Risk Factors Comparison 2024-03-22 to 2023-03-31 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to our Finances and Capital Requirements ● We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We have not generated any sales revenue from our development stage products, and we do not know when, or if, we will generate any revenue from sales of an approved product ~~. ● Our short operating history makes it difficult to evaluate our business and prospects~~ . ● There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. ● Our success is contingent upon raising additional capital for our development programs and commercialization efforts, which may fail. Even if successful, our future capital raising activities may dilute our current stockholders, restrict our operations, or require us to relinquish proprietary rights. ● Our limited resources may cause us to fail to capitalize on programs or product candidates presenting commercial opportunity or high likelihood of success. ● Weakness in the U. S. economy, including within our geographic footprint, has adversely affected us in the past and may adversely affect us in the future. Risks Pertaining to our Business Strategy, Structure and Organization ● Our future growth and success depend on our ability to successfully develop and commercialize our product candidates, which we have yet to do. ● Our future growth depends on our acquiring or in- licensing products or product candidates and integrating such products into our business. Risks Inherent in Drug Development and Commercialization ● Because results of preclinical studies and clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials. Moreover, interim, " top- line, " and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed. ● We may not receive the required regulatory approvals for any of our product candidates on our projected timelines, if at all, which may result in increased costs and delay our ability to generate revenue. ● If a product candidate demonstrates lack of efficacy or adverse side effects, we may need to abandon or limit the development of such product candidate. ● We may not obtain the desired labeling claims or intended uses for product promotion, or favorable scheduling classifications, to successfully promote our products. ● Even if a product candidate is approved, it may be subject to various post- marketing requirements, including studies or clinical trials, and increased regulatory scrutiny. ● Our competitors have developed or may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability. ● If our products are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited. ● Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products. Risks Related to Reliance on Third Parties ● We rely, and will rely in the future, on third- party contract research organizations and contract manufacturers for the conduct of our preclinical and clinical studies and trials, for the completion of commercial and pre-commercial manufacturing and, eventually, for commercialization. If such third parties fail to perform contractual obligations, **pass regulatory inspections,** meet deadlines, comply with applicable regulations, or if our relationships with such third parties are disrupted, our product candidates may be delayed, and our revenue potential may be limited. ● We rely on clinical data and results obtained by third parties, which may prove inaccurate or unreliable. Risks Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries ● We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations. ● We may be subject to 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. Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof ● If we are unable to maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize products similar or identical to ours, impairing our ability to successfully commercialize potential products. ● We or our licensors may be subject to costly and time- consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents. ● Any dispute with our licensors may affect our ability to develop or commercialize our product candidates. Risks Relating to Our Platform and Data ● Our business and operations would suffer in the event of computer system failures, cyber- attacks, or deficiencies in our or third parties' cybersecurity. Risks Relating to Our Control by Fortress Biotech, Inc. (" Fortress ") ● Fortress controls a voting majority of our common stock and has the right to receive significant share grants annually, which will result in dilution of our other stockholders and could reduce the value of our common stock. ● We have entered into certain agreements with Fortress and may have received better terms from unaffiliated third parties. Risks Related to Conflicts of Interest ~~● The Chairman of our Board of Directors is also the Executive Chairman, President, and Chief Executive Officer of TG Therapeutics, Inc. (" TGTX "). We have entered a collaboration agreement and a sublicense agreement with TGTX, and as a result, certain conflicts of interest may arise.~~ ● We share certain directors with Fortress, which could create conflicts of interest between us and Fortress. PART IItem 1. BusinessOVERVIEWWe are a clinical- stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. We are evaluating our lead antibody product candidate, cosibelimab, an anti- programmed death- ligand 1 (" PD- L1 ") antibody licensed from the Dana- Farber Cancer Institute (" Dana- Farber "), in an ongoing global, open- label, multicohort Phase 1 clinical trial in checkpoint therapy- naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma (" CSCC ") intended to support one or more applications for marketing approval. Based on top- line and interim results in metastatic and locally advanced CSCC, respectively, we submitted a

Biologics License Application (“ BLA ”) to the U. S. Food and Drug Administration (“ FDA ”) for these indications in January 2023 **. On December 15** , **2023, the FDA issued** ~~which application is filed and under review with~~ a **complete response letter** ~~Prescription Drug User Fee Act~~ (“ ~~PDUFA~~ **CRL** ”) ~~goal date~~ **for the cosibelimab BLA for the treatment** of ~~January 3~~ **patients with metastatic or locally advanced CSCC who are not candidates or curative surgery or radiation. The CRL only cites findings that arose during a multi- sponsor inspection of our third- party contract manufacturing organization as approvability issues to address in a resubmission. Following resolution of the inspection issues at the third- party contract manufacturing organization raised in the CRL** , ~~2024~~ **a resubmission of the BLA is planned to support the marketing approval of cosibelimab** . In addition, we are evaluating our lead small- molecule, targeted anti- cancer agent, olafertinib, a third- generation epidermal growth factor receptor (“ EGFR ”) inhibitor, as a potential new treatment for patients with EGFR mutation- positive non- small cell lung cancer (“ NSCLC **”). In January 2022, we announced top- line results from a registration- enabling cohort of our multi- regional, Phase 1 clinical trial of cosibelimab in patients with metastatic CSCC. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate (“ ORR ”) of 47. 4 % (95 % CI: 36. 0, 59. 1) based on independent central review of 78 patients enrolled in the metastatic CSCC cohort using Response Evaluation Criteria in Solid Tumors version 1. 1 (“ RECIST 1. 1** ”). In June 2022, we announced interim results from a registration- enabling cohort of our multi- regional, Phase 1 clinical trial of cosibelimab in patients with locally advanced CSCC that are not candidates for curative surgery or radiation. Cosibelimab demonstrated a confirmed ~~objective response rate (“~~ ORR ~~”)~~ of 54. 8 % (95 % CI: 36. 0, 72. 7) based on independent central review of 31 patients enrolled in the cohort ~~using Response Evaluation Criteria in Solid Tumors version 1. 1 (“ RECIST 1. 1 ”)~~. In ~~January~~ **July** ~~2022~~ **2023** , we announced ~~top~~ **longer** - ~~line~~ **term** results **for cosibelimab** from **its pivotal studies** ~~a registration- enabling cohort of our multi- regional, Phase 1 clinical trial of cosibelimab~~ in ~~patients with~~ **locally advanced and** metastatic CSCC. ~~The~~ **These results** ~~cohort met its primary endpoint, with cosibelimab demonstrating~~ **demonstrated** a **deepening of response over time, resulting in complete response rates of 26 % and 13 % in locally advanced and metastatic CSCC, respectively. Additionally, the** confirmed ORR ~~of 47~~ **in metastatic CSCC increased to 50** . ~~4~~ **0** % ~~(95 % CI: 36. 0, 59. 1)~~ based on independent central review ~~of 78 patients enrolled in the metastatic CSCC cohort~~ using RECIST 1. 1. **Furthermore** ~~In December 2021~~ , ~~we announced~~ **responses continue to remain durable over time with** the ~~initiation~~ **median duration** of ~~our CONTERNO~~ **response not yet reached in either group. Updated safety data across 247 patients enrolled and treated with cosibelimab in all cohorts of the ongoing** study **remain consistent** ~~, a multi- regional, open- label, multi- center, randomized Phase 3 trial of cosibelimab in combination~~ with ~~pemetrexed and platinum chemotherapy for the~~ **those previously reported** ~~first- line treatment of patients with NSCLC. The February 2022 Russian invasion of Ukraine and the ensuing response disrupted our ability to conduct clinical trials in Russia, Ukraine, and Belarus. The substantially longer enrollment period in other planned countries made the conduct of the CONTERNO study no longer viable. Accordingly, we expect that the study will be wound down and closed by the end of the first quarter of 2023~~ . 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. **Effective September 30, 2023, the Company and TGTX agreed to mutually terminate these collaborations, with full rights reverting back to us.** 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, ~~2022~~ **2023** , we have an accumulated deficit of $ ~~262~~ **314** . ~~5~~ **3** million. We are a majority- controlled subsidiary of Fortress Biotech, Inc. (“ Fortress ”). CORPORATE INFORMATIONCheckpoint Therapeutics, Inc. was incorporated in Delaware on November 10, 2014 and commenced principal operations in March 2015. Our executive offices are located at 95 Sawyer Road, Suite 110, Waltham, MA 02453. Our telephone number is (781) 652- 4500 and our email address is ir @ checkpointtx. com. ~~We~~ **2We** 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 Securities and Exchange ~~2Commission~~ - **Commission** (“ SEC ”). We are not including the information on our website as a part of, nor incorporating it by reference into, this report. 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. In addition, we may disclose material non- public information by disseminating press releases, by disclosing information during publicly accessible meetings or conference calls, or through our website or social media accounts. PRODUCTS UNDER DEVELOPMENTImmuno- Oncology AgentsCosibelimab (Anti- PD- L1) ProgramCosibelimab is a fully ~~-~~human monoclonal antibody of IgG1 subtype that directly binds to PD- L1 and blocks the PD- L1 interaction with the Programmed Death Receptor- 1 (“ PD- 1 ”) and B7. 1 receptors. Cosibelimab’ 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. Additionally, cosibelimab has a functional Fc domain that may be capable of inducing antibody- dependent cellular cytotoxicity (“ ADCC ”) and complement- dependent cytotoxicity (“ CDC ”) against tumor cells. Preclinical and clinical studies of PD- 1 and PD- L1 blocking antibodies conducted by third parties 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. Potent therapeutic anti- tumor responses due to blocking of PD- 1 / PD- L1 interaction have been demonstrated by these approved products in patients with numerous different solid tumors including, but not limited to, NSCLC, melanoma, RCC, head and neck cancer, CSCC and urothelial carcinoma. We are **initially** developing

cosibelimab 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. **Effective September 30, 2023, the Company and TGTX agreed to mutually terminate these collaborations, with full rights reverting back to us.** We commenced a Phase 1 **,** multi- center clinical study for cosibelimab in October 2017. The study is evaluating the safety and tolerability of ascending doses of cosibelimab 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, including ongoing cohorts in locally advanced and metastatic CSCC ~~,~~ intended to support one or more applications for marketing approval. The primary endpoint is ORR, and secondary endpoints include duration of response, progression- free survival (" PFS "), and overall survival (" OS "). In January 2022, we announced top- line results from a cohort of this study with cosibelimab administered as a fixed dose of 800 mg every two weeks in patients with metastatic CSCC. The cohort met its primary endpoint, with cosibelimab demonstrating a confirmed ORR of 47. 4 % (95 % CI: 36. 0, 59. 1) based on independent central review of 78 patients enrolled in the metastatic CSCC cohort using RECIST 1. 1. In June 2022, we announced interim results from another cohort of this study with cosibelimab administered as a fixed dose of 800 mg every two weeks in patients with locally advanced CSCC that are not candidates for curative surgery or radiation. Cosibelimab demonstrated a confirmed ORR of 54. 8 % (95 % CI: 36. 0, 72. 7) based on independent central review of 31 patients enrolled in the cohort ~~using RECIST 1. 1~~. The design of the interim analysis incorporated feedback from the FDA and is intended to potentially support the approval of cosibelimab in this indication. **In July 2023, we announced longer- term results for cosibelimab from its pivotal studies in locally advanced and metastatic CSCC. These results demonstrated a deepening of response over time, resulting in complete response rates of 26 % and 13 % in locally advanced and metastatic CSCC, respectively. Additionally, the confirmed ORR in metastatic CSCC increased to 50. 0 % based on independent central review. Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either group. Updated safety data across 247 patients enrolled and treated with cosibelimab in all cohorts of the ongoing study remain consistent with those previously reported.** ~~Based~~ **3Based** on these results, we submitted a BLA to the FDA for cosibelimab in January 2023 **. On December 15** , ~~which application~~ **2023, the FDA issued a CRL for the cosibelimab BLA for the treatment of patients with metastatic or locally advanced CSCC who are not candidates or curative surgery or radiation. The CRL only cites findings that arose during a multi- sponsor inspection of our third- party contract manufacturing organization as approvability issues to address in a resubmission. Following resolution of the inspection issues at the third- party contract manufacturing organization raised in the CRL, a resubmission of the BLA** is **planned to support the marketing approval** ~~filed and under review with a PDUFA goal date~~ of **cosibelimab** ~~January 3, 2024~~. We intend **to seek a partner** to submit a marketing authorization application (" MAA ") submission in Europe **, as well as** ~~in the second half of 2023 followed by~~ additional potential submissions in markets worldwide ~~. In December 2021, we announced the initiation of our CONTERNO study, a multi- regional, open- label, multi- center, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first- line treatment of patients with NSCLC. The February 2022 Russian invasion of Ukraine and the ensuing response disrupted our ability to conduct clinical trials in Russia, Ukraine, and Belarus. We evaluated our ability to expand the number of CONTERNO study sites in our planned Latin American, South 3African and Asian Pacific countries, as well as add additional countries to conduct this clinical trial. However, the substantially longer enrollment period as a result of the conflict made the conduct of the CONTERNO study no longer viable. At the time of the conflict, only Russia was open for enrollment. Accordingly, we expect that the study will be wound down and closed by the end of the first quarter of 2023~~. CK- 302 (Anti- GITR) ProgramOur anti- GITR monoclonal antibody, CK- 302, is a fully human agonistic antibody that is designed to bind to 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 has the potential to abrogate 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 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 one or more oncological indications as a monotherapy or in combination with an anti- PD- L1 antibody as well as other anti- tumor immune response potentiating compounds and targeted therapies. **Effective September 30, 2023, the Company and TGTX agreed to mutually terminate these collaborations.** Currently, we are in preclinical development for this program. Targeted Anti- Cancer AgentsOlafertinib (also known as CK- 101 and RX518) EGFR Inhibitor Program We are developing olafertinib 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 ORR and PFS 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 one or more EGFR activating mutations and the T790M resistance mutation with minimal inhibition of wild- type EGFR, thereby potentially improving tolerability and safety profiles. In November 2015, Tagrisso ® (osimertinib), a third- generation EGFR inhibitor developed by AstraZeneca plc, received accelerated FDA approval for the treatment of patients with metastatic EGFR T790M mutation- positive NSCLC who have progressed on or after receiving EGFR tyrosine kinase inhibitor therapy. Tagrisso received full approval from the FDA in 2017 based on data from a randomized, Phase 3 trial, in which Tagrisso significantly improved PFS versus platinum- based doublet chemotherapy, providing 10. 1 months of median PFS compared to 4. 4 months from chemotherapy. Subsequently, in April 2018, Tagrisso received FDA approval for the first- line treatment of adult patients with metastatic NSCLC whose tumors have the EGFR exon 19 deletion or exon 21 L858R activating 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 from the EGFR inhibitor comparators, erlotinib or gefitinib. ~~We~~ **4We** are developing olafertinib for the potential treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletion mutations. We believe that olafertinib has the potential to be effective in this population as a monotherapy or in combination with other anti- tumor immune response potentiating compounds. ~~4In~~ **In** March 2015, Fortress entered into an exclusive license agreement with NeuPharma, Inc., 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 Investigational New Drug application (“ IND ”) and we initiated a Phase 1 clinical trial in September 2016, which was completed in September 2022. The trial evaluated the safety and tolerability of ascending doses of olafertinib in patients with advanced solid tumors to determine the maximum tolerated dose and the safety and efficacy of olafertinib in patients with EGFR mutation- positive NSCLC. In September 2018, we announced preliminary interim data in an oral presentation at the International Association for the Study of Lung Cancer 19th World Conference on Lung Cancer in Toronto. In November 2020, NeuPharma, Inc. commenced a Phase 3 clinical trial in China evaluating olafertinib in treatment- naïve locally advanced or metastatic NSCLC patients whose tumors have EGFR exon 19 deletion mutations. We have met with the FDA to discuss the adequacy of the ongoing Phase 3 trial in China. CK- 103 BET Inhibitor ProgramWe are developing CK- 103, a novel, selective and potent small molecule inhibitor of bromodomain and extra- terminal (“ 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~~ **retained** the right to develop and commercialize CK- 103 in solid tumors **. Effective September 30, 2023, the Company and TGTX agreed to mutually terminate the Sublicense Agreement** . Currently, we have completed the required CMC, pharmacology and toxicology activities that we believe will support an IND application filing. Anti- CAIX Research ProgramOur anti- carbonic anhydrase IX (“ CAIX ”) antibody is a fully human preclinical antibody designed to recognize CAIX expressing cells and kill them via ADCC and 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 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. 5COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENTThe 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. Estimated DevelopmentCompletionEstimated Cost toProduct CandidateTarget Indication (s) Statusof PhaseComplete PhaseCosibelimab Locally advanced and metastatic cutaneous squamous cell carcinoma Phase 1 registration- enabling 2024 $ **3 to $** 4 ~~to $ 5~~ millionCompletion dates and costs in the above table are estimates due to the uncertainties associated with clinical trials and the related requirements of development. In the cases where the requirements for 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 PATENTSGeneralOur 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, 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 that 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~~ **6Generally** , 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 the claimed 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 in a pending patent application or issued patent, 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 ~~6be~~ **be** minimal and, in any case, is limited to a maximum of five additional years of patent term. But that maximum of five additional years is, itself, subject to a cap of a maximum of 14 years of patent protection from the date of marketing approval. 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~~ **a number of** countries ~~elsewhere~~ . The issued patents and pending patent applications relate generally to compositions and methods of treatment involving antibodies against PD- L1, CAIX, and GITR. The PD- L1 segment of the in- licensed portfolio from Dana- Farber includes two granted U. S. patents (U. S. Patent Nos. 9, 828, 434 and 10, 604, 581) directed to antibodies that bind to PD- L1 and methods of augmenting a patient' s immune response by administering an anti- PD- L1 antibody, respectively. The ' 434 patent is scheduled to expire October 4, 2033, and the ' 581 patent is scheduled to expire November 18, 2033, not including any patent term restorations, which might become available under the provisions of U. S. patent laws, based on regulatory delays associated with obtaining marketing approval. Two Australian (AU 2013326901 and AU 2018226425), one Japanese (JP 6461800), one South Korean (KR 101947702), one Israeli (IL 237737), one Mexican (MX 370848), two Colombian (CO 34878 and CO 39049), one Canadian (CA 2886433), and two Chinese (CN 104994873 and CN 10782719) counterpart patents have issued, as well as registration of the two Chinese patents in Hong Kong (HK 1211223 and HK 1253723) **.** ~~, and additional~~ **Additional** international counterpart applications are pending in Canada and China. The issued international patents and any patents maturing from these pending applications will expire no sooner than October 2033. Checkpoint has also licensed from Dana- Farber a further anti- PD- L1 antibody portfolio that claims variants of the antibodies disclosed in the earlier- filed in- licensed family. This additional portfolio includes PCT / US2020 / 062815, which was filed on December 2, 2020, and it had been nationalized in the US, Australia, Canada, Europe, and Japan. Any patents maturing from these pending applications will expire no sooner than December 2040. In June 2016, Checkpoint also filed a company- owned U. S. provisional application (U. S. 62 / 356, 105) directed to antibodies, including cosibelimab, 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 U. S. non- provisional application (U. S. Appl. No. 15 / 636, 610) was filed at the same time. **This portfolio** ~~The' 610 application has~~ now **includes two** issued ~~as~~ **U. S. patents,** U. S. Patent No. 10, 590, 199 ~~with~~ **and U. S. Patent No. 11, 834, 505. U. S. Patent No. 10, 590, 119 has** claims directed to specific anti- PD- L1 antibodies, including cosibelimab, and fragments thereof, as well as methods of treating tumors / cancers with anti- PD- L1 antibodies and fragments thereof. ~~The' 199~~ **U. S. Patent No. 11, 834, 505 has claims directed to treating cancer with anti- PD- L1 antibodies, including cosibelimab. Both of these** ~~patent~~ **patents** ~~is~~ **(U. S. Patent Nos. 10, 590, 119 and 11, 834, 505) are** scheduled to expire on May 31, 2038, not including any patent term restorations, which might become available under the provisions of U. S. patent laws, based on regulatory delays associated with obtaining marketing approval. A further U. S. application, U. S. Appl. No. ~~16~~ **18** / ~~818~~ **377** , ~~621~~ **702** , ~~was filed before the issuance of the ' 199 patent and~~ is currently pending. International counterpart patents have also granted in Israel (IL 263611), Japan (JP 7148414), South Korea (KR 10- 2422411), ~~and~~ Russia (RU 2749109), and **Singapore (SG 11201810927Q), and** additional ~~national stage~~ applications are pending in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore and Thailand. Any patents maturing from these pending applications will expire no sooner than June 2037. ~~The~~ **7The** CAIX segment of the in- licensed portfolio from Dana- Farber includes three granted U. S. patents (U. S. Patent Nos. 8, 466, 263, 10, 450, 383, and 11, 174, 323). 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 ‘ 383 patent is directed to methods of treating cancer with anti- CAIX antibodies, and its term runs until April 26, 2027. The ‘ 323 patent is directed to methods of treating renal cancer with anti- CAIX antibodies, and its term runs until February 11, 2027. The ‘ 263 patent, the ‘ 383 patent, the ‘ 323 patent may be entitled to any patent term restorations that might become available under the provisions of U. S. patent laws, based on regulatory delays associated with obtaining marketing approval. The European counterpart patent (EP 1979379) is in force in Switzerland, Liechtenstein, Germany, France and the United Kingdom. A Canadian counterpart patent (CA 2, 632, 094) has also been issued. Both the European and Canadian counterpart patents are scheduled to expire no sooner than December 2026. The GITR segment of the in- licensed portfolio from Dana- Farber includes an International Application No. PCT / US2015 / 054010, filed in October 2015, and International Application No. PCT / US2017 / 043504, filed in July 2017. All of the national stage applications claiming priority to PCT / US2015 / 054010 have lapsed; however, there is one granted patent (U. S. Patent No. 10, 463, 732) in this family. The ‘ 732 patent will not expire until at least October 2035, barring any patent term restorations that might become available under the provisions of U. S. patent laws. National stage applications claiming priority to PCT / US2017 / 043504 have resulted in one US patent (U. S. 11, 046, 777), one Chinese patent (CN 109689689), one Japanese patent (JP 7082967) **, one South Korean patent (KR 2534568),** and ~~are~~ **one patent in Singapore (SG 11201900500T). This family** also **includes** pending **patent applications** in the U. S. (U. S. Appl. No. 17 / 316, 141), Australia, Brazil, Canada, Europe, Israel, ~~South Korea, Singapore, Russian,~~ New Zealand **, Thailand,** and Mexico. Any of these national stage applications that issue or grant as patents would expire no earlier than July 2037. U. S. 11, 046, 777 will not expire until at least July 2037, barring any patent term restorations that might become available under the provisions of the U. S. patent laws. ~~7In~~ **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 olafertinib. EGFR is a receptor tyrosine kinase of the ErbB family and is also known as “ Her1 ” and “ ErbB1. ” The in- licensed patent estate includes ~~four~~ **six** granted U. S. patents, a granted European patent, a granted patent in Hong Kong, a granted patent in Singapore, a granted patent in the Philippines, a granted Japanese patent, a granted South Korean patent, a granted Malaysian patent, ~~two~~ **three** granted Australian patents, a granted New Zealand patent, two granted Israeli patents, a granted Mexican patent ~~and~~ **,** a granted Russian **patent, a granted Indian patent, a granted Canadian patent, and a granted Brazilian** patent. U. S. Patent No. 9, 550, 770 is directed to a generic formula of small molecules of substituted quinazolines for inhibiting kinase activity, and also has a specific claim directed to the compound, olafertinib. The granted claims also cover pharmaceutically acceptable salts, pharmaceutical compositions, particular dosage forms and packaged goods. U. S. 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, olafertinib. U. S. Patent No. 10, 172, 868 is directed to methods of treating non- small cell lung cancer with a specific list of compounds, including the compound, olafertinib. U. S. Patent No. 10, 653, 701 is directed to methods of treating cancer with a substituted quinazoline compound comprising an electrophilic group capable of forming a covalent bond with a nucleophile, which includes the compounds of the ‘ 868 patent (e. g., the compound, olafertinib). U. S. Patent No. 11, 304, 957 ~~is~~ **and U. S. Patent 11, 865, 120 are** directed to processes for preparing compounds, including the compound, olafertinib. Additionally, there is a pending U. S. application in this family (U. S. Appl. No. ~~17~~ **18** / ~~681~~ **519** , ~~387~~ **150**). The granted foreign patents cover the compound, olafertinib, 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 U. S. and foreign patents runs to August 22, 2034, not including any patent term restorations in the U. S., which might become available under the provisions of U. S. patent laws, based on regulatory delays associated with obtaining marketing approval. Additional counterpart applications exist in jurisdictions around the world, including, ~~Australia, Canada,~~ Hong Kong, the Philippines, Singapore, South Korea, Malaysia ~~, Brazil, India~~ , China and Europe. Any patents maturing from these pending applications would be scheduled to expire no sooner than August 2034. Checkpoint has also licensed from NeuPharma an additional international application, PCT / US2019 / 017117, which was filed on February 7, 2019, and it directed to additional EGFR inhibitors and methods of using the same. National stage applications claiming priority to PCT / US2019 / 017117 have resulted in one US patent (U. S. 11, 465, 975) and are pending in Australia, Canada, China, Europe, Hong Kong, the Philippines, Israel, Japan, South Korea, Singapore and New Zealand. Any of these national stage applications that issue or grant as patents would expire no earlier than February 2039. ~~In~~ **8In** 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, which claim the benefit of two earlier- filed Indian provisional applications. This patent estate has four granted U. S. patents, ~~a~~ **two** granted Indian ~~patent~~ **patents** , two granted Japanese patents, two granted Australian patents, two granted Russian patents, two granted Israeli patents, two granted patents in Hong Kong, two granted Chinese patents, two granted Mexican patents **, two Brazilian patents, one South Korean patent** , and two granted European patents that have each been validated across a broad range of European countries. National stage applications claiming priority to PCT / IN2016 / 050098 or PCT / IN2016 / 050300 are pending in ~~Brazil,~~ Canada ~~, India~~ , South Korea, New Zealand, and Thailand. U. S. Patent No. 10, 689, 390, which is the U. S. national phase entry of PCT / IN2016 / 050098, is directed to a generic formula of small molecule BET inhibitors and specifically claims exemplified small molecule BET inhibitors. The granted claims of the ‘ 390 patent also cover pharmaceutical compositions. U. S. Patent No. 11, 319, 326, which is a divisional of the ‘ 390 patent, is directed to methods of treatment with the compounds claimed in the ‘ 390 patent, including inhibiting one or more BET family bromodomains in the

cell and treating a proliferative disorder or cancer. U. S. Patent No. 10, 689, 395, which is the U. S. national phase entry of PCT / IN2016 / 050300, is directed to a generic formula of small molecule BET inhibitors that cover half of the exemplified small molecule BET inhibitors disclosed in PCT / IN2016 / 050300. The granted claims of the ‘ 395 patent also cover pharmaceutical compositions and a method of treating cancer. U. S. Patent No. 11, 267, 820, which is a divisional of the ‘ 395 patent, is directed to the remaining half of the exemplified compounds disclosed in PCT / IN2016 / 050300 and has claims similar to those granted from the ‘ 395 patent. Any patents maturing from this patent estate are expected to expire in 2036. Other Intellectual Property RightsWe 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 ~~8parties~~ **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 designation or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended (“ 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 drug product will be granted a seven- year period of marketing exclusivity for such FDA- approved orphan drug product. In September 2017, we received FDA Orphan Drug Designation for olafertinib for the treatment of EGFR mutation- positive NSCLC. ~~LICENSING~~ **9LICENSING** AGREEMENTS AND COLLABORATIONSDana- 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, for an exclusive, worldwide license to Dana- Farber’ s patents for a portfolio of fully human immuno-oncology targeted antibodies **targeting PD- L1, GITR and CAIX** . 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, on May 11, 2015, granted Dana- Farber five percent of our common stock on a fully ~~-~~ diluted basis, equal to 50, 000 shares valued at $ 32, 500 or $ 0. 65 per share. 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 13, 683 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. **As of December 31, 2023, $ 5. 0 million of these milestones have been achieved for the antibody targeting PD- L1.** 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. Dana- Farber also 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~~ . 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 the agreement will expire in its entirety with respect to such 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 $ 6. 2 million of upfront licensing and milestone payments under this license agreement. In connection with the license agreement with Dana- Farber, in March 2015 we entered into a collaboration agreement with TGTX, which was amended and restated in June 2019, to develop and commercialize the anti- PD- L1 and anti- GITR antibody research programs in the field of hematological malignancies. We ~~retain~~ **retained** the right to develop and commercialize these antibodies in 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 **. Effective September 30, 2023, we mutually agreed with TGTX to terminate the collaboration agreement, with full rights reverting back to us** . Under the terms of the original collaboration agreement, TGTX paid us $ 0. 5 million, representing an upfront licensing fee. Upon the signing of the amended and restated collaboration agreement in June 2019, TGTX paid us an additional $ 1. 0 million upfront licensing fee. We ~~are eligible to receive substantive potential milestone payments for the anti- PD- L1 program of up to an aggregate of approximately $ 27. 6 million upon TGTX’ s successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately $ 8. 4 million upon TGTX’ s successful completion of clinical development milestones, and up to approximately $ 19. 2 million upon regulatory filings and first commercial sales in specified territories. We are~~ also ~~eligible to receive~~ **received** ~~substantive potential milestone payments for the anti- GITR antibody program of up to an aggregate of approximately $ 21. 5 million 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 9commercial 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 for both programs, in addition to royalty payments based on a tiered low double- digit percentage of net sales. We also receive~~ an annual license maintenance fee, which ~~is~~ **was** creditable against milestone payments or royalties due to us. TGTX also ~~pays~~ **paid** us for our out- of- pocket costs of material used by TGTX for their development activities. ~~The 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, **2023 and** 2022 ~~and 2021~~, we recognized approximately $ **58, 000** ~~0. 1 million~~ and $ **121, 000** ~~0. 2 million~~ respectively, in revenue from our collaboration agreement with TGTX in the Statements of Operations. ~~Adimab~~ **10Adimab** , LLCIn 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 cosibelimab, 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 **additional** payments up to an aggregate of approximately $ ~~4~~ **2** . ~~8~~ **5** million 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 the agreement will 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. **In February 2023, the Company expensed a non- refundable milestone payment of $ 2. 2 million to research and development expenses upon the FDA' s filing acceptance of the Company' s BLA for cosibelimab in metastatic or locally advanced CSCC.** To date, we have incurred $ ~~3~~ **6** . ~~7~~ **0** million in milestone payments under our collaboration agreement with Adimab. 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 olafertinib, 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 us. The license agreement was amended on February 21, 2017. Under the terms of the license agreement, we paid NeuPharma an up- front licensing fee of $ 1. 0 million, and NeuPharma is eligible to receive **additional** payments of up to an aggregate of approximately $ 39. 0 million upon our successful achievement of certain clinical development and regulatory milestones ~~in~~ **covering** 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 **across all indications** , 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 the agreement will expire in its entirety with respect to such 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 10th 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 10th 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. Jubilant Biosys LimitedIn May 2016, we entered into a license agreement with Jubilant for an exclusive, worldwide license to Jubilant' s family of patents covering compounds that inhibit BET proteins such as BRD4, including CK- 103. The license agreement was amended on December 13, 2016 and March 31, 2017. Under the terms of the license 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 $ 88. 4 million upon our successful achievement of certain clinical development and regulatory milestones ~~for~~ **covering** two licensed products, 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. 3 million upon our successful achievement of certain sales milestones based on aggregate net sales for two licensed products, 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 ~~10product --~~ **product** - by- product basis until the royalty term in such country with respect to such product expires, at which time the agreement will 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~~ **11In** 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~~ **retained** the right to develop and commercialize these compounds in the field of solid tumors **. Effective September 30, 2023, we mutually agreed with TGTX to terminate the sublicense agreement** . 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. 4 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. 9 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. 3 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~~ **paid** us for 50 % of IND enabling costs and patent expenses. For each of the years ended December 31, **2023 and** 2022 ~~and 2021~~, we recognized approximately $ ~~0. 1 million~~ **46, 000 and $ 70, 000, respectively,** in revenue related to the sublicense agreement in the Statements of Operations. COMPETITIONCompetition 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 preclinical or clinical development, or with marketing approvals, to treat conditions for which we are also seeking to discover and develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier. In the immuno- oncology area, several major pharmaceutical companies have a PD- 1 and / or PD- L1 antibody 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 ®), Regeneron (approved PD- 1 with the brand name Libtayo ®) ~~and~~ **,** GlaxoSmithKline (approved PD- 1 with the brand name Jemperli ® **) and Coherus (approved PD- 1 with the brand name Loqtorzi ™**). We are aware of several anti- GITR antibody development programs that are or were 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. 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 mutation- positive NSCLC in the United States. 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 and for the adjuvant treatment of patients with early stage EGFR mutation positive NSCLC. 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' nazartinib, **and** Janssen' s lazertinib ~~, and EQRx' s almonertinib~~ . ~~11In~~ **In** the BET inhibitor space, there are a number of companies which have advanced to early stage clinical trials, including MorphoSys AG' s pelabresib, Bristol- Myers Squibb' s **trotabresib** ~~BMS- 986158~~ , Abbvie' s mivebresib, Incyte' s INCB57643 and Zenith Epigenetics' s ZEN003694. Additional information can be found under Item 1A- Risk Factors- Risks Related to Our Business and Industry. EMPLOYEESAs of December 31, ~~2022~~ **2023** , we had twenty- ~~four~~ **three** 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~~ **12SUPPLY** AND MANUFACTURINGWe 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 a sufficient 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 plan to 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 outside of the United States face similar challenges from the numerous local and regional 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 and corresponding foreign regulatory agency 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 REGULATIONSGovernmental authorities, including the FDA and corresponding state and foreign regulatory agencies, regulate the clinical development, manufacture, approval 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. ~~12The~~ -- **The** regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive preclinical 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. ~~Where~~ **13Where** appropriate, the FDA may designate certain drug candidates as eligible for expedited review when they are intended to treat persons with serious or life- threatening conditions for which there is an unmet medical need. A sponsor can apply for such designation, including fast track review, at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application (" NDA ") or BLA. 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 responds 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 are 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 may be eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of an NDA or BLA to the FDA for review before the complete application is submitted. Where applicable, sponsors of drugs 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. Accelerated approval will be subject to the requirement that the sponsor 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 may be underway at the time a sponsor files the NDA or BLA. When required to be conducted, such post-marketing studies must also be adequate and well- controlled. The sponsor must carry out any such post- marketing studies with due diligence. Drug candidates that have received accelerated approval have subsequently 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 or BLA to the FDA or foreign regulatory authorities for marketing approval. Clinical testing must meet requirements for institutional review board or ethics committee oversight, informed consent and good clinical practices, among others, and must be conducted pursuant to an IND, unless exempted. For purposes of NDA or BLA 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. ~~13The~~ -- **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, external factors such as pandemics or geopolitical conflicts 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; **14** ● 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, among other things. 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 terminate 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, among other things, the results of efficacy, the adverse event profile and an evaluation of the benefit / risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy. Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA 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 an NDA or BLA for filing if certain content criteria are not met and, even after accepting an 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 (“ REMS ”), as part of an 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 FDA has determined that the product is safe and effective, as demonstrated through data and information, including 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 monitoring and regulation ~~14by~~ **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 may constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements, including those related to drug manufacturing, 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~~ **15Failure** 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 RequirementsIn 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 ReimbursementIn 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. In addition, in the U. S., the Inflation Reduction Act contains provisions that have the potential to substantially impact the profitability of drugs. For example, the Inflation Reduction Act authorizes the Centers for Medicare & Medicaid Services (“ CMS ”) to negotiate drug prices for certain drugs in Medicare Part D, beginning in 2026, and Parts D and B, beginning in 2028. Additionally, the Inflation Reduction Act imposes inflation rebates on drugs reimbursed by Medicare Part B and Part D. Given the complexity of the Inflation Reduction Act and the uncertainty with respect to its impending implementation, the impact of the Inflation Reduction Act on our financial conditions and operations cannot be predicted, whether in its current form or as amended or repealed. International RegulationIn 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 FactorsThe 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. ~~15Risks~~ **16Risks** Related to Our Finances and Capital RequirementsWe have

incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We may never achieve or maintain profitability. We **have** ~~are an emerging growth company with~~ a limited operating history ~~. We~~ **, and 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 $ ~~262~~ **314** . ~~5~~ **3** million as of December 31, ~~2022~~ **2023** . 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 submitted for marketing approval, as is the case with cosibelimab, or are approved for commercial sale, due to our need to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including manufacturing to build pre- commercial inventory, 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; ● we initiate one or more clinical trials to pursue additional indications for our product candidates, or if 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 candidates receives regulatory approval. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from the sale of our development stage products, and we do not know when, or if, we will generate any revenue. 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. 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 16product 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 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, and resulting regulatory approval request submissions, of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including building a commercial organization ~~to~~ **17to** address certain markets. We will require additional capital for the further development and, if approved, commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. We believe **, assuming no business or corporate development transactions are consummated,** that our cash and cash equivalents are only sufficient to fund our operating expenses into the ~~second~~ **third** quarter of ~~2023~~ **2024 . Accordingly, we intend to continue our active discussions with third party pharmaceutical and biotechnology companies to evaluate potential partnerships or other types of corporate development transactions, including strategic mergers** . 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, if approved, 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 studies and clinical trials for our product candidates; ● the timing and process of regulatory approval reviews and 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 **or resubmission** 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 third- party 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, if approved. 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. ~~17In~~ **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 are also engaging in discussions with third party pharmaceutical and biotechnology companies to evaluate potential partnerships or other types of corporate development transactions, including a strategic merger** . We cannot be sure that any additional funding, if needed, **partnership or any other type of corporate development transaction,** will be available on terms favorable to us or at all. Furthermore, any additional equity or equity- related financing **, or equity that may be issued or sold in a corporate development transaction,** 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 **, merger,** 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. ~~There~~ **18There** is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. Our audited financial statements as of December 31, ~~2022~~ **2023 ,** have been prepared under the assumption that we will continue as a going concern for the next twelve months. ~~As of December 31, 2022, we had cash and cash equivalents of $ 12. 1 million and an accumulated deficit of $ 262. 5 million.~~ We do not believe that our cash and cash equivalents are sufficient for the next twelve months **after the date that our financial statements are issued** . As a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including potentially obtaining debt or equity financings or other arrangements. Our future success depends on our ability to raise capital. We cannot be certain that raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities or even terminate our operations. **Additionally, we intend to continue our active discussions with third party pharmaceutical and biotechnology companies to evaluate potential partnerships or other types of corporate development transactions, including strategic mergers.** 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, **mergers,** 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. ~~18We~~ **We** are ~~an " emerging growth company " and~~ a " smaller reporting company, " ~~and~~ **which means that** 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 Jumpstart Our Business Startups Act of 2012 (" 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 our 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~~ **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. We **no longer qualify as an " emerging growth company, " and as a result, we have to comply with increased disclosure and compliance requirements. We no longer qualify as an emerging growth company (" EGC ") as defined in the Jumpstart Our Business Startups Act (the " JOBS Act ") because in 2023, we reached the five- year anniversary of the first sale of our common stock pursuant to an effective registration statement under the Securities Act of 1933. As such, we are no longer exempt from certain disclosure and compliance requirements that apply to 19other public companies but did not previously apply to us due to our status as an EGC. These requirements include, but are not limited to: ● compliance with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements, including critical audit matters; ● the requirement that we provide more detailed disclosures regarding executive compensation, although we are still able to take advantage of exemptions provided to smaller reporting companies; and ● the requirement that we obtain stockholder approval of any golden parachute payments not previously approved. We anticipate increased expenses, including exchange listing and SEC requirements, director and officer insurance premiums, legal, audit and tax fees, regulatory compliance programs, and investor relations costs associated with being a public company and ceasing to be an emerging growth company. We** may expend our limited resources to pursue certain product candidates or indications 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 ~~19product~~ **product** candidates for specific indications may not yield any commercially viable products. If we do not accurately and / or effectively 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. Weakness in the U. S. economy, including within our geographic footprint, has adversely affected us in the past and may adversely affect us in the future. We have been, and will continue to be, impacted by general business and economic conditions in the United States. These conditions include short- term and long- term interest rates, inflation, money supply, political issues, war, legislative and regulatory changes, fluctuations in both debt and equity capital markets, broad trends in industry and finance, unemployment and the strength of the U. S. economy and the local economies in which we operate, all of which are beyond our control. Worldwide financial markets have recently experienced periods of extraordinary disruption and volatility, which have been exacerbated by the COVID- 19 pandemic ~~and~~ **,** the Russia / Ukraine conflict **and the evolving conflict in Israel and Gaza** , resulting in heightened credit risk, reduced valuation of investments, decreased economic activity,

heightened risk of cyberattacks, and inflation. Moreover, many companies have experienced reduced liquidity and uncertainty as to their ability to raise capital during such periods of market disruption and volatility. In the event that these conditions recur or result in a prolonged economic downturn, our results of operations, financial position and / or liquidity could be materially and adversely affected. In addition, as a result of recent financial and political events, we may face increased regulation. Risks Related to our Business Strategy, Structure, and OrganizationWe currently have no drug products for sale and are dependent on the future success of our product candidates. We can give no 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 a development- 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~~ **20candidates** , which may never occur. We currently have no drug products for sale, currently generate no revenues from sales of any drug products and may never be able to develop or commercialize a marketable drug. The successful development, and any commercialization of our technologies and any product candidates that may occur, would require us to successfully perform a variety of functions, including: ● developing our technology platform; ● identifying, developing, formulating, manufacturing and commercializing product candidates; ● entering into and maintaining successful licensing and other arrangements with product development partners; ● achieving clinical endpoints to support preparation of approval applications; ● participating in regulatory approval processes, including ultimately gaining approval to market a drug product, which may not occur; ● obtaining sufficient quantities of our product candidates from our third- party manufacturers to meet clinical trial needs and, if approved, to meet 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 a 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 establish; ● maintaining patent protection and regulatory exclusivity for our product candidates; and ● obtaining market acceptance for our product candidates. ~~20Each~~ -- **Each** of these requirements will require substantial time, effort and financial resources. We intend to use data from our ongoing Phase 1 clinical trial of cosibelimab, conducted outside the United States, in checkpoint therapy- naïve patients with selected recurrent or metastatic cancers, including CSCC, to potentially support one or more U. S. BLAs and comparable applications for marketing approval outside the U. S. In January 2020, we announced that we had initial discussions with the FDA to execute this strategy in CSCC. Based on top- line and interim results in metastatic and locally advanced CSCC, respectively, we submitted a BLA to the U. S. FDA for these indications in January 2023 **. In December 2023** , ~~which application is filed and under~~ **the FDA issued a complete response letter for the cosibelimab BLA due to inspection issues at the third- party contract manufacturing organization. Although no approvability issues regarding use of data from the Phase 1 clinical trial were noted in the complete response letter, upon resubmission of the BLA the FDA reserves the right to** review **the BLA again in its entirety** ~~with a PDUFA goal date of January 3, 2024~~ . Similarly, we intend to use data from our licensor' s ongoing Phase 3 clinical trial of olafertinib (formerly CK- 101), conducted only in China, in patients with EGFR mutation- positive NSCLC, to potentially support a U. S. NDA and comparable applications for marketing approval outside the U. S. We believe, based on published FDA guidance documents, public statements of companies with comparable product candidates, and past interactions with the FDA, that exclusively foreign clinical data from a single study may be acceptable to support marketing approval (s) under FDA regulations. If we prove to be incorrect, running additional studies in the U. S. will require substantial time, effort and financial resources or may not be possible at all. Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technologies 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 identify product candidates, develop and commercialize product candidates in our portfolio and any product candidates we are able to identify and enter into successful collaborative arrangements with other companies in the future, as well as for you to assess the advisability of investing in our securities. Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in the jurisdictions in which we plan to market the product, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales, which may not occur. We are not permitted to market or promote any of our product candidates in the U. S. or any other jurisdiction before we receive regulatory approval from the FDA or comparable foreign regulatory authority, respectively, and we may never receive such regulatory approval for any of our product candidates. ~~Our~~ **21Our** future growth depends on our ability to identify and acquire or in- license products and successfully integrating such acquired or in- licensed products into our existing operations. 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. ~~21Risks~~ **Risks** Inherent in Drug Development and CommercializationBecause results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, " top- line, " and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed. Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate through adequate and well- controlled clinical trials that our product candidates are effective with a favorable benefit- risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising preclinical results. Accordingly, no assurance can be made that a safe and effective dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials. Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. In addition, registration trials or larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region ~~or~~ **22or** country to country basis, which could materially adversely affect the outcome of the study or the opinion of the validity of the study results by applicable regulatory agencies. From time to time, we may publicly disclose top- line or preliminary data from our clinical trials, which is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the particular study or trial, including all endpoints and safety data. As a result, top- line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top- line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top- line, interim, or preliminary data we previously published. When providing top- line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top- line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints. Further, from time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, many of the results reported in our early clinical trials rely on local investigator- assessed efficacy outcomes which may be subject to greater variability or subjectivity than results assessed in a blinded, independent, centrally reviewed manner, often required of final or later phase, adequate and well- controlled registration- directed clinical trials. If the results from our registration- directed trials are different from the results found in the earlier studies, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Also, time- to- event based endpoints such as duration of response and progression- free survival have the potential to change, sometimes drastically, with longer follow- up. In addition, as patients continue on therapy, there can be no assurance given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company ~~22in~~ **in** general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top- line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, or successfully commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Delays in clinical testing could result in increased costs to us and delay our

ability to generate revenue. Although we are conducting and planning for certain clinical trials relating to our product candidates, there can be no assurance that the FDA, or any 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 (" 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 (" IRB "), or ethics committee, as applicable, approval at each site; ● recruiting a sufficient number of suitable patients to participate in a trial; ● clinical sites deviating from trial protocol or dropping out of a trial; ● having patients complete a trial or return for post- treatment follow- up; ● developing and validating companion diagnostics on a timely basis, if required; ● obtaining resolution for any clinical holds that arise from the FDA or any comparable foreign regulatory authority; ● adding new clinical trial sites; or ● availability of raw materials or manufacturing sufficient quantities of product candidate for use in clinical trials. ~~We~~ **23We** 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 monitoring 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 candidate, 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, or such revenues may not be generated at all. 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. Difficulties in the enrollment of patients in clinical trials may prevent or delay receipt of necessary regulatory approvals. 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 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 that we are ~~23targeting~~ -- **targeting** for 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 candidates or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Russian military action in Europe may impact foreign countries in which we enrolled patients in our clinical trials. In February 2022, Russia commenced a military invasion of Ukraine. Russia' s invasion and the ensuing response by Ukraine may prevent the FDA from auditing our five clinical sites that enrolled a total of 17 patients in these countries ~~upon~~ **during its** review of our BLA for cosibelimab. If we are delayed or not able to obtain regulatory approval, our business may be adversely affected. ~~We~~ **24We** 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, by other regulatory agencies in the United States, by the European Medicines Agency and by comparable foreign 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 CROs 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, 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 approval, 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 available therapies and standards of care, 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 study design, including the control arm used in our study, or data are 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. ~~24Under~~ -- **Under** the FDA' s accelerated approval regulations, which only apply to certain drug products, 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. While we may undertake development programs for one or more of our product candidates that we believe, if successful, could support a submission for marketing approval under the accelerated approval regulations, we may ultimately fail to meet the criteria to do so, which may cause delays in the approval or rejection of an application. 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 studies, including 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. ~~If~~ **25If** 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 or adverse events 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 adverse events, 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 adverse events that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of adverse events, 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 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. Adverse events or 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. Adverse events or 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, including specific warnings, black box warnings, adverse reactions, precautions, and / or contraindications; ● regulatory authorities may suspend or withdraw their approval of the product, and / 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, or any revenues, from its sale. ~~25Public~~ -- **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 (" 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. ~~Even~~ **26Even** 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. If one or more of our product candidates that we may license or acquire is approved, the approved product candidate will be subject to ongoing requirements and review by 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 authorities, 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, civil claims, and / or criminal charges 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, untitled letters, import alerts, and / or inspection observations; ● 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; ~~26~~ ● suspension of any ongoing clinical trials; ● refusal to permit the import or export of our products; ● product seizure; or ● injunctions, consent decrees, and / 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, or negatively affect those products for which we may have already received regulatory approval, if any. 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 be subject to the various actions listed above, including losing any marketing approval that we may have obtained. Regulatory approval by the FDA, or any similar regulatory authorities outside the United States, is limited to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. Any regulatory approval is limited to those indications for use for which a product is deemed to be safe and effective by the FDA, or other similar regulatory authorities outside the United States. In addition to the regulatory approval required for new drug products, new formulations or new or additional indications for use for an already approved product also require 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 prevented or reduced, and our business may be adversely affected. ~~While~~ **27While** 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 products is limited to those indications that are specifically approved by the FDA, or similar regulatory authorities outside the United States. These " off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in certain circumstances. Regulatory authorities in the U. S. generally do not regulate the practice of medicine or 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 penalties, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. 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 process, 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 United States Patent and Trademark Office (" USPTO "). The FDA typically conducts a review of proposed product brand names, including an evaluation of the 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. If our competitors develop treatments for any of our product candidates' target indications and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity for our product candidate will be reduced or eliminated. 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 ~~27render~~ **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. 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~~ **distributing** 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. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from ~~these~~ **28these** third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in- licensing new product candidates. Further, 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, including those 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 them 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. If any of our product candidates are successfully developed but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited. Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third- party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to: ● the efficacy and safety as demonstrated in clinical trials; ● the timing of market introduction of such product candidates as well as competitive products; ● the clinical indications for which the drug is approved; ● acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment; ● the potential and perceived advantages of product candidates over alternative treatments; ● the safety of product candidates in a broader patient group (i. e. based on actual use); ● the cost of treatment in relation to alternative treatments; ● the availability of adequate reimbursement and pricing by third parties and government authorities; ● changes in regulatory requirements by government authorities for our product candidates ● relative convenience and ease of administration; ● the prevalence and severity of side effects and adverse events; ● the effectiveness of our sales and marketing efforts; and ● unfavorable publicity relating to the product. ~~28If~~ **If** any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable. 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. 29Obtaining 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 be unsuccessful in commercializing our product candidates, if 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 approved product candidate, we would need to build marketing, sales, distribution, managerial and other non- technical capabilities, or arrange for third parties to perform these services, and we may be unsuccessful in doing so. In the event of successful development and regulatory approval of any of our current or future product candidates, 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 our own sales and marketing organization. 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; 30 ● 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. If we obtain marketing approval for one or more of our product candidates in development, we intend to expand our insurance coverage to include the sale of commercial products, 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. Risks Related to Reliance on Third PartiesWe have ~~or intend to contract~~ **contracted** with third parties for the manufacture of our approved products, if any. If such contract manufacturer fails to timely produce sufficient product volume **, to pass regulatory inspections,** or to comply with applicable regulations, the commercialization of our product candidates may be delayed, we may be unable to meet market demand, and we 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 have ~~or intend to enter~~ **entered** into development and supply agreements with one or more 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 establishment inspection program. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third- party suppliers and contract manufacturers, but we have little control over their compliance with these regulations. Any failure to **pass regulatory inspections or** comply with applicable regulations may result in fines and civil penalties, suspension of production, restrictions on imports and exports, 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, potential for breach of contract claims, damage to our reputation and potential for product liability claims. If the contract 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. We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. Those third parties may perform unsatisfactorily, fail to meet deadlines for trial completion, or to comply with applicable regulatory requirements. We rely on third- party CROs and site management organizations to conduct some of our preclinical studies and all our clinical trials for our product candidates, and plan to do the same for any future product candidate. We expect to continue to rely on third parties, such as CROs, site management organizations, image reading vendors, laboratories, 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~~ **31third** 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. ~~31Our~~ -- **Our** reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we 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 practices (“ GLPs ”) 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 or other third party vendors, institutions or investigators fail to **pass regulatory inspections or 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 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 and / 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 CROs or site management organizations terminate, we may not be able to enter into arrangements with alternative CROs or site management organizations or to do so on commercially reasonable terms. Switching or adding additional CROs or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO 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 CROs or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future. Forces beyond our control ~~, including the impacts of COVID- 19,~~ could disrupt the ability of our third- party CROs, site management organizations, image reading vendors, laboratories, clinical data management organizations, medical institutions and clinical investigators to conduct our preclinical studies and our clinical trials for our product candidates and for any future product candidate. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing and for the future commercialization of our approved products, if any. Reliance on third parties increases the risk that we will not have sufficient quantities of our products 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, and plan to do so for commercial manufacture of any of our product candidates that may 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 may obtain marketing approval. We may be unable to establish or maintain 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, while still being required by law to establish adequate oversight and control over products furnished by that third party; **32** ● the possible breach of the manufacturing agreement by the third party; ● manufacturing delays if our third- party manufacturers are unable to obtain raw materials due to supply chain disruptions, 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; ~~32~~ ● 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. Forces beyond our control ~~, including the effects of the COVID- 19 pandemic,~~ could disrupt the global supply chain and impact our or our third- party manufacturers' ability to obtain raw materials or other products necessary to manufacture our product candidates. 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 third- party manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate 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 third- party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third- party manufacturers, but we do not control the day- to- day manufacturing operations of, and are dependent on, our third- party 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 **and pass regulatory inspections** could result in sanctions being imposed on us, including clinical holds, fines, injunctions, restrictions on imports and exports, 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 **. In 2023, our contract manufacturer for cosibelimab received certain observations from the FDA on Form 483 related to a multi- sponsor on- site inspection. In December 2023, the FDA issued a CRL for the cosibelimab BLA due to those inspection issues. Following resolution of the inspection issues at the third- party contract manufacturing organization raised in the CRL, a resubmission of the BLA is planned to support the marketing approval of cosibelimab. There is no guarantee that the FDA will agree with the response and remediations in a timely manner or at all, which could negatively impact our ability to obtain regulatory approval for cosibelimab or obtain approval within reasonable timelines. Any further delays in approval will continue to increase our costs and could further delay or impede our ability to commence product sales and generate revenues** . 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 third- party 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 third- party 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 may receive marketing approval on a timely and competitive basis. ~~We~~ **33We** 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, if approved, 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 well- studied 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 ~~33or~~ **or** future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised. Risks Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other IndustriesWe cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We cannot predict the likelihood, nature

or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U. S. presidential administration may impact our business and industry. In particular, the U. S. President has taken several executive actions, specifically through rulemaking and guidance, that could impact the pharmaceutical business and industry. A few of the major administrative actions include: 1. On October 9, 2019, CMS issued a proposed rule entitled, Modernizing and Clarifying the Physician Self- Referral Regulations and on the same day the HHS Office of Inspector General issued a similar rule, entitled Revisions to Safe Harbors Under the Anti- Kickback Statute, and Civil Monetary penalty Rules Regarding Beneficiary Inducements. The proposed rules are an effort to reform regulations dealing with anti- kickback and self- referral laws. The proposals are attempting to allow certain financial arrangements that would otherwise violate anti- kickback and self- referral laws for providers that are participating in value- based payment arrangements. The proposed rule could impact drug purchasing behavior to ensure providers are within their budget and / or restructure existing payment structures between providers and manufacturers. 2. On October 30, 2019, the Administration issued an advanced notice of proposed rulemaking (" ANPRM ") entitled, International Pricing Index Model for Medicare Part B Drugs. This ANPRM is soliciting feedback on a potential proposal to align United States drug prices in the Medicare Part B program with international prices. It also solicits public feedback on a policy that would allowing private- sector vendors to negotiate prices, take title to drugs, and improve competition for hospital and physician business. Although this is only a notice for a potential rule, it signals the Administration' s desire to regulatorily influence the United States drug pricing system that could adversely affect the industry. 3. On November 15, 2019, CMS issued a proposed rule entitled, Transparency in Coverage and finalized the Calendar Year (" CY ") 2020 Outpatient Prospective Payment System (" OPPS ") & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Rule. Together the rules would increase price transparency through health plans and in hospitals. The affects may influence consumer purchasing habits in the health care sector as a whole. Although the transparency provisions are not yet in effect and the hospital price transparency requirements are subject to litigation, there could be implications for the industry related to drug pricing if or when it is enacted. 4. On November 18, 2019, CMS issued a proposed rule entitled, Medicaid Fiscal Accountability Regulation (" MFAR "). The proposed rule would significantly impact states' ability to finance their Medicaid programs. If finalized, the MFAR could force states to restructure their Medicaid financing that could disincentivize or change state prescription drug purchasing behavior that would adversely impact the industry. ~~5~~ **345** . On December 18, 2019, the FDA issued a proposed rule entitled, Importation of Prescription Drugs. The proposed rule would allow the importation of certain prescription drugs from Canada. If finalized, states or other non- federal government entities would be able to submit importation program proposals to FDA for review and authorization. This proposed rule could also influence pricing practices in the United States. 6. On January 30, 2020, CMS issued a state waiver option entitled, Health Adult Opportunity (" HAO "). The HAO would allow states to restructure benefits and coverage policies for their Medicaid programs. The HAO will provide states administrative flexibilities in exchange for a capped federal share. The cap on the federal share is commonly referred to as a " block grant. " Importantly, the HAO allows states to set formularies that align with Essential Health Benefit requirements while still requiring manufacturers to participate in the Medicaid Rebate Program. Depending on utilization of the HAO by states, it could impact the industry – especially if states elect to use a formulary. ~~34We~~ **We** are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital. In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15. 1 % to 23. 1 %; it required collection of rebates for drugs paid by Medicaid managed care organizations; it imposed a non- deductible annual fee on pharmaceutical manufacturers or importers who sell certain " branded prescription drugs " to specified federal government programs; it implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; it expanded the eligibility criteria for Medicaid programs; it created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and it established a Center for Medicare and Medicaid Innovation (" CMMI ") at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a process that is commonly referred to as the " individual mandate. " In addition, the Further Consolidated Appropriations Act, 2020 permanently eliminated, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax; and, effective January 1, 2021, it also eliminated the health insurance tax. On December 14, 2018, the U. S. District Court for the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U. S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District

Court to determine whether the remaining provisions of the ACA are invalid as well. On June 17, 2021, the U. S. Supreme Court reversed the ruling of the Fifth Circuit, holding that the challengers lacked standing to sue and otherwise abstaining from reaching the merits of the case. Notwithstanding the resolution of this legal challenge, there may be other efforts to challenge, repeal, or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future. President Joseph R. Biden, Jr. signed an Executive Order on Strengthening Medicaid and the Affordable Care Act, stating his administration' s intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are directed to review all existing regulations, orders, guidance documents, policies, and agency actions and to consider if they are consistent with ensuring coverage under the ACA making high- quality healthcare affordable and accessible to Americans. We are unable to predict the likelihood of changes to the ACA or other healthcare laws which may negatively impact our profitability. ~~President~~ **35President** Biden intends, as his predecessor did, to take action against drug prices which are considered " high. " Such measures could be addressed in a legislative package later in 2021 or with the reauthorization of the Prescription Drug User Fee Act (" PDUFA ") in 2022. Drug pricing continues to be a subject of debate at the executive and legislative levels of U. S. government and we expect to see legislation focusing on this in the coming year. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 with the exception of a temporary suspension implemented under various COVID- 19 relief legislation from May 1, 2020 through December 31, 2021 ~~, unless additional congressional action is taken~~. Moreover, there has recently been ~~35heightened~~ -- **heightened** governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient assistance programs, and to reform government program reimbursement methodologies for pharmaceutical products. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out- of- pocket expenses for Medicare Part D beneficiaries, and several changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act, proposes to enable direct price negotiations by the federal government for certain drugs (with the maximum price paid by Medicare capped based on an international index), requires manufacturers to offer these negotiated prices to other payers, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in 2019, and it has been introduced again in the 2021 term. We cannot predict whether any proposed legislation will become law and the effect of these possible changes on our business cannot be predicted at this time. 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 (" 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 (" 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~~ **36health** 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 (“ 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 ~~36payors~~ -- **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. Risks Related to Intellectual Property and Potential Disputes with Licensors ThereofIf we are unable to obtain and maintain sufficient patent protection for our technology and products, 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 our patent applications may change or be modified throughout the patent prosecution process, 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~~ **37in** 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, defense and enforcement of patents licensed or developed under such collaborations. Therefore, these patents and applications may not be prosecuted, defended, 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 patent laws of foreign countries may not protect our patent 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 patent 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 ~~37were~~ -- **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 USPTO 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 the 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. Moreover, the patents or patent applications owned or filed by us, or by our licensors or other collaborators, may be subject to a third- party pre- issuance submission of prior art to the USPTO, or to opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of our licensors or collaborators. 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. 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~~ **38candidates** , 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 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. ~~38We~~ **We** depend on our licensors to maintain and enforce the intellectual property covering certain of our product candidates. We have limited, if any, control over the resources that our licensors can or will devote to securing, maintaining, and enforcing patents protecting 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. Protecting our proprietary rights is difficult and costly, and we may be unable 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; **39** ● 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. ~~39We~~ **We** may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, and an unfavorable outcome in any litigation would harm our business. 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 patents or that we infringe their patents; or provoke those parties to petition the USPTO to institute inter partes review against the asserted patents, which may lead to a finding that all or some of the claims of the asserted patents 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 U. S. patents may affect related patents in our global portfolio. 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. 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. 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; **40** ● 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. ~~40If~~ **If** we fail to comply with our obligations under our intellectual property licenses and third- party funding arrangements, we could lose rights that are important to our business. We have in- licensed the rights to all of our product candidates from third parties. Any disputes between us and any of our licensors regarding our rights under our license agreements may impact our ability to develop and commercialize these product candidates. 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 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 Relating to Our Platform and DataOur business and operations would suffer in the event of computer system failures, cyber- attacks, or deficiencies in our or third parties' cybersecurity. We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our ~~intellectual~~ **41intellectual** property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk. ~~41Although~~ -- **Although** we have implemented internal security and business continuity measures and have developed an information technology infrastructure, our internal computer systems, as well as those of current and future third parties on which we rely, are vulnerable to damage from computer viruses and unauthorized access ~~,~~ and may fail. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, data center facilities, lab equipment, and internet connection, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets. In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and could significantly increase our costs to recover or reproduce the data. Likewise, we will rely on third parties for the manufacture of our current or future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may be unable to anticipate all types of security threats and to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal

and financial exposure and reputational damage that could adversely affect our business. Notifications and follow- up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. Our efforts to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, including those connected with any actual, potential, or anticipated attack, may cause us to incur significant cost, including those connected with the engagement of additional personnel (including third- party experts and consultants), employment protection technologies, and employee training. The costs related to significant security breaches or disruptions could be material and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may ~~have~~ **42have** to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. The occurrence of such a cybersecurity breach could result in interruptions in our operations, material disruption of our development programs or our business operations, and may cause us financial, legal, business, or reputational harm. ~~42Risks --~~ **Risks** Relating to Our Control by Fortress Biotech Inc. 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, which became effective as of March 17, 2015 and was amended and restated on July 11, 2016 **(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 January 1 of each year. This annual issuance of shares to Fortress will dilute your holdings in our common stock and, if the value of Checkpoint has not grown over the prior year, would result in a reduction in the value of your shares. We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress. The agreements we entered into with Fortress in connection with the separation include a Management Services Agreement and the Founders Agreement. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm' s- length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales and the provision of employment and transition services. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business. Risks Related to Conflicts of InterestThe Chairman of our Board of Directors is also the Executive Chairman, President and Chief Executive Officer of TGTX, with whom we ~~have~~ **previously had** a collaboration agreement and a sublicense agreement. As a result, during the ~~term~~ **terms** of these agreements, certain conflicts of interest ~~may~~ **could have** ~~arise~~ **arisen** which ~~will~~ **would have** ~~require~~ **required** the attention of our officers and independent directors who are unaffiliated with TGTX. In connection with our license agreement with Dana- Farber and Adimab, we entered into a collaboration agreement with TGTX to develop and commercialize the anti- PD- L1 and anti- GITR antibody research programs, including cosibelimab 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~~ **Michael S. Weiss** , **our Chairman** ~~as the sublicense agreement proceeds, certain conflicts~~ of ~~interest may arise between us~~ **the Board of Directors, is also the Executive Chairman, President** and **Chief Executive Officer of** TGTX. **Effective September 30, 2023, the Company** ~~Those conflicts will have to be resolved by our officers~~ and ~~directors who are unaffiliated with~~ TGTX **agreed** ~~, and also by officers and directors of TGTX who are unaffiliated with us. This may lead~~ to **mutually terminate these collaborations** ~~less than desirable complications and costs to both companies, which could harm our results of operations~~ . 43The 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. General RisksMajor public health issues, and specifically the pandemic caused by the spread of COVID- 19, could have an adverse impact on our financial condition and results of operations and other aspects of our business. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID- 19 outbreak had evolved into a pandemic. ~~In response to the pandemic, many governments around the world implemented a variety of measures to reduce the spread of COVID- 19.~~ The COVID- 19 pandemic negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. Although COVID- 19 has not had a material adverse effect on our business to date, ~~no assurance can be given that it will not in the future~~ if the ~~situation persists or worsens. Should the~~ coronavirus ~~continue~~ **were** to ~~spread~~ **worsen** , our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, or if new variants emerge, some participants and clinical investigators may not be able to comply with clinical trial protocols. We currently rely on third parties, such as contract laboratories, contract research organizations, medical institutions and clinical investigators to conduct these studies and clinical trials. If these third parties themselves are adversely impacted by restrictions resulting from the coronavirus outbreak, we will likely experience delays and / or realize additional costs. We also rely on third parties for the manufacture of our product candidates for preclinical and clinical testing. Disruptions to the global supply chain could impact our or our third- party manufacturers' ability to obtain raw materials or other products necessary to manufacture and distribute our product candidates. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or disrupted. 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 and / 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 or third- party contractors 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 or third- party contractors 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 ~~44industry~~ -- **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 or third- party contractors 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~~ **44harm** 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 and / or other civil and / or criminal sanctions. 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. 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;** 45