136,830 shares of common stock valued at approximately $0.6 million and the anti-dilution clause thereafter expired. Dana-Farber is eligible to receive payments of up to an aggregate of approximately $21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the license agreement, Dana-Farber receives an annual license maintenance fee of $50,000, which is creditable against milestone payments or royalties due to Dana-Farber. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX.

In September 2018 the Company expensed a non-refundable milestone payment of $1.0 million upon the twelfth patient dosed in a Phase 1 clinical study of its anti-PD-LI antibody, CK-301, which is included in the Statements of Operations for the year ended December 31, 2018.

In connection with the license agreement with Dana-Farber, the Company entered into a collaboration agreement with TGTX, a related party, to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies, while the Company retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the collaboration agreement, TGTX paid the Company $0.5 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments up to an aggregate of approximately $21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately $14.5 million upon first commercial sales in specified territories. In addition, the Company is eligible to receive up to an aggregate of $60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, the Company receives an annual license maintenance fee, which is creditable against milestone payments or royalties due to the Company. TGTX also pays the Company for its out-of-pocket costs of material used by TGTX for their development activities. The Company recognized approximately $3.0 million and $0.1 million, respectively, for the years ended December 31, 2018 and 2017, in revenue from its collaboration agreement with TGTX in the Statements of Operations.

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized CK-301, the Company's anti-PDL1 antibody which it originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to the Company, and Checkpoint entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive payments up to an aggregate of approximately $7.1 million upon the Company's successful achievement of certain clinical development and regulatory milestones, of which $4.8 million are due upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments based on a tiered low single digit percentage of net sales.

NeuPharma, Inc.

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

In September 2016, the Company dosed the first patient in a Phase 1/2 clinical study of CK-101, which is currently ongoing as of December 31, 2018.

In connection with the license agreement with NeuPharma, in March 2015, Fortress entered into an option agreement with TGTX, a related party, which agreement was assigned to the Company by Fortress on the same date, for a global collaboration of certain compounds licensed. The option agreement expired on December 31, 2018.

Also, in connection with the license agreement with NeuPharma, the Company entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid the Company for all amounts previously paid by the Company. This assumption of costs by TGTX survives any termination or expiration of the option agreement. For the years ended December 31, 2018 and 2017, the Company recognized approximately $35,000 and $0.6 million, in revenue in connection with the Sponsored Research Agreement in the 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"). This agreement was assigned to the Company by Fortress on the same date. Under the terms of the license agreement, Checkpoint obtained an exclusive, worldwide license to Cephalon's patents relating to CEP-8983 and its small molecule prodrug, CEP-9722, a PARP inhibitor, which the Company refers to as CK-102. The Company paid Cephalon an up-front licensing fee of $0.5 million. In August 2018, the Company gave notice to Cephalon of its intention to terminate the license agreement, which became effective in February 2019.

Jubilant Biosys Limited

In May 2016, the Company entered into a license agreement with Jubilant Biosys Limited ("Jubilant"), whereby the Company obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103. Under the terms of the agreement, the Company paid Jubilant an up-front licensing fee of $2.0 million, included in research and development expenses on the Company's Statements of Operations for the year ended December 31, 2016. In March 2017, the Company expensed a non-refundable milestone payment of $0.4 million upon the successful completion of toxicology studies under the terms of the license agreement with Jubilant, which is included in the Company's Statements of Operations for the year ended December 31, 2017. Jubilant is eligible to receive payments up to an aggregate of approximately $89.0 million upon the Company's successful achievement of certain preclinical, clinical development, and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales.

In connection with the license agreement with Jubilant, the Company entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retains the right to develop and commercialize these compounds in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Sublicense Agreement, TGTX paid the Company $1.0 million, representing an upfront licensing fee, and the Company is eligible to receive substantive potential milestone payments up to an aggregate of approximately $87.2 million upon TGTX's successful achievement of clinical development and regulatory milestones. This is comprised of up to approximately $25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately $61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, the Company is eligible to receive potential milestone payments up to an aggregate of $89.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays the Company 50% of IND enabling costs and patent expenses. For the years ended December 31, 2018 and 2017, the Company recognized approximately $0.4 million and $1.0 million, respectively, in revenue related to the sublicense agreement in the Statements of Operations.

The collaborations with TGTX each contain single material performance obligations under Topic 606, which is the granting of a license that is functional intellectual property. The Company's performance obligation was satisfied at the point in time when TGTX had the ability to use and benefit from the right to use the intellectual property. The performance obligations were satisfied prior to the adoption of Topic 606.

The milestone payments are based on successful achievement of clinical development, regulatory, and sales milestones. Because these payments are contingent on the occurrence of a future event, they represent variable consideration and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The sales-based royalty payments are recognized as revenue when the subsequent sales occur. The Company also receives variable consideration for certain research and development, out-of-pocket material costs and patent maintenance related activities that are dependent upon the Company's actual expenditures under the collaborations and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Revenue is recognized approximately when the amounts become due because it relates to an already satisfied performance obligation. For the year ended December 31, 2018, the Company did not receive any milestone or royalty payments.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, the Company entered into a Founders Agreement with Fortress, which was amended and restated on July 11, 2016 (the "Founders Agreement"). The Founders Agreement provides, that in exchange for the time and capital expended in the formation of Checkpoint and the identification of specific assets the acquisition of which resulted in the formation of a viable emerging growth life science company, the Company assumed $2.8 million in debt that Fortress accumulated under a promissory note through National Securities Corporation for expenses and costs of forming Checkpoint, and the Company shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one-half percent (2.5%) of the fully-diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Checkpoint's voting equity, equal to two and one-half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Checkpoint's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Checkpoint will pay a one-time change in control fee equal to five times (5x) the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%). The Founders Agreement has a term of fifteen years, after which it automatically renews for one-year periods unless Fortress gives the Company notice of termination. The Founders Agreement will also automatically terminate upon a change of control.

In October 2017, the Founder's Agreement was further amended to change the issuance date of the Annual Equity Fee from the anniversary date of the Agreement to January 1 of each year beginning in 2018. The Annual Equity Fee payable on January 1, 2018 was prorated such that it was only paid for the portion of 2017 between March 17, 2017 and December 31, 2017.

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 its Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. For the years ended December 31, 2018 and 2017, the Company recognized $0.5 million in expense on its Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. For the years ended December 31, 2018 and 2017, the Company recognized $87,000 and $70,000, respectively, in expense in its Statements of Operations related to the advisory agreement, including $27,000 and $10,000, respectively, in expense related to annual equity incentive grants.

March 2018 Common Stock Offering

National Securities Corporation acted as an underwriter in connection with the Company's offering of common stock which closed on March 12, 2018. At the time of the offering, an affiliate of Fortress held a majority interest in the parent of National Securities Corporation and Checkpoint is a majority-controlled subsidiary of Fortress. As a result, National Securities Corporation was deemed to have a "conflict of interest" under Rule 5121(f)(5) of FINRA. Accordingly, the offering was conducted in accordance with the applicable provisions of Rule 5121, which requires, among other things, that a "qualified independent underwriter" participate in the preparation of, and exercise the usual standards of "due diligence" with respect to, the registration statement and prospectus. Lake Street Capital Markets, LLC agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with the offering.

Note 5 - Commitments and Contingencies

Leases

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

License Agreements

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

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company accrues the most likely amount of such loss, and if such amount is not determinable, then the Company accrues the minimum of the range of probable loss. As of December 31, 2018 and 2017, there was no litigation against the Company.

Note 6 - Stockholders' Equity

Common Stock

At the Company's 2018 Annual Meeting of Stockholders held on June 13, 2018, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock to 60,000,000 shares and decrease the number of shares designated "Class A Common Stock" from 15,000,000 to 7,000,000. The amendment was filed with the Secretary of State of the State of Delaware on June 14, 2018.

As of December 31, 2018, 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.

In November 2017, the Company filed a shelf registration statement on Form S-3 (the "S-3"), which was declared effective in December 2017. Under the S-3, the Company may sell up to a total of $100 million of its securities. In connection with the S-3, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

Pursuant to the Founders Agreement, the Company issued 591,836 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2018 (see Notes 2 and 4).

In March 2018, the Company completed an underwritten public offering, whereby it sold 5,290,000 shares of its common stock at a price of $4.35 per share for gross proceeds of approximately $23.0 million. Total net proceeds from the offering were approximately $20.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million, including approximately $1.8 million to National Securities Corporation, a related party (see Note 4). The shares were sold under a Registration Statement (No. 333-221493) on Form S-3, filed by the Company with the SEC.

During the year ended December 31, 2018, the Company sold a total of 1,841,774 shares of common stock under the ATM for aggregate total gross proceeds of approximately $8.0 million at an average selling price of $4.33 per share, resulting in net proceeds of approximately $7.7 million after deducting commissions and other transactions costs.

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, the Company issued 178,292 shares to Fortress and recorded expense of approximately $815,000 related to these stock grants, which is included in general and administrative expenses in the Company's Statements of Operations for the year ended December 31, 2018.

Pursuant to the Founders Agreement, the Company issued 960,428 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully-diluted outstanding equity of Checkpoint on January 1, 2019 (see Notes 2 and 4).

The S-3 is currently the Company's only active shelf registration statement. Subsequent to the offerings noted above, approximately $69.0 million of the shelf remains available for sale under the S-3. The Company may offer the securities under the S-3 from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders. The Company believes that the S-3 provides it with the flexibility to raise additional capital to finance its operations as needed.

Equity Incentive Plan

The Company has in effect the Amended and Restated 2015 Incentive Plan ("2015 Incentive Plan"). The 2015 Incentive Plan was adopted in March 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. An amendment to the 2015 Incentive Plan was approved by stockholders in June 2017 to increase the shares available for issuance to 5,000,000 shares. The plan expires 10 years from the effective date of the amendment and limits the term of each option to no more than 10 years from the date of grant.

As of December 31, 2018, 2,345,457 shares are available for issuance under the 2015 Incentive Plan.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activity for the year ended December 31, 2018 and 2017:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2016	2,533,063	$ 2.93
Granted	359,303	7.69
Vested	(281,250)	0.07
Nonvested at December 31, 2017	2,611,116	$ 3.89
Granted	616,240	3.75
Vested	(295,250)	0.29
Nonvested at December 31, 2018	2,932,106	$ 4.22

As of December 31, 2018, there was $3.0 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 1.31 years. This amount does not include, as of December 31, 2018, 333,334 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones; and 590,866 shares of restricted stock outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense is recognized over the vesting period of the award. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Options

The following table summarizes stock option award activity for the year ended December 31, 2018 and 2017.

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2016	60,000	$ 5.43	9.96
Granted	-	-	
Outstanding as of December 31, 2017	60,000	$ 5.43	9.09
Granted	-	-	
Outstanding as of December 31, 2018	60,000	$ 5.43	8.09

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

Warrants

A summary of warrant activities for year ended December 31, 2018 and 2017 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2016	4,331,106	$ 6.62	4.67
Granted	-	-	
Exercised	(4,551)	-	
Outstanding as of December 31, 2017	4,326,555	$ 6.62	3.67
Granted	-	-	
Exercised	(45,583)	-	
Outstanding as of December 31, 2018	4,280,972	$ 6.69	2.33

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

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the years ended December 31, 2018 and 2017 ($ in thousands).

	For the year ended December 31,	
	2018	2017
Research and development	$ 95	$ 1,180
General and administrative	1,899	1,937
Total stock-based compensation expense	$ 1,994	$ 3,117

Note 7 - Income Taxes

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit during the years ended December 31, 2018 and 2017.

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

	For the Year Ended December 31,	
	2018	**2017**
Percentage of pre-tax income:		
Statutory federal income tax rate	21%	35%
State taxes, net of federal tax benefit	4%	11%
Credits	3%	2%
Change in federal tax rate	-%	(27)%
Change in state tax rate	(6)%	8%
Provision to return	(4)%	5%
Stock based compensation shortfall	(1)%	(4)%
Other	-%	-%
Change in valuation allowance	(17)%	(30)%
Income taxes provision (benefit)	-%	-%

The components of the net deferred tax asset as of December 31, 2018 and 2017 are the following (in thousands):

	As of December 31,	
	2018	**2017**
Deferred tax assets:		
Net operating loss carryovers	$ 17,056	$ 10,662
Stock compensation and other	1,674	1,839
Change in fair value of warrant liabilities	-	149
Amortization of license	4,346	5,410
Accruals and reserves	6	11
Tax credits	1,938	905
Start Up Costs	32	46
Total deferred tax assets	25,052	19,022
Less valuation allowance	(25,052)	(19,022)
Deferred tax asset, net of valuation allowance	$ -	$ -

On December 22, 2017, "H.R.1", formerly known as the "Tax Cuts and Jobs Act", was signed into law. Among other items, H.R.1 reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company recorded a decrease related to deferred tax assets and valuation allowance of $6.2 million, with a corresponding net adjustment to deferred income tax expense of zero for the year ended December 31, 2017.

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset. A valuation allowance of approximately $25.1 million and $19.0 million was recorded for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the Company had federal and state net operating loss carryforwards of approximately $63.4 million and $55.2 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2035 and 2035, respectively. The Company has $1.9 million of research and development credit carryforwards, which will begin to expire, if not utilized, by 2035. Utilization of the net operating loss and credit carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions.

There are no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740 "Income Taxes" ("ASC 740"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the year ended December 31, 2018. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the period ended December 31, 2018. The Company would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable.

The federal and state tax returns for the periods ended December 31, 2015, 2016, 2017 and 2018 are currently open for examination under the applicable federal and state income tax statues of limitations.

Note 8 - Accounts Payable and Accrued Expenses

At December 31, 2018 and 2017, accounts payable and accrued expenses consisted of the following:

	For the year ended December 31,	
	2018	2017
Accounts payable	$ 9,750	$ 3,645
Accrued compensation	439	405
Research and development	1,751	1,466
Other	377	246
Accounts payable and accrued expenses - related party	776	610
Total accounts payable and accrued expenses	$ 13,093	$ 6,372

Note 9 - Quarterly Financial Data (Unaudited)

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2018				
Total Revenue	$ 343	$ 127	$ 5	$ 3,031
Operating expenses	$ 9,126	$ 6,805	$ 9,392	$ 14,923
Other income	$ 18	$ 39	$ 43	$ 273
Net loss	$ (8,765)	$ (6,639)	$ (9,344)	$ (11,619)
Basic and diluted net loss per common share	$ (0.35)	$ (0.23)	$ (0.32)	$ (0.37)
2017				
Total Revenue	$ 693	$ 351	$ 349	$ 332
Operating expenses	$ 5,107	$ 6,823	$ 6,299	$ 6,271
Other income	$ 31	$ 24	$ 22	$ 21
Net loss	$ (4,383)	$ (6,448)	$ (5,928)	$ (5,918)
Basic and diluted net loss per common share	$ (0.20)	$ (0.28)	$ (0.26)	$ (0.26)

SIGNATURES

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

Checkpoint Therapeutics, Inc.

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

March 15, 2019

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ James F. Oliviero James F. Oliviero	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2019
/s/ Garrett Gray Garrett Gray	Vice President, Finance and Accounting (Principal Financial Officer)	March 15, 2019
/s/ Michael S. Weiss Michael S. Weiss	Chairman of the Board	March 15, 2019
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 15, 2019
/s/ Scott Boilen Scott Boilen	Director	March 15, 2019
/s/ Neil Herskowitz Neil Herskowitz	Director	March 15, 2019
/s/ Barry Salzman Barry Salzman	Director	March 15, 2019
/s/ Christian Bechon Christian Bechon	Director	March 15, 2019

EXHIBIT 10.31

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

COLLABORATION AGREEMENT

This Collaboration Agreement (the "**Agreement**") is made effective as of January 22, 2019 (the "**Effective Date**"), by and between Adimab, LLC, a Delaware limited liability company having an address at 7 Lucent Drive, Lebanon, NH 03766 ("**Adimab**"), and Checkpoint Therapeutics, Inc., having an address at 2 Gansevoort Street, 9th Floor, New York, NY 10014 ("**Checkpoint**").

Background

Whereas, Adimab is a leader in yeast-based, fully human antibody discovery and optimization using its proprietary core technology platform;

Whereas, Checkpoint is a biotechnology company in the business of, among other things, developing and commercializing therapeutic products;

Whereas, Adimab and Fortress collaborated on multiple Research Programs, including the PD-L1 Research Program (as defined below), and Fortress relinquished rights to the PD-L1 Antibodies (as defined below) such that Adimab and Checkpoint may enter into this Agreement;

Whereas, Checkpoint, by virtue of a previous option exercise, has a license to develop, manufacture and commercialize the PD-L1 Antibodies in accordance with the terms hereof; and

Now, Therefore, in consideration of the foregoing premises and the mutual covenants set forth below, and for other good and valuable consideration, the receipt of which is hereby acknowledged, Adimab and Checkpoint hereby agree as follows:

ARTICLE 1

DEFINITIONS.

The following initially capitalized terms have the following meanings (and derivative forms of them shall be interpreted accordingly):

1.1 "**AAA**" has the meaning set forth in Section 10.2(c)(i) (*Arbitration*).

1.2 "**Adimab**" has the meaning set forth in the recitals.

1.3 "**Adimab Indemnitees**" has the meaning set forth in Section 8.2 (*Indemnification by Checkpoint*).

1.4 "**Adimab Materials**" means any tangible biological or chemical materials (including all vectors, antibodies and other Know-How in the form of tangible biological or chemical materials) used or created by Adimab under a Research Program, including quantities of Program Antibodies (and DNA encoding these Program Antibodies), but excluding from and after the time of Option exercise for the relevant Target any quantities of Optioned Antibodies (and DNA encoding these Optioned Antibodies) provided to Checkpoint for such Target.

1.5 "**Adimab Platform Patents**" means all Patents Adimab Controls during the term of this Agreement that claim or Cover Adimab Platform Technology. (For clarity, Adimab Platform Patents exclude Program Antibody Patents.)

1.6 "**Adimab Platform Technology**" means (a) the discovery and optimization of antibodies via methods that include the use of synthetic DNA antibody libraries and engineered strains of yeast, (b) all methods, materials and other Know-How used in the foregoing and (c) platforms embodying, components, component steps and other portions of any of the foregoing in (a) or (b). For clarity, Adimab Platform Technology excludes Program Antibodies, but includes technology used in the discovery and optimization of any Program Antibody, in each case not based on the specific composition of such Program Antibody (or product containing a Program Antibody), but based instead on the manner in which such Program Antibody was discovered or optimized under a Research Program.

1.7 "**Adimab Platform Technology Improvement**" means all Know-How developed or discovered through or as a result of a Research Program, and all Program Inventions (and Patents claiming them) that constitute, Cover, claim or are directed to Adimab Platform Technology, including any and all improvements, enhancements, modifications, substitutions, alternatives or alterations to Adimab Platform Technology.

1.8 "**Adimab Program Inventions**" means all Program Inventions made solely by employees of, or others obligated to assign Program Inventions to, Adimab.

1.9 "**Affiliate**" means an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with a Party. For this purpose, "control" means the ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management of the entity.

1.10 "**Agreement**" has the meaning set forth in the recitals.

1.11 "**Back-Up Candidate"** means a Product that (a) is directed to the same Target (or, with respect to a multispecific antibody, the same set of Targets) as another Product (the "**Lead Product**"), and (b) has been selected by Checkpoint as a back-up to the Lead Product for development and commercialization.

1.12 "**Checkpoint Indemnitees**" has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

1.13 "**Checkpoint Materials**" means (a) any tangible biological or chemical materials (including antigen samples and other Know-How in the form of tangible biological or chemical materials) provided by Checkpoint to Adimab under a Research Program (other than commercial material purchased by Checkpoint and delivered to Adimab), and (b) from and after the time of the Option exercise for a Target, the quantities of Optioned Antibody to such Target provided to Checkpoint by Adimab under this Agreement.

1.14 "**Checkpoint Program Inventions**" means all Program Inventions made solely by employees of, or others obligated to assign Program Inventions to, Checkpoint.

1.15 "**Commercially Reasonable Efforts**" means the level of efforts required to carry out a task in a diligent and sustained manner without undue interruption, pause or delay; which level is at least commensurate with the level of efforts that a similarly situated biopharmaceutical company would devote to a product of similar potential and having similar commercial and scientific advantages and disadvantages resulting from the company's own research efforts (i.e., explicitly ignoring the royalty, milestone and other payments due Adimab under this Agreement), taking into account safety and efficacy; the competitiveness of alternative products; the proprietary position of the product; pricing and reimbursement; and all other relevant commercial factors.

1.16 "**Confidential Information**" has the meaning set forth in Section 6.1(a) (*General Confidentiality Obligations*).

1.17 "**Combination Product**" means a Product (a) containing a Licensed Product together with one or more other active ingredients (excluding antibody-drug conjugates, CAR-T products and bispecifics), or (b) marketed 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 full price of the other) or for a single price.

1.18 "**Control**" means, with respect to any Know-How or Patent, possession by a Party, whether by ownership or license (other than pursuant to this Agreement) of the ability to grant a license or sublicense as provided for in this Agreement without violating the terms of any written agreement with any Third Party.

1.19 "**Cover**" means, with respect to a particular item and a particular Patent, that such Patent claims or covers, in any of the countries of manufacture, use, and/or sale, (a) the composition of such item, or of any product containing such item or that is made using such item by virtue of such product containing or being made using such item; and (b) a method of making or using any of the things referred to in (a).

1.20 "**Dispute**" has the meaning set forth in Section 10.2(a) (*Initial Dispute Resolution*).

1.21 "**Effective Date**" has the meaning set forth in the recitals.

1.22 "**Evaluation Term**" means, with respect to each Research Program, the time period beginning at the end of the Research Term for such Research Program and ending twenty four (24) months thereafter.

1.23 "**Excluded Technology**" means technology (and the Patents that Cover such technology) related to:

(a) product formulation;

(b) manufacturing or production;

(c) the sequence of, or any modification to, a Program Antibody (including Patents relating to pegylation or other chemical modification) or sequences of antibodies against a Target;

(d) technology used in activities performed by or on behalf of Checkpoint or its Licensees, including assays, *in vivo* testing, and modifications to Program Antibodies;

(e) any Target (including any antigen representation thereof), or any mechanism of action via interaction with a Target, or antibodies based on their interaction with a Target, or their having been tested for their activity against a Target in a biological assay;

(f) the use of Checkpoint Materials;

(g) if other than an IgG, the construct of any Product; and

(h) technology related to anything other than the manner in which Adimab discovered the antibody, the Adimab Platform, or its operation generally.

1.24 "**Field**" means any and all uses and purposes, including, without limitation, diagnostic, prophylactic, and therapeutic uses, in humans and animals.

1.25 "**First Commercial Sale**" means, with respect to a Product in any country, the first sale, transfer or disposition for value or for end use or consumption of such Product in such country after Marketing Approval for such Product has been received in such country.

1.26 "**Force Majeure**" means conditions beyond a Party's reasonable control or ability to plan for, including acts of God, war, terrorism, civil commotion, labor strike or lock-out; epidemic; failure or default of public utilities or common carriers; and destruction of facilities or materials by fire, earthquake, storm or like catastrophe; *provided, however*, the payment of invoices due and owing under this Agreement shall not be excused by reason of a Force Majeure affecting the payor.

1.27 "**Fortress**" means Fortress Biotech, Inc., 2 Gansevoort, 9th Floor, New York, NY 10014.

1.28 "**FTE**" means the equivalent of a full-time employee's working days over a twelve (12) month period (taking account of normal vacations, sick days and holidays not being considered working days), which equates to a total of one thousand eight hundred (1,800) hours per twelve (12) month period of work performed by a fully qualified Adimab employee or consultant in a Research Program. To provide an FTE over a given time period that is less than a year means to provide the proportionate share (corresponding to the proportion that such time period bears to a full year) during such time period of a full year's FTE. In no event shall the work over the course of a year of one individual person account for more than one (1) FTE year.

1.29 "**FTE Rate**" means * dollars ($*) per FTE.

1.30 "**Indemnify**" has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

1.31 "**Joint Inventions**" means any and all Program Inventions made jointly by employees of, or others obligated to assign Program Inventions to, each of Adimab and Checkpoint.

* Confidential material redacted and filed separately with the Commission.

1.32 "**Joint Serendipitous Inventions**" means all Joint Inventions other than those claimed by Program Antibody Patents or constituting Adimab Platform Technology Improvements.

1.33 "**Know-How**" means all technical information and know-how, including (i) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (ii) all data, instructions, processes, formula, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines.

1.34 "**Lead Product**" has the meaning set forth in Section 1.11 (*Back-Up Candidate*).

1.35 "**License Agreements**" has the meaning set forth in Section 9.6 (*Additional Effects of Termination*).

1.36 "**Licensee**" means a Third Party to whom Checkpoint has granted, directly or indirectly, rights to research, develop, manufacture, and/or commercialize Program-Benefited Antibodies; *provided, however*, that Licensees shall exclude fee-for-service contract research organizations or contract manufacturing organizations acting in such capacity. For clarity, licensees of the rights assigned to Checkpoint by Adimab and sublicensees of the license granted by Adimab to Checkpoint pursuant to Section 3.2 (*Commercial Rights*) shall be Licensees.

1.37 "**Losses**" has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

1.38 "**Marketing Approval**" each means, with in any given country, approval to market a Product legally as a drug or biologic, including approval of a Biologic License Application (as defined in the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §§ 600-680) in the United States, or approval of a comparable filing in the United States or any other jurisdiction. Pricing approval need not be obtained in order for Marketing Approval to be achieved.

1.39 "**Milestone Event**" has the meaning set forth in Section 4.4 (*Milestone Events*).

1.40 "**Milestone Payment**" has the meaning set forth in Section 4.4 (*Milestone Events*).

1.41 "**Net Sales**" means the gross amounts invoiced for a Product by Checkpoint, its Affiliates and Licensees for sales or other commercial disposition of such Product to a Third Party purchaser, less the following:

(a) trade and quantity discounts (other than early pay cash discounts) actually allowed with respect to such sales which effectively reduce the selling price and are appropriately deducted from sales under appropriate accounting principles, consistently applied;

(b) discounts, returns, rebates, chargebacks and other allowances actually allowed with respect to such sales;

(c) retroactive price reductions that are actually allowed or granted;

(d) deductions to the gross invoice price of Product imposed by regulatory authorities or other governmental entities;

(e) Shipping, handling, freight, postage, insurance and transportation charges.

(f) any tax imposed on the production, sale, delivery or use of the Product, including, without limitation, sales, use, excise or value added taxes, or the annual fee imposed on the pharmaceutical manufacturers by the U.S. government; and

(g) a fixed amount equal to one and one-half percent (1.5%) of the amount invoiced to cover bad debt, early payment cash discounts, transportation and insurance

Products are considered "sold" when billed, invoiced or payment is received, whichever comes first.

Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to Products provided by or on behalf of Checkpoint, an Affiliate or a Licensee to Checkpoint, an Affiliate or a Licensee for purposes of resale, provided such resale is included in Net Sales.

If any Optioned Antibody is sold as part of a Combination Product, the Net Sales for such Optioned Antibody 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 the Product with only the Optioned Antibody (i.e., without the additional active ingredient in the Combination Product) if sold separately for the same dosage (or form) as contained in the Combination Product, and B is the net selling price in such country of any other active ingredients 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 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 Product (containing only such Optioned Antibody 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 Optioned Antibody portion of the combination, and D is the standard fully-absorbed manufacturing cost of the other active ingredients included in the Combination Product, as determined by Checkpoint using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed manufacturing cost of the Optioned Antibody and/or the other active ingredients included in such Combination Product cannot be determined, Net Sales allocable to the Combination Product in each such country shall be determined by mutual agreement (such agreement to not be unreasonably withheld) reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the 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).

1.42 **"Optimized Antibody"** means an antibody resulting from the optimization, pursuant to a Research Plan, by Adimab of Checkpoint Antibody. For the avoidance of doubt, any activities conducted by Adimab under a Research Plan using an antibody provided by Checkpoint shall be deemed "optimization." Optimized Antibodies shall themselves be Program Antibodies. For clarity, the PD-L1 Antibodies are Optimized Antibodies.

1.43 **"Optimized Product"** means any Product that contains one or more Optimized Antibodies and does not contain Program Antibodies other than Optimized Antibodies.

1.44 "**Option**" has the meaning set forth in Section 3.2(a) (*Option*).

1.45 "**Option Fee**" has the meaning set forth in Section 4.3 (*Option Fee*).

1.46 "**Optioned Antibody**" means any Program Antibody selected by Checkpoint pursuant to Section 3.2(a) (*Option*), and any Program-Benefited Antibody generated from such selected Program Antibody.

1.47 "**Optioned Program Antibody Patents**" means those Program Antibody Patents that solely Cover Optioned Antibodies.

1.48 "**Optioned Program Antibody Know-How**" means Know-How included in Program Inventions that relates solely to Optioned Antibodies.

1.49 "**Original Fortress Agreement**" means that certain Collaboration Agreement between Fortress and Adimab dated June 29, 2015.

1.50 "**Party**" means Adimab or Checkpoint.

1.51 "**Patent**" means any patent application or patent anywhere in the world, including all of the following categories of patents and patent applications, and their foreign equivalents: provisional, utility, divisional, continuation, continuation-in-part, and substitution applications; and utility, re-issue, re-examination, renewal and extended patents, and patents of addition, and any Supplementary Protection Certificates, restoration of patent terms and other similar rights.

1.52 "**PD-L1 Antibodies**" means the Program Antibodies generated in the PD-L1 Research Program.

1.53 "**PD-L1 Research Program**" means that Research Program designed to generate Program Antibodies against the Target known as programmed death-ligand 1 ("**PD-L1**").

1.54 "**Phase I Trial**" means a human clinical trial (whether a phase la or a phase lb trial) in any country of the type described in 21 C.F.R. §312.21(a), or an equivalent clinical study required by a Regulatory Authority outside of the United States.

1.55 "**Phase II Trial**" means a human clinical trial conducted in any country of the type described in 21 C.F.R. §312.21(b), or an equivalent clinical study required by a Regulatory Authority outside of the United States.

1.56 "**Phase III Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. § 312.21(c), or an equivalent clinical study required by a Regulatory Authority outside the United States. For purposes of this Agreement, a human clinical trial that combines elements of a Phase II Trial and a Phase III Trial (a Phase II/III trial) shall be deemed a Phase III Trial.

1.57 "**Product**" means a pharmaceutical preparation in any form that comprises or contains one or more Program-Benefited Antibodies (whether or not such product is currently under evaluation for safety, efficacy, or other factors).

1.58 "**Program Antibody**" means any PD-L1 Antibody. It is understood and agreed that even if Adimab delivers nucleic acid sequences or amino acid sequences to Checkpoint instead of protein samples, antibodies encoded by such nucleic acid sequences or amino acid sequences are Program Antibodies, in addition to antibodies samples of which are physically delivered to Checkpoint under this Agreement.

1.59 "**Program Antibody Know-How**" means Know-How (a) included in Program Inventions that relates to Optioned Antibodies, excluding Optioned Program Antibody Know-How and (b) does not relate to Adimab Platform Technology or Adimab Platform Technology Improvements.

1.60 "**Program Antibody Patents**" means Patents that (a) Cover a Program-Benefited Antibody or any Product and (b) do not Cover Adimab Platform Technology or Adimab Platform Technology Improvements.

1.61 "**Program Assets**" has the meaning set forth in Section 9.6 (*Additional Effects of Termination*).

1.62 "**Program-Benefited Antibody**" means any Program Antibody and any modified or derivative form of any such Program Antibody (including an scFv) created by or on behalf of Checkpoint or its Licensees, including any fragment thereof, pegylated version thereof (whether or not including amino acid changes) and including chemically modified versions (including associated amino acid substitutions) of a Program Antibody, and including an antibody designed or derived using the sequence of any Program Antibody, nucleotide coding for it, any cell line or cellular or bacterial expression system or vector expressing any Program Antibody or incorporating the nucleotide coding for a Program Antibody.

1.63 "**Program Inventions**" means any invention that is conceived and/or first reduced to practice in the course of or as a result of the activities conducted under this Agreement (including in exercise of a license under this Agreement) or as a result of the use of Confidential Information exchanged hereunder. For clarity, Program Inventions include all Know-How made, developed, invented or discovered by employees, contractors or agents of either Party or of both Parties pursuant to this Agreement.

1.64 "**Program Patent**" means any Patent Covering a Program Invention.

1.65 "**Regulatory Assets**" has the meaning set forth in Section 9.6 (*Additional Effects of Termination*).

1.66 "**Regulatory Authority**" means the FDA or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a pharmaceutical product (including a Product), which may include the authority to grant the required reimbursement and pricing approvals for such sale.

1.67 [Intentionally Omitted.]

1.68 "**Research Plan**" means the research plan to be agreed upon by the Parties with respect to a Target in accordance with Section 2.1 (*Research Programs*) hereof.

1.69 "**Research Program**" means each program of research conducted under this Agreement in accordance with a Research Plan.

1.70 "**Research Term**" means the period beginning on the Effective Date and ending, on a Research Program-by-Research Program basis, when Adimab delivers final antibodies under a Research Plan; *provided, however*, that in the event that Adimab is unable to deliver antibodies pursuant to a Research Plan within one (1) year of commencing work on such Research Plan, then either Party may terminate the Research Term with respect to such Research Program at such point.

1.71 "**Royalty Payment**" has the meaning set forth in Section 4.5(a) (*Royalty Payments*).

1.72 "**Royalty Term**" means, on a Product-by-Product and country-by-country basis, the term ending at the later to occur of (a) the expiration of the last Valid Claim Covering the Product in the country in which such Product is manufactured or sold, or (b) twelve (12) years after the First Commercial Sale of such Product in such country.

1.73 "**Senior Executive Discussions**" has the meaning set forth in Section 10.2(a) (*Initial Dispute Resolution*).

1.74 "**Sublicense Agreement**" has the meaning set forth in Section 3.2 (*Licenses*).

1.75 "**Tangible Assets**" has the meaning set forth in Section 9.6 (*Additional Effects of Termination*).

1.76 "**Target**" means PD-L1.

1.77 "**Third Party**" means an entity other than a Party or a Party's Affiliates.

1.78 "**Third Party Claims**" has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

1.79 "**Third Party Patent Licenses**" means Patent licenses obtained by Checkpoint after Checkpoint determines in good faith that one or more such Patent licenses from Third Parties are reasonably required by Checkpoint because such Patents Cover the way in which Program Antibodies were discovered or optimized using Adimab Platform Technology under a Third Party Patent Covering the Adimab Platform Technology, in order to avoid Third Party claims of patent infringement relating to the discovery or optimization of a Optioned Antibody, which claims are reasonably believed by Checkpoint to be reasonably likely not to be dismissed at summary judgment and are reasonably likely to succeed overall. For clarity, Third Party Patent Licenses explicitly excludes licenses to any Excluded Technology.

1.80 "**Transferred Assets**" has the meaning set forth in Section 9.6 (*Additional Effects of Termination*).

1.81 "**Valid Claim**" means a claim of a Patent, which claim (i) is issued and unexpired and has not been found to be unpatentable, invalid or unenforceable by a court or other authority having jurisdiction, from which decision no appeal is taken, will be taken or can be taken; or (ii) is pending and has not been finally abandoned or finally rejected and has been pending for no more than eight (8) years.

1.82 References in the body of this Agreement to "Sections" refer to the sections of this Agreement. The terms "include," "includes," "including" and derivative forms of them shall be deemed followed by the phrase "without limitation" regardless of whether such phrase appears there (and with no implication being drawn from its inconsistent inclusion or non-inclusion).

1.83 To avoid doubt, the term "antibody" as used everywhere else in this Agreement includes both full-length antibodies, fragments thereof, and chemically modified versions thereof (including pegylated versions and regardless of whether containing amino acid substitutions), all of the foregoing whether naturally occurring, artificially produced, raised in an artificial system, or created through modification of an antibody produced in any of the foregoing ways or otherwise, and whether represented by physical material, nucleic acid sequences, or amino acid sequences.

ARTICLE 2

RESEARCH PROGRAMS.

2.1 Research Programs.

(a) Research Plans. As of the Effective Date, the Parties do not intend to collaborate on additional Research Programs, provided that the Research Program established under the Original Fortress Agreement with respect to PD-L1 and the PD-L1 Antibodies shall be deemed the Research Program (and the Research Plan established thereunder with respect thereto shall be deemed the Research Plan) for purposes of this Agreement.

2.2 Project Management.

(a) Alliance Managers. Each Party shall designate in writing within thirty (30) days after signing this Agreement an "Alliance Manager" to be the primary contact for such Party. The Alliance Manager shall be responsible for managing communications between the Parties with respect to a Research Program, including responsibility for scheduling teleconferences.

2.3 Reports; Records.

(a) By Adimab. During the applicable Research Term, at the junctures specified in the applicable Research Plan, Adimab shall provide written reports to Checkpoint regarding the Research Plan. Notwithstanding the foregoing or anything express or implied anywhere in this Agreement, Adimab shall not be required to disclose any Adimab Platform Technology or Adimab Platform Technology Improvements to Checkpoint. Adimab shall maintain records, in reasonable scientific and technical detail and in a manner appropriate for patent purposes, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of a Research Program. In the event that such records and data include disclosure of Adimab Platform Technology or Adimab Platform Technology Improvements, Adimab may redact those portions that would disclose Adimab Platform Technology or Adimab Platform Technology Improvements prior to any review or inspection by Checkpoint.

(b) By Checkpoint. During the applicable Research Term, at the junctures set forth in the applicable Research Plan, Checkpoint shall provide written reports to Adimab which provide any data Checkpoint is required to provide under the applicable Research Plan.

2 . 4 Use of Adimab Materials. With respect to each Target, Checkpoint shall only use Adimab Materials (a) as is necessary to conduct a Research Program during the Research Term and the Evaluation Term, (b) pursuant to the license granted under Section 3.1(a) (*Research License to Checkpoint*) of this Agreement while such license is in effect, (c) to generate and test Program-Benefited Antibodies in accordance with Section 9.3 (*Commitments Regarding Program-Benefited Antibodies*) and (d) in connection with the exercise of its rights under Section 3.2(b). Checkpoint shall not use Adimab Materials for any other purposes. For clarity, this means that, except as specified pursuant to the foregoing sentence, Checkpoint shall not (i) provide Adimab Materials to any Third Party, or (ii) use any Program-Benefited Antibodies or Adimab Materials, or information related thereto (including the sequences thereof), for any purpose other than to research and develop antibodies that will be milestone- and royalty-bearing to Adimab hereunder. For clarity, the "sequence" of an antibody includes the amino acid sequence of the antibody and the corresponding nucleic acid sequences. Adimab acknowledges and agrees that upon receipt of Program Antibodies, Checkpoint may conduct testing on such Program Antibodies to optimize such Program Antibodies (and, to avoid doubt, the optimized versions thus created shall be Program-Benefited Antibodies).

Adimab retains title to the Adimab Materials, including all quantities of Program Antibodies that it provides under a Research Program, including during the Evaluation Term. Such quantities of Program Antibodies are (i) for use solely in assessing whether to exercise the Option for the applicable Target, and (ii) shall not be used in humans or for any commercial purpose. Should Checkpoint not exercise its Option as described in Section 3.2(a) (*Option*), Checkpoint shall return to Adimab or destroy any Program-Benefitted Antibodies in its possession on expiration of the Evaluation Term for such Target. Without limiting the generality of the foregoing, during the Evaluation Term and after expiration of the Options, if unexercised, Checkpoint shall not provide Program-Benefitted Antibodies to Third Parties. Notwithstanding the foregoing, should Checkpoint exercise the Option for a given Target, all right, title and interest in and to those Program-Benefitted Antibodies shall belong to and vest in Checkpoint (subject to the terms and conditions of this Agreement with respect to Program-Benefited Antibodies, including Section 9.3 (*Commitments Regarding Program-Benefited Antibodies*) hereof).

2.5 Use of Checkpoint Materials. Adimab shall use the Checkpoint Materials solely to perform the Research Program for the applicable Target. Adimab shall not transfer or otherwise provide the Checkpoint Materials to any Third Party. Adimab shall not use Checkpoint Materials for any other purposes. For clarity, this means that, except as specified pursuant to the foregoing sentence, Checkpoint retains title to the Checkpoint Materials that it provides under a Research Program. Within ninety (90) days after the Research Term for such Target ends, Adimab will return to Checkpoint or destroy any remaining Checkpoint Materials (at Checkpoint's direction).

2.6 Certain Restrictions on the Use of Antibodies.

(a) Adimab Restrictions. Adimab shall not provide any Third Party with any Program Antibody delivered to Checkpoint. Adimab shall not deliver to Checkpoint as a Program Antibody any antibody previously delivered to a Third Party.

To avoid doubt and notwithstanding anything to the contrary in this Agreement:

(i) nothing herein shall prevent Adimab from licensing or transferring some or all of the Adimab Platform Technology and/or Adimab Platform Technology Improvements to a Third Party (including technical support in connection therewith) nor shall anything herein require Adimab to in any way limit the use of the Adimab Platform Technology and/or Adimab Platform Technology Improvements by Adimab or a Third Party; and

(ii) nothing herein shall require Adimab to physically remove from its libraries, or to prevent from being included in future libraries, any Program-Benefited Antibodies. Adimab hereby reserves the right for Adimab, its Affiliates, and those deriving rights from them (a) to include Program-Benefited Antibodies in antibody library(ies) transferred or licensed by Adimab to Third Parties (including the transfer of physical possession of samples of Program-Benefited Antibodies to a Third Party as part of such transactions) and (b) to conduct any activity with respect to Program-Benefited Antibodies that are not Optioned Antibodies if Adimab (or such other party) arrives at such Program-Benefited Antibodies independent from the activities performed under a Research Plan and in a manner fully compliant with Adimab's other covenants and obligations under this Agreement; *provided, however*, that, except as permitted by Section 6.7 (*Certain Data*) in no event shall Adimab disclose to any Third Party, or otherwise directly or indirectly exploit, any Confidential Information of Checkpoint, including Confidential Information regarding the relationship between the Target and Program-Benefited Antibodies and the characterization of Program Antibodies by Adimab.

(b) Checkpoint Restrictions. Checkpoint hereby covenants that it, its Affiliates and its Licensees shall not seek to or actually research, develop or commercialize any Program-Benefited Antibody, or product containing the foregoing (other than the activities permitted hereunder during the Research Term and the Evaluation Term for the purpose of determining whether or not to exercise the Option for such Target) except as Optioned Antibodies and Products under this Agreement.

ARTICLE 3

LICENSES; OPTION; DEVELOPMENT & COMMERCIALIZATION

3.1 Mutual Research Program Licenses.

(a) Research License to Checkpoint. During the Research Term and Evaluation Term for each Research Program, Adimab hereby grants Checkpoint a non-exclusive, non-sublicensable license with respect to the Target that is the subject of such Research Program under the Adimab Platform Patents and Program Antibody Patents to perform research in the Field, including for Checkpoint to perform Checkpoint's responsibilities under the Research Plan and this Agreement for such Target. For clarity, the license to Checkpoint excludes the right to (i) discover or optimize antibodies using the Adimab Platform Technology or Adimab Platform Technology Improvements, or (ii) use Program-Benefited Antibodies or Adimab Materials to (a) screen for other antibodies' activity vis-à-vis the applicable Target or (b) design other antibodies (in the case of either (a) or (b), other than Program-Benefited Antibodies that will be milestone- and royalty-bearing to Adimab under this Agreement).

(b) Research License to Adimab. During the Research Term and Evaluation Term for each Research Program, Checkpoint hereby grants to Adimab a non-exclusive, nontransferable (except in connection with a permitted assignment of this Agreement) license with respect to such Target under all Patents and Know-How Controlled by Checkpoint which Cover the Targets (including any that so relate by claiming antibodies directed to the Targets or a mechanism of action via the Targets) or any Checkpoint Materials provided to Adimab, solely to perform Adimab's responsibilities as provided for in the applicable Research Plan.

3.2 Commercial Rights.

(a) Option. On April 10, 2017, Checkpoint, via Fortress, exercised the exclusive option (each, an "**Option**") to obtain the licenses of Section 3.2(b) (*Development and Commercialization License and Assignment*) for the PD-L1 Antibodies and the PD-L1 Antibodies are the "**Optioned Antibodies**."

(b) Development and Commercialization License and Assignment.

(i) Assignment. Adimab hereby, effective as of the Effective Date, assigns to Checkpoint, subject to the terms and conditions of this Agreement, all right, title and interest in and to Optioned Program Antibody Know-How and Optioned Program Antibody Patents.

(ii) License. Adimab hereby, effective as of the Effective Date, grants to Checkpoint a worldwide, royalty-bearing, sublicenseable (solely as provided in Section 3.2(b)(iii) (*Licensees*)) license under the Adimab Platform Patents, Program Antibody Know-How and Program Antibody Patents, if any, which are not assigned to Checkpoint pursuant to Section 3.2(b)(i) (*Assignment*), in the Field, to research, develop, have developed, make, have made, use, sell, offer to sell, import and export the Optioned Antibodies and Products during the term of this Agreement. Such license shall be non-exclusive under the Adimab Platform Patents and exclusive under Program Antibody Know-How and the Program Antibody Patents. For clarity, the license to Checkpoint excludes the right to (i) discover or optimize antibodies using the Adimab Platform Technology or Adimab Platform Technology Improvements, or (ii) use Program-Benefited Antibodies or Adimab Materials to (a) screen for other antibodies' activity vis-à-vis the applicable Target or (b) design other antibodies (in the case of either (a) or (b), other than Program-Benefited Antibodies that will be milestone- and royalty-bearing to Adimab under this Agreement).

(iii) Licensees. Any license of any Optioned Antibody and any sublicense of the rights granted under Section 3.2(b) (*Development and Commercialization License and Assignment*) shall be made solely pursuant to agreements ("**Sublicense Agreements**") that are consistent with all relevant terms and conditions of this Agreement and to Licensees who explicitly agree in writing to comply with all applicable terms of this Agreement, including Section 9.3 (*Commitments Regarding Program-Benefited Antibodies*) hereof. Checkpoint shall remain responsible for all payments and other performance obligations due under this Agreement, notwithstanding any license or sublicense that it may grant.

3.3 Diligent Development and Commercialization. Checkpoint shall use Commercially Reasonable Efforts to clinically develop, seek Marketing Approval for, and launch and actively commercialize at least one (1) Program Antibody discovered in each Research Program for which it exercises the Option. Annually, Checkpoint will provide Adimab with a written report of Product progress in development and commercialization, Checkpoint's activities in that regard. If requested by Adimab, Checkpoint shall meet via teleconference with Adimab to discuss such report at least annually at a time mutually agreed upon by Checkpoint and Adimab.

3.4 No Implied Licenses. Other than the licenses, options and assignments explicitly set forth in this Article 3 (*Licenses; Option; Development & Commercialization*) or in Article 5 (*Intellectual Property*), neither Party grants any intellectual property licenses, options or assignments to the other Party under this Agreement. This Agreement does not create any implied licenses.

3.5 Covenant Not to Exceed License. Each Party hereby covenants that it shall not practice any Patent or item of Know-How licensed to it under this Agreement outside the scope of the license to such Party set forth in this Agreement (or any subsequent agreement between the Parties providing for an additional license under such Patent or item of Know-How). For the avoidance of doubt, Checkpoint will not research, develop, manufacture or commercialize Optioned Antibodies except as Products under this Agreement.

3.6 Bankruptcy Code. If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code or similar provision in the bankruptcy laws of another jurisdiction (the "Code"), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against a Party under the Code, the other Party shall be entitled to a complete duplicate of, or complete access to (as such other Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, if not already in such other Party's possession, shall be promptly delivered to such other Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by such other Party, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. The foregoing provisions of this Section 3.6 are without prejudice to any rights a Party may have arising under the Code.

ARTICLE 4

FINANCIAL TERMS.

4.1 Technology Access Fee. There is no technology access fee hereunder.

4.2 Research Stage Fees.

(a) Research Funding. For each Research Plan, Checkpoint shall pay Adimab, within thirty (30) days of completion of each calendar quarter, an amount equal to * percent (*%) of the actual FTEs expended by Adimab on the Research Programs during such calendar quarter (at the FTE Rate).

(b) Technical Milestones.

(i) ***[Intentionally Omitted]***

(ii) Technical Milestone II. On a Research-Program-by-Research Program basis, Checkpoint shall pay Adimab * dollars ($*) within thirty (30) days of Adimab's delivery to Checkpoint of a panel of Program Antibodies meeting the criteria identified in the applicable Research Plan as the "Technical Milestone II Criteria". Adimab and Checkpoint hereby acknowledge that such technical milestone payment with respect to the PD-L1 Research Program has, as of the Effective Date, already been paid in full.

4 . 3 Option Fee. In order to exercise the Option under Section 3.2(a) (*Option*) for a Research Program, Checkpoint shall pay to Adimab a non-creditable, nonrefundable option exercise fee of * dollars ($*) for each such Research Program (each, an "**Option Fee**") plus any unpaid Technical Milestone with respect to such Research Program; *provided, however*, that such amount shall be reduced to * dollars ($*) with respect to the third Option exercised hereunder and each Option exercised thereafter. Adimab and Checkpoint hereby acknowledge that the Option Fee with respect to the PD-L1 Research Program and the Program Antibody has, as of the Effective Date, already been paid in full.

4.4 Milestone Payments.

(a) Milestone Events. On a Product-by-Product basis, Checkpoint shall report in writing to Adimab the achievement of each event (each, a "**Milestone Event**") and pay the corresponding milestone payment (each, a "**Milestone Payment**") to Adimab, each within thirty (30) days after the achievement of the corresponding Milestone Event in the following table:

Milestone Event	Milestone Payment
*	*
*	*
*	*
*	*
*	*
*	*

Adimab and Checkpoint hereby acknowledge that the first milestone payment in the table above with respect to * has, as of the Effective Date, already been paid in full with respect to the Program Antibody.

* Confidential material redacted and filed separately with the Commission.

Milestones Payments are payable one time per Product, the first time each is achieved for such Product. If a later-stage clinical Milestones Event is achieved for any Product without one or more earlier-stage clinical Milestone Events having been achieved for that Product, then Checkpoint shall pay the Milestone Payment(s) for such previous clinical Milestone Event(s) along with the payment for the most recently achieved Milestone Event. If a Milestone Event related to filing for Marketing Approval is achieved without one or more of the clinical Milestone Events being achieved, then Checkpoint shall pay the Milestone Payment(s) for such previous clinical Milestone Event(s) along with the payment for the first Milestone Event related to filing for Marketing Approval.

(b) Back-Up Candidates. In the event that a Milestone Event that was already achieved with respect to a Lead Product is also achieved with respect to a Back-Up Candidate to such Lead Product prior to receipt Marketing Approval for the Lead Product, then Checkpoint's obligation to pay the corresponding Milestone Payment with respect to the achievement of the applicable milestone event with respect to such Back-Up Candidate shall be deferred until receipt of marketing approval of the Lead Product. If Checkpoint continues to develop such Back-Up Candidate after receipt of Marketing Approval for the Lead Product, all deferred Milestone Payments for such Back-Up Candidate shall become payable within thirty (30) days after receipt of such Marketing Approval and all subsequent Milestone Payments for such Back-Up Candidate shall be payable within ten (10) days after achievement of the corresponding Milestone Event with respect to such Back-Up Candidate. If Checkpoint promptly discontinues all development activities with respect to a Back-Up Candidate upon Marketing Approval of the Lead Product and provides Adimab with written notice thereof within thirty (30) days after such Marketing Approval, Checkpoint will not be obligated to pay the deferred Milestone Payments for such Back-Up Candidate. If Checkpoint continues to develop such Back-Up Candidate after discontinuation of development of the Lead Product (but prior to Marketing Approval of such Lead Product), Checkpoint will not be obligated to pay the deferred Milestone Payments for such Back-Up Candidate, but all Milestone Payments for Milestone Events achieved with respect to such Back-Up Candidate that were not paid to Adimab with respect to such Lead Product shall be payable within ten (10) days after achievement of the corresponding Milestone Event.

(c) Optimized Products. Notwithstanding the foregoing, Milestone Payments made with respect to Optimized Products shall be * percent (*%) of the amounts that would otherwise be due pursuant to Section 4.4(a) (*Milestone Payments*).

4.5 Royalties.

(a) Royalty Payments. As to each Product sold during the applicable Royalty Term, on a Product-by-Product basis, Checkpoint shall pay Adimab the following royalties, based on the royalty rate applicable to the relevant portion of annual worldwide Net Sales for such Product ("**Royalty Payments**"):

Portion of Worldwide Calendar Year Net Sales	**Royalty Rate**
*	* percent (*%)
*	* percent (*%)

* Confidential material redacted and filed separately with the Commission.

(b) Optimized Products. Notwithstanding the foregoing, Royalty Payments made with respect to Optimized Products shall be * percent (*%) of the amounts that would otherwise be due pursuant to Section 4.5(a) (*Royalty Payments*).

(c) Royalty Term. On a Product-by-Product and country-by-country basis, upon expiration of the Royalty Term for a Product in a country, the rights, licenses and sublicenses granted to Checkpoint hereunder with respect to such Product in such country shall continue in effect but become fully paid-up, royalty-free and perpetual.

(d) Royalty Buy-Down.

(i) Royalty Buy-Down Prior to Phase III. On a Product-by-Product basis, Checkpoint, at its sole option any time prior to the dosing of the first patient in the first Phase III Trial, may elect to reduce the royalty owed to Adimab pursuant to Section 4.5(a) (*Royalty Payments*) to * percent (*%) of aggregate worldwide Net Sales by paying Adimab a one-time fee equal to * dollars ($*).

(ii) No Royalty Buy-Down After Commencement of Phase III Trial. If the royalty buy-down option has not been exercised at the time of dosing of the first patient in a Phase III Trial, the royalty buy-down option shall then expire.

(e) Adjustment for Third Party IP. If Checkpoint enters into any Third Party Patent Licenses, then * percent (*%) of the net sales royalties actually paid to the Third Party under the Third Party Patent License with respect to Net Sales of any given Product in any given calendar quarter in any given country may be offset against the Royalty Payment, if any, that would otherwise have been payable to Adimab with respect to such same Net Sales; *provided, however*, that in no event shall the royalty owed to Adimab be reduced by more than * percent (*%) than the payment which would otherwise be due hereunder. It is understood, agreed and acknowledged that Adimab's allowing Checkpoint to claim the credit of this Section 4.5(e) (*Adjustments for Third Party IP*) as to any particular Third Party Patent License: (a) does not mean Adimab believes that the licensed Patents were infringed or Cover any aspect of the discovery or optimization work by Adimab; (b) does not mean Adimab agrees with Checkpoint's opinion as to the likelihood of success of a claim of such infringement or Coverage; (c) does not mean that Adimab believes Checkpoint's opinion as to any of the foregoing is reasonable; and (d) is not, will not be, and shall not be under any circumstances construed as an admission of any kind. Adimab may have many reasons not to challenge any given assertion of the credit of this Section 4.5(e) (*Adjustment for Third Party IP*) by Checkpoint, including: (1) maintaining good relations with a counterparty; (2) an assessment that the costs of the credit are outweighed by the benefits of Checkpoint having a license in place that makes it feel comfortable to proceed with the Product (resulting in a greater likelihood of milestones and royalties being paid to Adimab); (3) resource limitations that make it impracticable to challenge Checkpoint's assertion of such credit even though Adimab may disagree whether this is proper; and (4) other reasons other than thinking that the relevant Patents Cover or were infringed.

* Confidential material redacted and filed separately with the Commission.

(f) No Challenge to Royalty Term. Checkpoint, on behalf of itself, its Affiliates and its Licensees, hereby agrees not to challenge the length of the Royalty Term, including through the assertion that the Royalty Term should be reduced to less than twelve (12) years as a result of the lack of a Valid Claim Covering the relevant Product. Checkpoint agrees that if Checkpoint, its Affiliates or its Licensees attempt to assert any such claim, then: (a) the royalty rate applicable to payments due to Adimab under this Agreement shall automatically be retroactively adjusted to a rate twice the previously-applicable rate, and Checkpoint shall make a payment to Adimab of such amount (including accrued interest) within fifteen (15) days of asserting such claim; and (b) Checkpoint shall reimburse Adimab on a monthly basis (within fifteen (15) days after the end of the calendar month) for all Adimab legal costs in connection with assessing, responding to and/or defending against such assertion in such calendar month. Checkpoint hereby irrevocably agrees that such amounts will not be refundable or repayable by Adimab regardless of the outcome of any proceeding resulting from any such assertion.

4.6 Quarterly Payment Timings. All royalties due under Section 4.5 (*Royalties*) shall be paid quarterly within ninety (90) days after the end of the relevant calendar quarter for which royalties are due.

4.7 Royalty Payment Reports. With respect to each calendar quarter, within ninety (90) days after the end of the calendar quarter, Checkpoint shall provide to Adimab a written report stating the number and description of all Products sold during the relevant calendar quarter; the gross sales associated with such sales; and the calculation of Net Sales on such sales, including the amount of any deduction provided for in the definition of Net Sales. The report shall provide all such information on a country-by-country and Product-by-Product basis.

4.8 Payment Method. All payments due under this Agreement to Adimab shall be made by bank wire transfer in immediately available funds to an account designated by Adimab. All payments hereunder shall be made in the legal currency of the United States of America, and all references to "**$**" or "**dollars**" shall refer to United States dollars (i.e., the legal currency of the United States).

4.9 Taxes. The Parties agree to cooperate with one another and use reasonable efforts to minimize obligations for any and all income or other taxes required by applicable law to be withheld or deducted from any royalties, milestone payments or other payments made by Checkpoint to Adimab under this Agreement, including by completing all procedural steps, and taking all reasonable measures, to ensure that any withholding tax is reduced or eliminated to the extent permitted under applicable law, including income tax treaty provisions and related procedures for claiming treaty relief. To the extent that Checkpoint is required to deduct and withhold taxes on any payment to Adimab, Checkpoint shall deduct and withhold such taxes and pay the amounts of such taxes to the proper government authority in a timely manner and promptly submit to Adimab an official tax certificate or other evidence of such withholding sufficient to enable Adimab to claim such payment of taxes. Checkpoint shall provide Adimab with reasonable assistance in order to allow Adimab to recover, as permitted by applicable law, withholding taxes, value added taxes or similar obligations resulting from payments made hereunder or to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. Adimab shall provide Checkpoint with any tax forms that may be reasonably necessary in order for Checkpoint to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty. Adimab shall use reasonable efforts to provide any such tax forms to Checkpoint at least thirty (30) days prior to the due date identified by Checkpoint for any payment for which Adimab desires that Checkpoint apply a reduced withholding rate. Checkpoint shall make all payments to Adimab from the United States.

4.10 Records; Inspection.

(a) Checkpoint shall keep complete and accurate records of its sales and other dispositions (including use in clinical trials, or provision on a compassionate use basis or as marketing samples) of Program Antibody and Product including all records that may be necessary for the purposes of calculating all payments due under this Agreement.

(b) At Adimab's expense no more than once per calendar year, Adimab has the right to retain an independent certified public accountant from a nationally recognized (in the U.S.) accounting firm to perform on behalf of Adimab an audit, conducted in accordance with U.S. generally accepted accounting principles (GAAP), of such books and records of Checkpoint as are deemed necessary by the independent public accountant to report on Net Sales for the period or periods requested by Adimab and the correctness of any report or payments made under this Agreement.

(c) If the audit reveals an underpayment, Checkpoint shall promptly pay to Adimab the amount of such undisputed underpayment plus interest in accordance with Section 4.14 (*Late Payments*). If the audit reveals that the undisputed monies owed by Checkpoint to Adimab has been understated by more than five percent (5%) for the period audited, Checkpoint shall, in addition, pay the costs of such audit. If the audit reveals that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods.

4.11 Licensee Reports, Records and Audits. Any agreements with Licensees shall include an obligation for the Licensee to (i) maintain records adequate to document and verify the proper payments (including milestones and royalties) to be paid to Adimab; (ii) provide reports with sufficient information to allow such verification; and (iii) allow an independent certified public accountant from a nationally recognized (in the U.S.) accounting firm appointed by Adimab to verify the payments due on behalf of Adimab.

4.12 Foreign Exchange. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the exchange rates reported on the fifth (5th) business day prior the payment due date for the purchase and sale of U.S. dollars, as reported by the Wall Street Journal. With any payment in relation to which a currency conversion is performed to calculate the amount of payment due, Checkpoint shall provide to Adimab a true, accurate and complete copy of the exchange rates used in such calculation.

4.13 Non-refundable, non-creditable payments. Each payment that is required under this Agreement is non-refundable and non-creditable except to the extent set forth in Section 4.5(e) (*Adjustment for Third Party IP*).

4.14 Late Payments. Any amount owed by Checkpoint to Adimab under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the rate of four percent (4%) above the then-applicable short-term three-month London Interbank Offered Rate (LIBOR) as quoted in the Wall Street Journal (or if it no longer exists, a similarly authoritative source) calculated on a daily basis, or, if lower, the highest rate permitted under applicable law.

ARTICLE 5

Intellectual Property.

5.1 Ownership and Inventorship.

(a) Program Patents and Program Know-How. Adimab shall solely own, regardless of inventorship, all Program Patents directed to Adimab Platform Technology Improvements and, prior to Option exercise, all Program Antibody Patents. Checkpoint shall own, regardless of inventorship, from and after the date of Option exercise, those Optioned Program Antibody Patents that relate solely Optioned Antibodies and Adimab shall own all other Optioned Program Antibody Patents, subject to the terms and conditions of this Agreement. All Program Patents other than those referred to in the foregoing two (2) sentences shall be owned based on inventorship. Program Know-How that constitutes Adimab Platform Technology Improvements shall be owned by Adimab and all other Program Know-How shall be owned by the Party that created it.

(b) Other Patents. To avoid doubt, nothing in this Agreement shall alter the ownership of the Parties' pre-existing Patents. Section 5.1(a) (*Program Patents and Program Know-How*) speaks only to ownership of Program Patents.

(c) Inventorship. Inventorship for purposes of this Agreement, and all intellectual property-related definitions in this Agreement, shall be determined in accordance with United States patent law.

5.2 Implementation.

(a) Assignments. Each Party hereby assigns to the other Party Program Inventions, associated Patents, and Program Know-How as necessary to achieve ownership as provided in Section 5.1 (*Ownership and Inventorship*). Each assigning Party shall execute and deliver all documents and instruments reasonably requested by the other Party to evidence or record such assignment or to file for, perfect or enforce the assigned rights. Each assigning Party hereby appoints the other Party as attorney-in-fact solely to execute and deliver the foregoing documents and instruments if such other Party after making reasonable inquiry does not obtain them from the assigning Party. Each Party shall perform its activities under this Agreement through personnel who have made a similar assignment and appointment to and of such Party. Each assigning Party shall make its relevant personnel (and their assignments and signatures on such documents and instruments) reasonably available to the other Party for assistance in accordance with this Article 5 (*Intellectual Property*) at no charge.

(b) Joint Ownership Implementation. As regards Joint Serendipitous Inventions and the Program Patents to the extent claiming them, either Party is entitled to practice and license them without consent of and without a duty of accounting to the other Party. Each Party hereby grants all permissions, consents and waivers with respect to, and all licenses under, the Joint Serendipitous Inventions and the Program Patents claiming them as necessary to achieve throughout the world the nature of joint ownership rights of the foregoing as described in Section 5.1 (*Ownership and Inventorship*) and the foregoing sentence. To avoid doubt, this Section 5.2(b) (*Joint Ownership Implementation*) does not imply any permission, consent or waiver with respect to, or license under, any Patent or item of Know-How other than the Joint Serendipitous Inventions and the Program Patents to the extent claiming them.

5.3 Disclosure. During the term of the Agreement, each Party shall promptly disclose to the other Party the making, conception or reduction to practice of any Program Inventions that would be Covered by Program Antibody Patents or in Checkpoint's case that are Adimab Platform Technology Improvements (which, to avoid doubt, are assigned to Adimab under this Agreement). Such disclosure shall occur as soon as possible, but in any case within sixty (60) days after the Party determines such Program Inventions have been invented. To avoid doubt, this Section 5.3 (*Disclosure*) shall not be read to require Adimab to disclose Program Inventions constituting Adimab Platform Technology Improvements to Checkpoint.

5.4 Program Patent Prosecution and Maintenance.

(a) Adimab Platform Technology. Adimab shall have the sole right (but not the obligation) to file, prosecute, maintain, defend and enforce all Program Patents directed to Adimab Platform Technology Improvements and all Adimab Platform Patents, all at its own expense.

(b) Program Antibody Patents. Checkpoint shall have the sole and exclusive right to file, prosecute and maintain, defend and enforce all Program Antibody Patents, at Checkpoint's expense, and prior to Option exercise, in Adimab's name, and after Option exercise, in Checkpoint's name. Such right shall continue for the duration of the longer of the Evaluation Term and, if Checkpoint exercises the Option, the Term. Such right shall include, following the exercise of the Option, having the exclusive right, but not the obligation, to, at its expense, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect to the Program Antibody Patents. In any such litigation brought by Checkpoint with respect to the Program Antibody Patents, Checkpoint shall have the right to join Adimab as a party to such litigation, and Adimab shall cooperate reasonably with respect thereto, as requested by Checkpoint and at Checkpoint's cost. The exercise of the right to file and prosecute the Program Antibody Patents shall be subject to all of the following:

(i) Prior to Option exercise, Checkpoint shall not file any Program Antibody Patent that discloses the sequence of any Program Antibody unless such Program Antibody Patent can be prevented from publishing.

(ii) Prior to Option exercise, to the extent that individual Program Antibodies represent distinct patentable inventions, they shall be disclosed in separate applications and not as a group (e.g., as a filing on multiple patentable inventions), unless Adimab consents in its discretion in writing in advance to another approach.

(iii) Both prior to and after Option exercise, Adimab shall have the right to review and comment on prosecution of the Program Antibody Patents, and Checkpoint shall provide Adimab with copies of all correspondence with patent offices relating thereto (including office actions and the like) promptly after receipt and drafts of all filings and correspondence with such offices no less than 20 business days in advance of filing.

(iv) If Checkpoint does *not* exercise the Option, then all Program Antibody Patents that had been filed (if any) shall be promptly abandoned without being published and within thirty (30) days after the Option expiring Checkpoint shall make any and all filings necessary to result in such abandonment without publication (at Checkpoint's expense) and provide documentation thereof to Adimab.

(v) If Checkpoint *does* exercise the Option, then all Program Antibody Patents that had been filed for such Target that disclose Program Antibody sequences other than the sequences of Optioned Antibodies for that Target shall be promptly abandoned without being published and within thirty (30) days after Option exercise Checkpoint shall make any and all filings necessary to result in such abandonment without publication (at Checkpoint's expense) and provide documentation thereof to Adimab.

(v i) Checkpoint shall ensure that the sequences of Program Antibodies that are not Optioned Antibodies shall not become published through Program Antibody Patents.

(vii) If Checkpoint *does* exercise the Option, then Checkpoint shall prosecute at least one Optioned Program Antibody Patent in the United States, Japan and Europe, and such other countries as are required to be consistent with the Commercially Reasonable Efforts standard.

(viii) Checkpoint shall be solely responsible for all Checkpoint's costs of the activities under this Section 5.4(b) (*Program Antibody Patents*).

(c) **Responsibility**. It is understood and agreed that searching for, identification and evaluation of Third-Party Patents that may apply to any Program Antibodies based on sequence, Target or the like is the responsibility of Checkpoint, and that Adimab shall have no responsibility for the foregoing nor liability if any such Third-Party Patents exist.

(d) **Serendipitous Program Inventions**.

(i) **Adimab Program Inventions**. As between the Parties, Adimab shall have the sole right, at its sole expense and in its sole discretion, to prepare, file, prosecute, enforce and maintain (including conducting or participating in interferences and oppositions) all Patents directed to Adimab Program Inventions but not falling within the Optioned Program Antibody Patents or the Adimab Platform Technology Improvements (which, to avoid doubt, are both addressed above).

(ii) **Checkpoint Program Inventions**. Checkpoint shall be responsible, at its sole expense and in its sole discretion, to prepare, file, prosecute, enforce and maintain (including conducting or participating in interferences and oppositions) all Program Patents on Checkpoint Program Inventions, other than Optioned Program Antibody Patents and Adimab Platform Technology Improvements (which, to avoid doubt, are both addressed above).

(iii) **Serendipitous Joint Program Inventions**. The Parties shall mutually agree which of them shall be responsible for either using its in-house patent attorneys or through mutually agreed upon outside counsel to prepare, file, prosecute, enforce and maintain Program Patents on Joint Serendipitous Inventions, and how the costs of such activities will be shared.

5.5 **Patent Term Restoration**. The Parties shall cooperate with each other, including by providing necessary information and assistance as the other Party may reasonably request, to obtain patent term restoration or supplemental protection certificates or their equivalents in any country where applicable to Patents Covering the Product. If elections with respect to obtaining such patent term restoration are to be made with respect to such Patents, and the Parties do not agree, Checkpoint shall have the right to make the election and Adimab agrees to abide by such election, except that if Checkpoint does not elect to extend any such Patent where it would have been possible to do so, Checkpoint shall pay to Adimab royalties on Net Sales in the applicable country through the time until which such Patent could have been extended, but for Checkpoint's electing not to do so.

5.6 Cooperation of the Parties. At the reasonable request of the responsible (as provided for in this Article 5 (*Intellectual Property*)) Party, the other Party agrees to cooperate fully in the preparation, filing, prosecution, enforcement and maintenance of any Program Patents under this Agreement. Such cooperation includes executing all papers and instruments (or causing its personnel to do so) reasonably useful to enable the other Party to apply for and to prosecute patent applications in any country; and promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, enforcement or maintenance of any such Patents. Adimab shall not be required pursuant to this Section 5.6 (*Cooperation of the Parties*) to disclose Adimab Platform Technology to Checkpoint.

ARTICLE 6

CONFIDENTIALITY; PUBLICITY.

6.1 General Confidentiality Obligations.

(a) Any and all information disclosed or submitted in writing or in other tangible form to one Party by the other Party under this Agreement is the "**Confidential Information**" of the disclosing Party. In addition, information embodied in Adimab Materials is Adimab's Confidential Information, and information embodied in the Checkpoint Materials is Checkpoint's Confidential Information.

(b) To avoid doubt, sequence information (whether as to amino acid sequence or nucleic acid sequence) with respect to Program Antibodies shall be deemed the Confidential Information of Adimab, except that from and after the date of Option exercise, the sequence information as to the CDRs of Optioned Antibodies shall be Confidential Information of Checkpoint. For clarity, either Party shall be entitled to disclose the non-CDRs of the Optioned Antibodies.

(c) Each Party shall receive and maintain the other Party's Confidential Information in strict confidence. Neither Party shall disclose any Confidential Information of the other Party to any Third Party. Neither Party shall use the Confidential Information of the other Party for any purpose other than as required to perform its obligations or exercise its rights hereunder. Each Party may disclose the other Party's Confidential Information to the receiving Party's officers, directors, employees, Affiliates, agents, representatives and contractors requiring access thereto for the purposes of this Agreement, *provided, however*, that prior to making any such disclosures, each such person shall be bound by terms at least as restrictive as those hereof to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Each Party agrees to take all steps necessary to ensure that the other Party's Confidential Information shall be maintained in confidence including such steps as it takes to prevent the disclosure of its own proprietary and confidential information of like character. Each Party agrees that this Agreement shall be binding upon its officers, directors, employees, Affiliates, agents, representatives and contractors involved in the Research Program. Each Party shall take all steps necessary to ensure that its officers, directors, employees, Affiliates, agents, representatives and contractors shall comply with the terms and conditions of this Agreement. The foregoing obligations of confidentiality and non-use shall survive, and remain in effect for a period of five (5) years from, the termination or expiration of this Agreement in accordance with Article 9 (*Term*).

6.2 Exclusions from Nondisclosure Obligation. The nondisclosure and nonuse obligations in Section 6.1 (*General Confidentiality Obligations*) shall not apply to any Confidential Information to the extent that the receiving Party can establish by competent written proof that it:

(a) at the time of disclosure is publicly known;

(b) after disclosure, becomes publicly known by publication or otherwise, except by breach of this Agreement by such Party;

(c) was in such Party's possession at the time of the earlier of disclosure hereunder and disclosure under the agreement referred to in Section 6.1 (*General Confidentiality Obligations*);

(d) is received by such Party from a Third Party who has the lawful right to disclose the Confidential Information and who shall not have obtained the Confidential Information either directly or indirectly from the disclosing Party; or

(e) is independently developed by such Party (i.e., without reference to Confidential Information of the disclosing Party).

6.3 Required Disclosures. If either Party is required, pursuant to a governmental law, regulation or order, to disclose any Confidential Information of the other Party, the receiving Party (i) shall give advance written notice to the disclosing Party, (ii) shall make a reasonable effort to assist the other Party to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required and (iii) shall use and disclose the Confidential Information solely to the extent required by the law or regulation.

6.4 Terms of Agreement. The terms of this Agreement are the Confidential Information of both Parties. However, each Party shall be entitled to disclose the terms of this Agreement under legally binding obligations of confidence and limited use to: legal, financial and investment banking advisors; and potential and actual investors, acquirers and licensees or sublicensees doing diligence and counsel for the foregoing. In addition, if legally required, a copy of this Agreement may be filed by either Party with the SEC (or relevant ex-U.S. counterpart). In that case, the filing Party will if requested by the other Party diligently seek confidential treatment for terms of this Agreement for which confidential treatment is reasonably available, and shall provide the non-filing Party reasonable advance notice of the terms proposed for redactions and a reasonable opportunity to request that the filing Party make additional redactions to the extent confidential treatment is reasonably available under the law. The filing Party shall seek and diligently pursue such confidential treatment requested by the non-filing Party.

6.5 Return of Confidential Information. Promptly after the termination or expiration of this Agreement for any reason, each Party shall return to the other Party all tangible manifestations of such other Party's Confidential Information at that time in the possession of the receiving Party.

6.6 Publicity. Either Party may make an initial press release announcing the execution of this Agreement, 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 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, however*, 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 be unreasonably withheld. Other than repeating information in any mutually agreed press release, neither Party will generate or allow any further publicity regarding this Agreement or the transaction or research contemplated hereunder in which the other Party is identified, without giving the other Party the opportunity to review and comment on the press release. The Parties recognize the importance of announcing Option and the achievement of Milestones, and that Adimab is entitled to disclose these occurrences. Accordingly, the Parties hereby agree that each such event shall be publicly announced by the Parties if requested by Adimab, and the Parties shall mutually agree upon the text of a press release to announce each such event. Checkpoint shall not unreasonably withhold its consent to the manner in which Adimab proposes to make such disclosure. It is understood and agreed that Adimab sometimes issues press releases that group multiple achievements of the company, and that if Adimab chooses to group the initially approved text or the announcement of Option exercise and/or a milestone achievement under this Agreement with other accomplishments or events not relating to this Agreement, then the only portion of the press release into which the Checkpoint shall have a consent right (such consent not to be unreasonably withheld), shall be those portions that relate to this Agreement.

6.7 Certain Data. Notwithstanding this Article 6 (*Confidentiality; Publicity*), without disclosing Checkpoint's identity or the identity of the Target (although the class of protein of the Target may be disclosed), or the sequence of any Program Antibody, in order to describe the general capabilities and performance of the Adimab platform, Adimab shall be entitled to disclose generally Program Antibody attributes and Program Know-How, including the following: (a) Program Antibody binding affinities (K_D), (b) expression range regarding Program Antibodies, and (c) germline distribution of Program Antibodies.

ARTICLE 7

REPRESENTATIONS AND WARRANTIES.

7.1 Mutual Representations. Each of Adimab and Checkpoint hereby represents and warrants to the other of them that the representing and warranting Party is duly organized in its jurisdiction of incorporation; that the representing and warranting Party has the full power and authority to enter into this Agreement; that this Agreement is binding upon the representing and warranting Party; that this Agreement has been duly authorized by all requisite corporate action within the representing and warranting Party; and that the execution, delivery and performance by the representing and warranting Party of this Agreement and its compliance with the terms and conditions hereof does not and shall not conflict with or result in a breach of any of the terms and conditions of or constitute a default under (a) any agreement or other instrument binding or affecting it or its property, (b) the provisions of its bylaws or other governing documents or (c) any order, writ, injunction or decree of any governmental authority entered against it or by which any of its property is bound.

7.2 Representations of Adimab. **Adimab**. Adimab hereby represents, warrants and covenants to Checkpoint that, as of the Effective Date:

(a) There are no complaints filed in court or, to Adimab's knowledge, otherwise threatened, in each case pending relating to Adimab Platform Patents which, if decided in a manner adverse to Adimab, would materially affect Adimab's practice of the Adimab Platform Technology as contemplated by this Agreement.

(b) There are no judgments or settlements against Adimab or its Affiliates or to which they are Party which will materially affect Adimab's practice of the Adimab Platform Technology as contemplated in this Agreement. Adimab is not party to any settlement discussions that, if concluded as of the Effective Date, would result in a settlement which would materially affect Adimab's practice of the Adimab Platform Technology as contemplated in this Agreement.

(c) To Adimab's knowledge, the conception, development and reduction to practice of the Adimab Platform Technology, as it exists on the Effective Date, have not constituted or involved the misappropriation of trade secrets, know-how or similar rights or property of any person.

(d) In Adimab's reasonable judgment, the practice of the Adimab Platform Technology as practiced by Adimab as of the Effective Date, does not infringe a valid, issued Patent owned by a Third Party of which Adimab has knowledge.

(e) Adimab has the right to grant to Checkpoint the licenses set forth in Section 3.1 and 3.2;

(f) Notwithstanding the foregoing, Adimab specifically excludes any representations with respect to any Excluded Technology.

7.3 DISCLAIMER OF WARRANTIES. OTHER THAN THE EXPRESS WARRANTIES OF SECTION 7.1 (MUTUAL REPRESENTATIONS) AND SECTION 7.2 (REPRESENTATIONS OF ADIMAB), EACH PARTY DISCLAIMS ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT ANY PRODUCTS DEVELOPED UNDER THIS AGREEMENT ARE FREE FROM THE RIGHTFUL CLAIM OF ANY THIRD PARTY, BY WAY OF INFRINGEMENT OR THE LIKE OR THAT ANY PROGRAM PATENTS WILL ISSUE OR BE VALID OR ENFORCEABLE.

ARTICLE 8

INDEMNIFICATION

8.1 Indemnification by Adimab. Adimab hereby agrees to indemnify, defend and hold harmless (collectively, "**Indemnify**") Checkpoint, its Affiliates and its and their directors, officers, agents and employees (collectively, "**Checkpoint Indemnitees**") from and against any and all liability, loss, damage or expense (including without limitation reasonable attorneys' fees) (collectively, "**Losses**") they may suffer as the result of Third-Party claims, demands and actions (collectively, "**Third-Party Claims**") arising out of or relating to (a) any breach of a representation or warranty made by Adimab under Article 7 (*Representations and Warranties*), (b) Checkpoint's use of any Adimab's Materials (other than Program Antibodies), (c) following termination of this Agreement pursuant to Section 9.2, Adimab's, or its Affiliates' or Licensees' research, testing, development, manufacture, use, sale, distribution, licensing and/or commercialization of Program Antibodies and/or Products (or Program-Benefited Antibodies or products incorporating them) and (d) contractual obligations of Adimab and its Affiliates, except in each case to the extent of any Losses (i) attributable to the negligence or intentional misconduct of any Checkpoint Indemnitee, or (ii) arising out of any breach of a representation or warranty made by Checkpoint in Article 7 (*Representations and Warranties*).

8.2 Indemnification by Checkpoint. Checkpoint hereby agrees that it and its Licensees shall Indemnify Adimab, its Affiliates and its and their directors, officers, agents and employees (collectively, "**Adimab Indemnitees**") from and against any and all Losses they may suffer as the result of Third-Party Claims arising out of or relating to (a) any breach of a representation or warranty made by Checkpoint under Article 7 (*Representations and Warranties*), (b) Checkpoint's research, testing, development, manufacture, use, sale, distribution, licensing and/or commercialization of Program Antibodies and/or Products (or Program-Benefited Antibodies or products incorporating them), (c) Adimab's use of any Checkpoint Materials, (d) the use by Checkpoint or its Licensees of any Excluded Technology, and (e) contractual obligations of Checkpoint and its Affiliates, except in each case to the extent of any Losses (i) attributable to the negligence or intentional misconduct of any Adimab Indemnitee, or (ii) arising out of any breach of a representation or warranty made by Adimab in Article 7 (*Representations and Warranties*).

8.3 Indemnification Procedures. Each of the foregoing agreements to Indemnify is conditioned on the relevant Adimab Indemnitees or Checkpoint Indemnitees (i) providing reasonable assistance in the defense of such claim at the indemnifying Party's reasonable expense, and (ii) not compromising or settling such Third-Party Claim without the indemnifying Party's advance written consent. If the Parties cannot agree as to the application of the foregoing Sections 8.1 (*Indemnification by Adimab*) and 8.2 (*Indemnification by Checkpoint*), each may conduct separate defenses of the Third-Party Claim, and each Party reserves the right to claim indemnity from the other in accordance with this Article 8 (*Indemnification*) upon the resolution of the underlying Third-Party Claim.

8.4 Limitation of Liability. EXCEPT TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY UNDER THIS ARTICLE 8 (INDEMNIFICATION) OR AS REGARDS A BREACH OF A PARTY'S RESPONSIBILITIES PURSUANT TO ARTICLE 6 (CONFIDENTIALITY; PUBLICITY), NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES HEREUNDER, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE.

ARTICLE 9

TERM.

9.1 Term. The term of this Agreement shall commence on the Effective Date and shall expire upon (a) in the event that no Option is exercised, the conclusion of the last-to-expire Evaluation Term; or (b) in the event that an Option is exercised, on a country-by-country and Product-by-Product basis on the expiration of the last Royalty Term for a Product in the particular country, in each case, unless earlier terminated by a Party as set forth below in this Article 9 (*Term*).

9.2 Material Breach. Either Party may terminate this Agreement for the material breach of this Agreement by the other Party, if such breach remains uncured ninety (90) days following notice from the non-breaching Party to the breaching Party specifying such breach.

9.3 Commitments Regarding Program-Benefited Antibodies. If Checkpoint or any of its Licensees researches, develops, manufactures, or commercializes any Program-Benefited Antibody, they shall pay fees to Adimab as provided in Article 4 (Financial Terms), including the Option Fee, Milestone Payments and Royalty Payments, as applicable, on the Program-Benefited Antibody as (or as if) a Product under this Agreement. In the event that Checkpoint is unwilling or unable to pay such fees to Adimab (because, for example, of the dissolution of Checkpoint for bankruptcy or other reasons), then each Licensee shall make such payments directly to Adimab. If this Agreement expires or terminates (other than an expiration under Section 9.1 following an Option exercise after all applicable Royalty Terms have expired), Checkpoint and its Licensees (a) shall not research, develop or commercialize any Program-Benefited Antibody or Product containing such an antibody except as a Product under this Agreement, (b) shall not license or otherwise grant rights to any entity to do the foregoing, and (c) shall not practice, license or assign to a Third Party, option to a Third Party or covenant not to sue a Third Party with respect to Program Antibody Patents (regardless of inventorship), Program-Benefited Antibodies, or products containing them.

9.4 Survival in All Cases. Termination of this Agreement shall be without prejudice to or limitation on any other remedies available to nor any accrued obligations of either Party. In addition, Sections 2.3 (*Reports; Records*), 2.4 (*Use of Adimab Materials*), 2.5 (*Use of Checkpoint Materials*), 2.6 (*Certain Restrictions on the Use of Antibodies*), 3.4 (*No Implied Licenses*), 3.5 (*Covenant Not to Exceed License*), 4.6 (*Quarterly Payment Timings*) through 4.14 (*Late Payments*) (with respect to payment obligations outstanding or having accrued as the effective date of termination or expiration), 5.1 (*Ownership and Inventorship*), 5.2 (*Implementation*), 5.4 (*Program Patent Prosecution and Maintenance*), 5.6 (*Cooperation of the Parties*), and 7.3 (*Disclaimer of Warranties*), and Articles 1 (*Definitions*), 6 (*Confidentiality; Publicity*), 8 (*Indemnification*), 9 (*Term*) and 10 (*Miscellaneous*) shall survive any expiration or termination of this Agreement.

9.5 Return of Adimab Materials. Checkpoint shall either return to Adimab or destroy all Adimab Materials (other than Adimab Materials relating to Optioned Antibodies) Target upon expiration or termination of the Evaluation Term without the Option being exercised, and all Adimab Materials on expiration or termination of this Agreement.

9.6 Additional Effects of Termination. If Adimab terminates this Agreement pursuant to Section 9.2 for Checkpoint's uncured material breach, then : (a) Checkpoint and its Affiliates would assign to Adimab all right, title and interest in and to the Program Patents, Program Know-How, all data with respect to Program-Benefited Antibodies, and all producing cell lines for Program-Benefited Antibodies (the "**Program Assets**"); (b) Checkpoint and its Affiliates would transfer such cell lines to Adimab (under conditions intended to ensure their viability) along with all master batch records and SOPs for production of such antibodies (the "**Tangible Assets**"); (c) Checkpoint and its Affiliates would transfer all filings with regulatory authorities with respect to Program-Benefited Antibodies to Adimab if Adimab so requests (the "**Regulatory Assets**" and, together with the Program Assets and Tangible Assets, the "**Transferred Assets**"); and (d) Adimab shall pay Checkpoint a royalty equal based on the date of termination of this Agreement as set forth below.

Effective Date of Termination	Royalty Rate
*	*
*	*
*	*

For purposes of this Section 9.6 (*Additional Effects of Termination*), Sections 4.5 (*Royalties*) through 4.14 (*Late Payments*), the definition of Net Sales and all other defined terms (including their respective definitions) in such Sections shall apply mutatis mutandis to the Adimab's obligations to pay royalties under this Section 9.6 and each reference in each such Section (and any related definitions) to (i) Adimab shall be deemed to be a reference to Checkpoint, (ii) Checkpoint shall be deemed to be a reference to Adimab and (iii) a Licensee shall be deemed to be a reference to a licensee or sublicensee of Adimab or any of its Affiliates with respect to the Product. Any license of any Transferred Assets shall be made solely pursuant to written agreements ("**License Agreements**") that are consistent with all relevant terms and conditions of this Agreement and to Licensees who explicitly agree in writing to comply with all applicable terms of this Agreement. Adimab shall remain responsible for all payments and other performance obligations due under this Section 9.6 (*Additional Effects of Termination*), notwithstanding any license that it may grant. Adimab shall not (i) assign or transfer the Transferred Assets (in whole or in part) to any third party unless (a) such transfer or assignment is pursuant to a binding written agreement pursuant to which such third party to be bound by the terms of this Section 9.6 (*Additional Effects of Termination*)and (b) such agreement provides that Checkpoint is a third party beneficiary thereof for the purposes of enforcing its rights under this Section 9.6 and (ii) take any action avoid the payment obligations under this Section 9.6 (*Additional Effects of Termination*) or to circumvent or frustrate the purposes of this Section 9.6 (*Additional Effects of Termination*). Checkpoint shall not (i) assign or transfer the Program-Benefited Antibodies or Products (in whole or in part) to any third party unless (a) such transfer or assignment is pursuant to a binding written agreement pursuant to which such third party to be bound by the terms of Article 4 (*Financial Terms*) and (b) such agreement provides that Adimab is a third party beneficiary thereof for the purposes of enforcing its rights under Article 4 (*Financial Terms*) and (ii) take any action avoid the payment obligations under this Agreement or to circumvent or frustrate the purposes of Article 4 (*Financial Terms*).

* Confidential material redacted and filed separately with the Commission.

9.7 Survival of Sublicenses. Notwithstanding any provision herein to the contrary, in the event (a) Checkpoint has entered into any Sublicense Agreements consistent with the terms of this Agreement, (b) this Agreement is terminated, and (c) such Sublicense Agreements are in effect at the time of such termination, such Sublicense Agreement will survive such termination, with Adimab as the Licensee's direct licensor solely with respect to rights sublicensed pursuant to this Agreement, provided that the Licensee pays all amounts due hereunder with respect to its exercise of rights regarding Optioned Antibodies.

ARTICLE 10

MISCELLANEOUS.

10.1 Independent Contractors. The Parties shall perform their obligations under this Agreement as independent contractors. Nothing contained in this Agreement shall be construed to be inconsistent with such relationship or status. This Agreement and the Parties' relationship in connection with it shall not constitute, create or in any way be interpreted as a joint venture, fiduciary relationship, partnership or agency of any kind.

10.2 Dispute Resolution.

(a) Initial Dispute Resolution. Either Party may refer any dispute in connection with this Agreement ("**Dispute**") not resolved by discussion of the BD/Contract Liaisons to senior executives of the Parties (for Adimab, its CEO or his designee and for Checkpoint, its CEO or his designee) for good-faith discussions over a period of not less than sixty (60) days (the "**Senior Executives Discussions**"). Each Party will make its executives reasonably available for such discussions.

(b) Disputes Not Resolved Between the Parties. If the Parties are unable to resolve the dispute through the Senior Executives Discussions within such sixty (60) days, then either Party may, as the sole and exclusive means for resolving disputes under this Agreement, proceed to demand confidential arbitration by written notice to the other Party and making a filing with the AAA in accordance with Section 10.2(c) (*Arbitration*). For clarity, each Party hereby acknowledges that both the fact of and nature of a dispute is the Confidential Information of both Parties, and any disclosure of the fact of or the nature of such a dispute would be highly damaging to the non-disclosing Party.

(c) Arbitration.

(i) Any Dispute referred for arbitration shall be finally resolved by binding arbitration in accordance with the most applicable rules of the American Arbitration Association ("**AAA**") and judgment on the arbitration award may be entered in any court having jurisdiction.

(ii) The arbitration shall be conducted by a panel of three (3) people experienced in the business of biopharmaceuticals. If the issues in dispute involve scientific, technical or commercial matters, then any arbitrator chosen under this Agreement shall have educational training and/or industry experience sufficient to demonstrate a reasonable level of relevant scientific, technical and commercial knowledge as applied to the pharmaceutical industry. If the issues in dispute involve patent matters, then at least one (1) of the arbitrators shall be a licensed patent attorney or otherwise knowledgeable about patent law matters. Within thirty (30) days after a Party demands arbitration, each Party shall select one person to act as arbitrator, and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days after their own appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, then the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, NY. All proceedings and communications as part of the arbitration shall be in English. Following selection of the third arbitrator, the arbitrators shall complete the arbitration proceedings and render an award within six (6) months after the last arbitrator is appointed.

(iii) Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees or arbitration, unless in each case the arbitrators agree otherwise, which they are hereby empowered, authorized and instructed to do if they determine that to be fair and appropriate.

(iv) Except to the extent necessary to confirm an award or as may be required by law, regulation, or the requirement of any exchange on which a Party's shares are traded, neither Party shall disclose the existence, content or results of an arbitration under this Agreement without the prior written consent of the other Party.

(v) In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the subject matter of the Dispute would be barred by the applicable statute of limitations under New York law.

10.3 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding its conflicts of laws principles.

10.4 Entire Agreement. This Agreement (including its Exhibits) set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings between the Parties with respect to such subject matter. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

10.5 Assignment. Neither Party may assign in whole or in part this Agreement without the advance written consent of the other Party, except as set forth in the following sentence. Either Party may assign this Agreement in its entirety to an Affiliate at any time or to a successor to all or substantially all of its stock or assets to which this Agreement relates in connection with its merger with, or the sale of all or substantially all of its stock or assets to which this Agreement relates to, another entity, regardless of the form of the transaction. In addition, Adimab may assign this Agreement or any of its rights under this Agreement, in connection with the sale of, monetization of, transfer of, or obtaining financing on the basis of the payments due to Adimab under this Agreement or debt or project financing in connection with this Agreement; *provided, however*, that in such case Adimab shall remain liable for the performance of all of its assignee's obligations hereunder as if Adimab has not assign this Agreement. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns. Notwithstanding the foregoing, Adimab may not assign or otherwise transfer (by operation of law or otherwise) this Agreement if the assignee does not assume all of Adimab's obligations under this Agreement or Adimab does not remain bound to perform all obligations that are not assigned to the assignee. Any assignment of this Agreement not made in accordance with this Agreement is prohibited hereunder and shall be null and void.

10.6 Severability. If one or more of the provisions in this Agreement are deemed unenforceable by law, then such provision shall be deemed stricken from this Agreement and the remaining provisions shall continue in full force and effect.

10.7 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by a Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition, but no longer than six (6) months. For purposes of this Agreement,

10.8 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid, delivered by express delivery service or personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

If to Adimab:

Adimab, LLC
7 Lucent Drive
Lebanon, NH 03766
Attention: General Counsel

with a required copy to:

Attention: Head, Business Development at the same address.

In the case of Checkpoint:

Checkpoint Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Attn: CEO

10.9 Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

10.10 Headings. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on, nor to be used to interpret, the meaning of the language contained in the particular article or section.

10.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the subsequent enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time executed by an authorized officer of the waiving Party.

10.12 Performance by Affiliates. A Party may perform some or all of its obligations under this Agreement through Affiliate(s) or may exercise some or all of its rights under this Agreement through Affiliates. However, each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if such Party were performing such obligations itself, and references to a Party in this Agreement shall be deemed to also reference such Affiliate. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article 6 (*Confidentiality; Publicity*), and shall (to avoid doubt) be subject to the intellectual property assignment and other intellectual property provisions of Article 5 (*Intellectual Property*) as if they were the original Party to this Agreement (and be deemed included in the actual Party to this Agreement for purposes of all intellectual property-related definitions). A Party and its Affiliates shall be jointly and severally liable for their performance under this Agreement.

10.13 Counterparts. This Agreement may be executed in one or more identical counterparts, each of which shall be deemed to be an original, and which collectively shall be deemed to be one and the same instrument. In addition, signatures may be exchanged by facsimile or PDF.

[Remainder of Page Left Intentionally Blank; Signature Page Follows]

In Witness Whereof, the Parties have by duly authorized persons executed this Agreement as of the Effective Date.

Checkpoint Therapeutics, Inc.:		**Adimab, LLC:**	
By:	/s/ James F. Oliviero	By:	/s/ Tillman U. Gerngross
Title:	CEO	Title:	CEO
Date:	1/22/2019	Date:	1/22/2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Checkpoint Therapeutics, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (No. 333-221493) and Form S8 (No. 333-216856 and 333-221488) of Checkpoint Therapeutics, Inc. of our report dated March 15, 2019, relating to the financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP
New York, New York

March 15, 2019

EXHIBIT 31.1

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James F. Oliviero certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2018 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 15, 2019

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garrett Gray, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2018 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 15, 2019

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

EXHIBIT 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James F. Oliviero, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 15, 2019

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

EXHIBIT 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrett Gray, Principal Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 15, 2019

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