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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2024

or

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

For the Transition Period from to .

Commission File Number 001-38128

CHECKPOINT THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-2568632**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
95 Sawyer Road, Suite 110 **Waltham, Massachusetts 02453** (Address of Principal Executive Offices)	**02453** (Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per	**CKPT**	**NASDAQ Capital Market**

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

As of June 30, 2024, the last business day of the registrant's mostly recently completed second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the registrant was $69,336,565 based upon the closing sale price of our common stock of $2.15 on that date. Common stock held by each officer and director and by each person known to own in excess of 5% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

Class of Common Stock	Outstanding Shares as of March 25, 2025
Class A Common Stock, $0.0001 par value	700,000
Common Stock, $0.0001 par value	83,063,733

DOCUMENTS INCORPORATED BY REFERENCE

None.

CHECKPOINT THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the clinical and preclinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product or product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations as to the timing of commencing or completing preclinical and clinical trials and the expected outcomes of those trials, including global health crises' or other crises' potentials to negatively affect the hospitals and clinical sites in which we may conduct any of our clinical trials, and patients' willingness to access those sites to continue the trials;
- intention to use data from our ongoing and planned clinical trials of our products and product candidates to support the submissions of one or more U.S. Biologics License Applications ("BLAs") and relatedly, our assumption that exclusively foreign clinical data may be acceptable to support marketing approval under U.S. Food and Drug Administration ("FDA") regulations;
- expectations regarding our commercialization of UNLOXCYT (TM) or any future products or product candidates, including the anticipated rate and degree of market acceptance and pricing and reimbursement;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- approval and closing of the Merger (as defined below), including the timing of the Merger;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build a commercial infrastructure to manufacture, market and sell our product or product candidates;
- expectations for the acceptance of our product by doctors, patients or payors;
- ability to compete against other companies and research institutions;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- ability to obtain reimbursement for our product;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- stock price and the volatility of the equity markets;
- expected losses; and
- expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions as of the effective date of this report, and are not predictions of actual performance. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us. We caution that a number of important factors, including those described in this document, could cause actual results to differ materially from those contemplated in any forward-looking statements. The reader is cautioned not to rely on any forward-looking statements made by us. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Unless required by law, we are under no duty and undertake no obligation to update or revise any forward-looking statement after the distribution of this communication, whether as a result of new information, future events or otherwise.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC").

Risks Related to Drug Development, and the Commercialization of our FDA Approved Product UNLOXCYT™

- Because results of preclinical studies and clinical trials are not necessarily predictive of future results, any product or 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.
- Besides UNLOXCYT, 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 UNLOXCYT, a product or product candidate demonstrates lack of efficacy or adverse side effects, we may need to abandon or limit the development or commercialization of such product candidate.
- We may not obtain the desired labeling claims or intended uses for product or UNLOXCYT promotion, or favorable scheduling classifications, to successfully promote our products or UNLOXCYT.
- Even if a product candidate is approved, such as UNLOXCYT, it may be subject to various post-marketing requirements, including studies or clinical trials, and increased regulatory scrutiny.
- Approval of UNLOXCYT or one of our product candidates in the United States does not assure approval of UNLOXCYT in foreign jurisdictions.
- Our competitors have developed or may develop treatments for UNLOXCYT's or our products' target indications, which could limit UNLOXCYT's or our product candidates' commercial opportunity and profitability.
- If UNLOXCYT or 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 UNLOXCYT or 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 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 UNLOXCYT.
- 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, UNLOXCYT 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 Related to the Merger, our Business Strategy, Structure and Organization

- Our future growth and success depend on our ability to successfully develop and commercialize our product candidates and UNLOXCYT, either ourselves, or through a distributor or partner.
- There is no assurance that the proposed Merger among us, Sun Pharmaceutical Industries, Inc. and Snoopy Merger Sub, Inc. will be completed in a timely manner or at all. The pendency and/or completion of the Merger could have an adverse effect on the trading price of our common stock and our business, financial condition, and prospects.
- Our future growth depends on our acquiring or in-licensing products or product candidates and integrating such products into our business.

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 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, UNLOXCYT, or 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 Related 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 Related to Intellectual Property and Potential Disputes with Licensors Thereof

- If we are unable to obtain or 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, market and sell UNLOXCYT or 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 UNLOXCYT or our product candidates.

Risks Related 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 Related 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

- We share certain directors with Fortress, which could create conflicts of interest between us and Fortress.

PART I

Item 1. Business

OVERVIEW

We are a commercial-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. On December 13, 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted approval of cosibelimab-ipdl, now referred to as UNLOXCYT™, for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("CSCC") or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The approval was granted for this indication based upon data from an ongoing multi-regional, 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 CSCC.

To date, we have not generated any product sales from our approved product or investigational product candidates in our research pipeline. 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, 2024, we have an accumulated deficit of $370.6 million.

On March 9, 2025, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sun Pharmaceutical Industries, Inc., a Delaware corporation ("Sun Pharma" or "Parent"), and Snoopy Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"). The Merger Agreement provides that, on the terms and subject to the conditions set forth in the Merger Agreement, Parent, Merger Sub and us will effect a merger of Merger Sub with and into us (the "Merger"), with us continuing as the surviving corporation of the Merger and a wholly owned subsidiary of Parent. The Merger Agreement contains customary representations, warranties and covenants made by each of Parent, us and Merger Sub, including, among others, customary covenants regarding the operation of our business prior to the effective time of the Merger. For a more detailed description of the Merger Agreement, see Note 11 to our financial statements.

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

CORPORATE INFORMATION

Checkpoint Therapeutics, Inc. (the "Company") 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 maintain a corporate website with the address www.checkpointtx.com and also maintain a website related to UNLOXCYT with the address www.unloxcyt.com. We also maintain a social media account on LinkedIn. 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 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.

OUR PRODUCTS AND PRODUCT CANDIDATES

Immuno-Oncology Agents

UNLOXCYT (cosibelimab-ipdl) Overview

UNLOXCYT is the first and only programmed death-ligand 1 ("PD-L1") blocking antibody to receive FDA marketing approval for the treatment of adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

UNLOXCYT 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. The 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, UNLOXCYT has been shown to induce antibody-dependent cellular cytotoxicity ("ADCC") in vitro.

We initially developed cosibelimab-ipdl 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 Cancer Institute ("Dana-Farber") in March 2015. Also in March 2015, we entered into a Global Collaboration Agreement with TG Therapeutics, Inc. ("TGTX"), a related party, to develop and commercialize anti-PD-L1 antibodies in the field of hematological malignancies. We retain the right to develop and commercialize our anti-PD-L1 antibodies in solid tumors. Effective September 30, 2023, 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 to evaluate the safety and tolerability of ascending doses 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 cohorts in locally advanced and metastatic CSCC. The primary endpoint is objective response rate ("ORR"), and secondary endpoints include duration of response, progression-free survival ("PFS"), and overall survival. 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 Response Evaluation Criteria in Solid Tumors version 1.1 ("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 in which 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. 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 on these results, we submitted a Biologics License Application ("BLA") to the FDA in January 2023. On December 15, 2023, the FDA issued a complete response letter ("CRL") citing only findings that arose during a multi-sponsor inspection of our third-party contract manufacturing organization as approvability issues to address in a resubmission. In July 2024, we announced that we had completed a resubmission of the BLA to the FDA to potentially address the approvability issues cited in the CRL. In December 2024, we announced that the FDA granted approval for UNLOXCYT (cosibelimab-ipdl) for the treatment of adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The recommended commercial dosage of UNLOXCYT is 1,200 mg administered as an intravenous infusion over 60 minutes every three weeks. In January 2025, we submitted a labeling supplement to the FDA to update the UNLOXCYT label to reflect the longer-term data announced in July 2023.

We have entered into a Merger Agreement to enable the launch of UNLOXCYT in the United States and to submit a marketing authorization application ("MAA") submission in Europe, as well as additional potential submissions in markets worldwide.

CK-302 (Anti-GITR) Overview

Our 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, TGTX agreed to mutually terminate these collaborations, with full rights reverting back to us.

Currently, we are in preclinical development for this program.

Targeted Anti-Cancer Agents

Olafertinib (also known as CK-101 and RX518) EGFR Inhibitor Overview

We are developing olafertinib as an oral, third-generation, irreversible kinase inhibitor against selective mutations of epidermal growth factor receptor ("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 non-small cell lung cancer ("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 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.

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. This study was terminated prior to completion due to lack of enrollment.

CK-103 BET Inhibitor Overview

We 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 retained the right to develop and commercialize CK-103 in solid tumors. Effective September 30, 2023, TGTX agreed to mutually terminate the Sublicense Agreement, with full rights reverting back to us. Currently, we have completed the required CMC, pharmacology and toxicology activities that we believe will support an IND application filing.

CK – 303 Anti-CAIX Research Overview

Our 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.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

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

Product Candidate	Target Indication(s)	Development Status	Estimated Completion of Phase	Estimated Cost to Complete Phase
Cosibelimab-ipdl	Locally advanced and metastatic cutaneous squamous cell carcinoma	Phase 1 registration-enabling	2025	$2 to $3 million

Completion 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 PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, 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 proprietary know-how that 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, 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 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 licensed under the original agreement and later amendments includes issued patents and pending patent applications in the U.S. and a number of other countries. 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. The PD-L1 segment also includes 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 that have issued, as well as registration of the two Chinese patents in Hong Kong (HK 1211223 and HK 1253723). 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.

In June 2016, we 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 treating cancer and/or 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 now includes two issued U.S. patents, U.S. Patent No. 10,590,199 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. U.S. Patent No. 11,834,505 has claims directed to treating cancer with anti-PD-L1 antibodies, including cosibelimab. Both of these patents (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. 18/377,702, is currently pending. International counterpart patents have also granted in India (IN 547170), Israel (IL 263611), Japan (JP 7148414 and JP 7520072), South Korea (KR 10-2422411), Mexico (MX 412483), Russia (RU 2749109), Thailand (TH 1801007897), and Singapore (SG 11201810927Q), and additional applications are pending in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, New Zealand, and Singapore. Any patents maturing from these pending applications will expire no sooner than June 2037.

The 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 February 5, 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 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 Australian patent (AU 2017300788), two Chinese patents (CN 109689689 and CN 40008679), one Japanese patent (JP 7082967), one New Zealand patent (NZ 750097), one South Korean patent (KR 2534568), and one patent in Singapore (SG 11201900500T). This family also includes pending patent applications in Australia, Brazil, Canada, Europe, Israel, , 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.

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 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, three granted Australian patents, a granted New Zealand patent, two granted Israeli patents, a granted Mexican patent, 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 genus 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 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. 18/519,150). 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, Hong Kong, the Philippines, Singapore, South Korea, Malaysia, China, and Europe. Any patents maturing from these pending applications would be scheduled to expire no sooner than August 2034. We have 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 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, two granted Indian patents, two granted Japanese patents, two granted Australian patents, one granted New Zealand patent, 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 Canada, South Korea, 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 genus 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 genus 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 as well as pharmaceutical composition claims and a method of treating cancer. Any patents maturing from this patent estate are expected to expire in 2036.

Other Intellectual Property Rights

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

In addition to patent protection, we may utilize orphan drug 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 AGREEMENTS AND COLLABORATIONS

Dana-Farber Cancer Institute, Inc.

In March 2015, we entered into a license agreement with Dana-Farber, which license was amended effective on October 5, 2015, April 12, 2016, and October 24, 2016, 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 and first commercial sale milestones. As of December 31, 2024, $5.0 million of clinical development 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 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 retained the right to develop and commercialize these antibodies in solid tumors. Michael Weiss, Chairman of our Board of Directors 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 also received an annual license maintenance fee, which was creditable against milestone payments or royalties due to us. TGTX also paid us for our out-of-pocket costs of material

used by TGTX for their development activities and for 50% of patent expenses. For the years ended December 31, 2024 and 2023, we recognized approximately $41,000 and $58,000 respectively, in revenue from our collaboration agreement with TGTX in the Statements of Operations.

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized UNLOXCYT, 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 $2.5 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 UNLOXCYT in metastatic or locally advanced CSCC. To date, we have incurred $6.0 million in milestone payments under our collaboration agreement with Adimab, including $3.7 million in clinical development milestone payments and $2.3 million in regulatory milestone payments.

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 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 clinical development milestone payments under the license agreement.

Jubilant Biosys Limited

In 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 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 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 pre – clinical development milestone payments under the license agreement.

In connection with the license agreement with Jubilant, we entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while we 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, with full rights reverting back to us. Under the terms of the sublicense agreement, TGTX paid us $1.0 million in 2016, representing an upfront licensing fee. TGTX also paid us for 50% of IND enabling costs and patent expenses. For the year ended December 31, 2023, we recognized $46,000 in revenue related to the sublicense agreement in the Statements of Operations.

COMPETITION

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

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. Other companies have products or product candidates in various stages of 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®), GlaxoSmithKline (approved PD-1 with the brand name Jemperli®) and Coherus (approved PD-1 with the brand name Loqtorzi®). Keytruda and Libtayo are both approved in metastatic and locally advanced CSCC in the United States. 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., 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. Janssen's Lazcluze® is also approved in combination with Rybrevant® for the treatment of first-line EGFR mutation-positive NSCLC in the United States. 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.

In the BET inhibitor space, there are a number of companies which have advanced to early stage clinical trials, including Novartis's pelabresib, Bristol-Myers Squibb's trotabresib, 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.

EMPLOYEES

As of December 31, 2024, we had twenty-four full and part-time employees. None of our employees are represented by a labor union and we consider our employee relations to be good.

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities. We have established, or intend to establish, contract manufacturing relationships for the supplies of our product and 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.

To the extent possible and commercially practicable, we plan to seek to engage a back-up supplier for our product and each of our product candidates. Given the long lead times and cost of establishing additional manufacturing sites 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 and product candidates can be produced and will have limited experience in manufacturing our product and 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 REGULATIONS

Governmental authorities, including the FDA and corresponding state and foreign regulatory agencies, regulate the clinical development, manufacture, approval and marketing of our product and product candidates, as well as our ongoing research and development activities. Before marketing in the U.S., any drug that we develop must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive 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 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.

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;

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

Other Healthcare Laws and Compliance Requirements

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

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment in research and product development. 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 Regulation

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

Item 1A. Risk Factors

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

Risks Related in Drug Development, and the Commercialization of our FDA Approved Drug UNLOXCYT (cosibelimab-ipdl)

Because 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 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 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, market and sell 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 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 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.

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

UNLOXCYT, our pipeline 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. Besides UNLOXCYT, 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. UNLOXCYT, or 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, such as with UNLOXCYT, may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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, such as with UNLOXCYT, 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 UNLOXCYT, or one or more of our product candidates or any future product candidate.

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

If one or more of our product candidates or any future product candidate are associated with undesirable side effects 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 UNLOXCYT, 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.

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 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 UNLOXCYT or 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 UNLOXCYT or our product candidates may be otherwise adversely impacted.

Even if one or more of our product candidates receives regulatory approval, such as UNLOXCYT, it and any other products we may market will remain subject to substantial regulatory scrutiny. If we are unable to maintain current approvals of UNLOXCYT, our business will be materially harmed.

We currently have one product, UNLOXCYT, that received regulatory approval from the FDA on December 13, 2024. We are in the process of developing a commercial launch plan for UNLOXCYT. This product, our product candidates, and any future product that we may license or acquire, if approved, 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 UNLOXCYT or 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 UNLOXCYT, 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 or UNLOXCYT;
- restrictions on UNLOXCYT or other 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 UNLOXCYT or other products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;

- recall of UNLOXCYT or other products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of UNLOXCYT or our products;
- Seizure of UNLOXCYT or other products; 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 UNLOXCYT and those products for which we 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.

Approval of UNLOXCYT or any of our product candidates in the United States does not assure approval of UNLOXCYT in foreign jurisdictions.

We intend to seek additional product approvals in certain countries outside of the United States. The approval procedures for pharmaceuticals vary among countries and obtaining approval in one jurisdiction does not guarantee approval in another jurisdiction. Even though the FDA has granted approval of UNLOXCYT, comparable regulatory authorities in foreign jurisdictions may not approve UNLOXCYT, or the same indications for use for UNLOXCYT, or may require additional evidence for approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In many countries outside the United States, the product must be approved for reimbursement before it can be marketed. Therefore, we cannot guarantee that we, or future collaborators, will obtain approvals of our product and product candidates in any foreign jurisdiction on a timely basis, if at all. Failure to receive approval in certain foreign markets could impact the total consideration of the Merger, if consummated, due to the contingent value right, which represents the right for stockholders after closing of the Merger to receive a contingent cash payment of up to $0.70 per share upon achievement of a specified milestone related to obtaining regulatory approval in certain foreign jurisdictions within specified time periods. Furthermore, failure to receive approval in certain foreign markets could also significantly impact the full market potential of our product and product candidates and may negatively impact the regulatory process in other countries. If we obtain regulatory approval for a product or product candidate in a foreign jurisdiction, we will be subject to the burden of complying with complex regulatory, legal, and other requirements that could be costly and could subject us to additional risks and uncertainties.

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 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 UNLOXCYT or other 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 UNLOXCYT or another 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, like with UNLOXCYT, 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 UNLOXCYT, our product candidates, 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 UNLOXCYT and our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT or 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, 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 UNLOXCYT or 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 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 UNLOXCYT and our product candidates, if approved, 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 UNLOXCYT or our product candidates translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

If UNLOXCYT, which received FDA approval in December 2024, or 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 UNLOXCYT or any such product candidates generate from sales will be limited.

Our product UNLOXCYT, and our product candidates that receive regulatory approval, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our UNLOXCYT or product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of UNLOXCYT or any other 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 UNLOXCYT and such product candidates as well as competitive products;
- the clinical indications for which UNLOXCYT or the drug is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of UNLOXCYT or the product as a safe and effective treatment;
- the potential and perceived advantages of UNLOXCYT or product candidates over alternative treatments;
- the safety of UNLOXCYT or 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 UNLOXCYT and 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 UNLOXCYT or the product.

If UNLOXCYT, and any product candidate that is approved, do 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 UNLOXCYT and product candidates, which could make it difficult for us to sell UNLOXCYT and 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 UNLOXCYT and product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for UNLOXCYT and 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 UNLOXCYT or product candidates. These payors may conclude that UNLOXCYT or product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve UNLOXCYT or product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for UNLOXCYT or the product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of UNLOXCYT or 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 UNLOXCYT and 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 UNLOXCYT or our product candidates to other available therapies. If reimbursement of UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT and product candidates, we may be unsuccessful in commercializing UNLOXCYT and 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 UNLOXCYT or 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. 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 UNLOXCYT and 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 UNLOXCYT or 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.

In addition, we have entered into a Merger Agreement, along with additional agreements related to the Merger Agreement, to facilitate the commercialization and launch of UNLOXCYT in the U.S. and to submit a marketing authorization application submission in Europe and potentially other markets worldwide. To the extent we do expand into other markets outside of the U.S. in which we are responsible for building and maintaining a commercial infrastructure, we expect to incur significant expenses in establishing an infrastructure to commercialize our drug products. Depending on the expenses incurred, it could have a negative impact on our cash resources. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for UNLOXCYTor 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 UNLOXCYT or any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if UNLOXCYT or 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

UNLOXCYT or 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 UNLOXCYT or any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize UNLOXCYT, product candidates 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. Since we obtained marketing approval for UNLOXCYT, 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 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 may never achieve or maintain profitability.

We have a limited operating history, 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 $370.6 million as of December 31, 2024. 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 or are approved for commercial sale, as is the case with UNLOXCYT, due to our need to establish the necessary commercial infrastructure to launch this product 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 UNLOXCYT or our product candidates, or if there are any delays in completing our clinical trials or the development of UNLOXCYT or 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
- the success of commercialization of UNLOXCYT and any other of our product candidates that receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. Currently, other than UNLOXCYT, our products are investigational and have not been approved by the FDA or any foreign regulatory authority for sale. To date, we have not generated any revenue from the sale of UNLOXCYT or our development stage products, and we do not know when, or if, we will generate any revenue. To obtain revenues from sales of UNLOXCYT or 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 our product candidates, or any future product candidate that we may license or acquire;
- manufacture commercial quantities of UNLOXCYT and 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 UNLOXCYT and 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.

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 and UNLOXCYT, 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 pre-clinical 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, such as with UNLOXCYT, including building a commercial organization to address certain markets. We will require additional capital for the further development, and commercialization of UNLOXCYT or our product candidates, as well as to fund our other operating expenses and capital expenditures. We believe that our cash and cash equivalents are only sufficient to fund our operating expenses into the fourth quarter of 2025.

Failure to complete the Merger may result in us having to raise additional capital to fund our operations and commercialize UNLOXCYT. 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 commercialization of UNLOXCYT and the development or, if approved, commercialization of one or more of our product candidates. We may also seek collaborators for UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT or 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;

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

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, 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 UNLOXCYT or 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 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, 2024, have been prepared under the assumption that we will continue as a going concern for the next twelve months. 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 stockholders 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.

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, UNLOXCYT 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 UNLOXCYT or our product candidates that we would otherwise prefer to develop and market ourselves.

We are a "smaller reporting company," which means that the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

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. 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 may expend our limited resources to pursue certain product candidates or indications and fail to capitalize on UNLOXCYT, 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 UNLOXCYT, other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately and/or effectively evaluate the commercial potential or target market for UNLOXCYT or 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, 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 the Merger, our Business Strategy, Structure, and Organization

There is no assurance that the proposed Merger among us, Sun Pharma and Merger Sub will be completed in a timely manner or at all. Failure to complete the Merger may result in us paying a termination fee to Sun Pharma and could harm our common stock price and future business and operations.

The consummation of the Merger among us, Sun Pharma and Merger Sub is subject to a number of closing conditions, including approval by the holders of a majority of the voting power of outstanding shares of our common stock, and by the holders of a majority of the shares of our common stock that are not held by Fortress or by certain other of our affiliates and other customary closing conditions. The parties are targeting a closing of the transaction in the second quarter of 2025, however, there can be no assurance that the Merger will be consummated within this desired timeframe, or at all. If the Merger among us, Sun Pharma and Merger Sub is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected. In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that we will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger or any partner at all.

If the conditions to the closing of the Merger are not met, the Merger may not occur.

Even if the Merger and other stockholder matters are approved by our stockholders, specified conditions set forth in the Merger Agreement must be satisfied or waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

The pendency of the Merger could have an adverse effect on the trading price of our common stock and our business, financial condition, and prospects.

While there have been no significant adverse effects to date, the pendency of the Merger could disrupt our business in many ways, including:

- our ability to retain and hire key personnel and our ability to maintain relationships with our customers, distributors, suppliers or third parties or our operating results and business generally may be impeded;
- the attention of our management and employees may be directed toward the completion of the Merger and related matters and may be diverted from our day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise.

Should they occur, any of these matters could adversely affect the trading price of our common stock or harm our business, financial condition, and prospects.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

While the Merger Agreement with Sun Pharma is in effect, we are subject to customary restrictions on our business activities, generally requiring us to conduct our business in the ordinary course, consistent with past practice, and subjecting us to a variety of specified limitations absent Sun Pharma's prior consent. These limitations include, among other things, restrictions on our ability to make any capital expenditures exceeding certain dollar thresholds, incur indebtedness exceeding certain dollar thresholds, commence, settle or release any legal proceedings (subject to certain exceptions), commence preclinical or clinical development, study, trial or test with respect to any new products or product candidates (subject to certain exceptions), sell, assign, transfer, lease, license, encumber, abandon, offer to surrender or surrender any of the Company's material intellectual property (subject to certain exceptions), repurchase or issue securities (subject to certain exceptions), pay dividends or amend our organizational documents. These restrictions could prevent us from pursuing strategic business opportunities, taking actions with respect to our business that we may consider advantageous and responding effectively and/or timely to competitive pressures and industry developments, and may as a result materially and adversely affect our business, results of operations and financial condition.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending merger with Sun Pharma.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the pending Merger. We must pay substantially all of these costs and expenses whether or not the Merger is completed.

There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

Litigation relating to the Merger could require us to incur significant costs and suffer management distraction, and could delay or enjoin the Merger.

We could be subject to demands or litigation related to the Merger, whether or not the Merger is consummated. Such demands or litigation may create uncertainty relating to the Merger, or delay or enjoin the Merger, and responding to such demands or litigation could divert management time and resources. In addition, such demands or litigation could potentially lead to our dissolution or bankruptcy if the costs associated with such demands or litigation are significant enough.

The Merger Agreement contains provisions that could discourage a potential competing acquirer.

We are subject to certain restrictions on our ability to solicit alternative acquisition proposals from third parties, to provide information to third parties, to enter into or continue discussions with third parties regarding alternative acquisition proposals, enter into any commitment with respect to any alternative acquisition proposal, to recommend or approve any alternative acquisition proposal or for our board of directors to change their recommendation in favor of the Merger, subject to customary exceptions. In addition, we may be required to pay Sun Pharma a termination fee of $12.5 million in certain circumstances if the Merger Agreement is terminated following our receipt of an alternative acquisition proposal. These provisions could discourage a potential third-party acquirer that might have an interest in acquiring all or a significant portion of our business from considering or proposing the acquisition, even if it was prepared to pay consideration with a higher per share value than the value proposed to be received or realized in the Merger, or might otherwise result in a potential third-party acquirer proposing to pay a lower price to our shareholders than it might otherwise have proposed to pay because of the added expense of the termination fee that may become payable in certain circumstances.

We currently have no drug products for sale on the market and are dependent on the future success of UNLOXCYT and our product candidates. We can give no assurances that any of our product candidates will receive regulatory approval or that UNLOXCYT will be successfully commercialized, marketed or sold.

We currently have one product, UNLOXCYT, which received approval from the FDA on December 13, 2024, for the treatment of adults in metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or radiation.

To date, we have invested a significant portion of our efforts and financial resources in UNLOXCYT and the acquisition and development of our product candidates. We have not yet built the commercial infrastructure necessary to launch UNLOXCYT and have limited experience as a commercial company. Therefore, our ability to successfully overcome many of the risks associated with commercializing drugs in the biopharmaceutical industry, including the risk that our products do not achieve an adequate level of acceptance, remains uncertain. As a result, we may not generate significant revenues or meet our revenue projections or guidance and may not become profitable. Our business depends entirely on UNLOXCYT and the successful development and commercialization of our product candidates, which may never occur. We currently have no drug products for sale, currently generate no revenues from sales of UNLOXCYT or any drug products and may never be able to develop or successfully commercialize a marketable drug.

The successful development, and any commercialization of UNLOXCYT, 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 UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT or our product candidates through our own marketing and sales activities, and any other arrangements to promote UNLOXCYT or our product candidates that we may establish;
- maintaining patent protection and regulatory exclusivity for UNLOXCYT or our product candidates; and
- obtaining market acceptance for UNLOXCYT or our product candidates.

Each of these requirements will require substantial time, effort and financial resources.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technologies and obtaining preclinical data or clinical data for UNLOXCYT and various product candidates. These operations provide a limited basis for you to assess our ability to continue to identify product candidates, develop and commercialize UNLOXCYT and 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.

Our 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.

Risks Related to Reliance on Third Parties

We have contracted with third parties for the manufacture of UNLOXCYT and our product candidates. If such contract manufacturer fails to timely produce sufficient product volume, to pass regulatory inspections, or to comply with applicable regulations, the commercialization of UNLOXCYT and 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 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 UNLOXCYT and 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 and 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 UNLOXCYT or one or more of our product candidates, and any future product or 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 UNLOXCYT and 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 parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities 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, market and sell 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 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 commercialization of UNLOXCYT or our other approved products, if any. Reliance on third parties increases the risk that we will not have sufficient quantities of UNLOXCYT or 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 for commercial manufacture of UNLOXCYT and 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 UNLOXCYT, 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 UNLOXCYT or 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;
- 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 UNLOXCYT or our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our preclinical and clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture UNLOXCYT and 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 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 UNLOXCYT or 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 UNLOXCYT or a product candidate, the commercial launch of UNLOXCYT or 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 UNLOXCYT or our product candidates.

Our current long-term supply agreement for UNLOXCYT contains certain minimum purchases. To the extent our demand does not meet the minimum supply required amounts, we could be forced to spend more than required, which could impact our on-going operations and entail curtailing other important research and development or commercialization efforts, all of which could have a material adverse effect on us. In negotiating our supply agreement for UNLOXCYT, there is no guarantee that we have foreseen all eventualities or that our third-party manufacturer will be able to accommodate unforeseen changes in business direction in a timely fashion or at all. Scheduling of manufacturing at our third-party manufacturer is governed by contractual terms that require us to make investments in inventory of materials, with limited shelf-life, based on preliminary commercial forecasting, and such inventory may not be used if timelines and supply needs shift.

The facilities used by our third-party manufacturers to manufacture UNLOXCYT and 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 UNLOXCYT and 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.

One or more of the product candidates that we may develop may compete with UNLOXCYT or 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. Drug Enforcement Agency 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 UNLOXCYT or one or more of our product candidates.

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

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of UNLOXCYT or 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 UNLOXCYT or 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 UNLOXCYT or our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about UNLOXCYT and our product candidates and our research and development efforts could be compromised.

Risks Related to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

We 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.

Of note, the Biden Administration issued a proposed rule on November 27, 2024 entitled, *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly*. CMS proposed, anti-obesity medications (AOMs)—when used for weight loss or chronic weight management for the treatment of obesity—would no longer be excluded from Part D coverage. The aforementioned proposal would also apply to the Medicaid program. It is possible that the Trump Administration does not finalize the proposal or finalizes the proposal with modification. However, if finalized, this could have a significant financial impact on Part D coverage and Medicaid drug coverage.

Further, on January 17, 2025, the Biden Administration announced the selection of 15 additional drugs covered under Medicare Part D for price negotiations, as required by the Inflation Reduction Act. It is important to note that weight loss drugs, including Ozempic, Rybelsus, and Wegovy, have been chosen for drug price negotiation. While negotiations are still in progress, the Trump Administration has stated that lowering the cost of prescription drugs for Americans is a top priority and it will continue to pursue drug price negotiations. There will have a significant impact on reimbursement for these particular Part D drugs. In addition, the Trump Administration may take additional actions or diverge from the Biden Administration's approaches. We cannot predict how this might change or how any changes might impact our business.

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

In the United States and 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 Biden 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. However, on January 20, 2025, President Trump rescinded this Executive Order. While it is unlikely that the ACA will be repealed, it is possible that the Trump Administration takes steps to weaken the ACA or change how it operates. We are unable to predict the likelihood of changes to the ACA or other healthcare laws which may negatively impact our profitability.

President Trump intends, as his predecessor did, to take action against drug prices which are considered "high." Such measures could be addressed in a legislative package or through administrative actions. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government. 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. This combined with the implementation of the Inflation Reduction Act creates challenges for manufacturers at multiple levels. Further actions by the Trump Administration could present risks or opportunities for our business depending on the scope and nature of those policies.

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. Moreover, there has recently been 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.

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 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 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 Thereof

If we are unable to obtain and maintain sufficient patent protection for UNLOXCYT, our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize, market and sell UNLOXCYT, 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 UNLOXCYT, 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 UNLOXCYT or one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance, 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 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 UNLOXCYT or our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference or derivation 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. For example, the Leahy-Smith America Invents Act went into effect on March 16, 2013 and was a significant change in U.S. patent law.

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 UNLOXCYT, or current or future product candidates.

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

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

We 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 product. 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 UNLOXCYT or 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.

We depend on our licensors to maintain and enforce the intellectual property covering certain of our product and 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 and 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 UNLOXCYT, our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the scope of our issued patents may not extend to competitive products developed or produced by others;
- the issued patents covering UNLOXCYT, our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- intellectual property rights of others may have an adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, 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 UNLOXCYT, 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 UNLOXCYT or one or more of our product candidates may infringe. There could also be existing patents of which we are not aware that UNLOXCYT or 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 UNLOXCYT or our product infringes a competitor's patent;
- a court prohibiting us from selling or licensing UNLOXCYT or our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds, time, and may result in an inferior or less-desirable process or product.

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

Risks Related to Our 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.

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 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.

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 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.

Risks Related 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 us 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 the Company 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 Interest

The Chairman of our Board of Directors is also the Executive Chairman, President and Chief Executive Officer of TGTX, with whom we previously had a collaboration agreement and a sublicense agreement. As a result, during the terms of these agreements, certain conflicts of interest could have arisen which would have 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. 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. Michael S. Weiss, our Chairman of the Board of Directors, is also the Executive Chairman, President and Chief Executive Officer of TGTX.

Effective September 30, 2023, the Company and TGTX agreed to mutually terminate these collaborations.

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

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

General Risks

Major public health issues and global health crises could have an adverse impact on our financial condition and results of operations and other aspects of our business.

Major public health issues and global health crises may negatively impact the global economy, disrupt global supply chains, and create significant volatility and disruption of financial markets. A major health issue or global health crisis may cause our business operations to be delayed or interrupted. For instance, our clinical trials may be affected. 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 response efforts, or other reasons related to a major public health issue or global health crisis. If a major health issue develops or a global health crisis occurs, 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 a major public health issue or global health crisis, 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 and 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 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 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 and 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 or product candidates;
- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize our product and 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 or product candidates, if approved;
- the depth and liquidity of the market for our common stock;
- investor perceptions about us and our business;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole, which may be impacted by economic or other crises or external factors, including the effects of the COVID-19 pandemic on the global economy;
- price and volume fluctuations in the overall stock market;

- the failure of UNLOXCYT or one or more of our product candidates or any future product candidate, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of UNLOXCYT and our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

The market price and trading volume of our common stock has been highly volatile and is likely to continue to be highly volatile. In addition, the stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. See Part I, Item 3, Legal Proceedings.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have established certain processes for identifying, evaluating, and managing material risks from cybersecurity threats as a part of our overall technology management strategy. These processes are designed and reassessed on a periodic basis to help protect our technology assets and operations from internal and external security threats. We also engage with third parties, including consultants, to enhance our security processes.

We have previously engaged and currently engage third parties to assess the effectiveness of our cybersecurity and technology management strategy and continue to seek to implement new, and improve existing, processes regularly to adjust for changes in technology, internal or external threats, business strategy, and regulatory requirements. We, and our third parties, have deployed managed detection and response services to monitor our technology infrastructure and information systems for possible threats. Our technology management strategy also includes ongoing security training and education for employees regarding threats, including their role and responsibility in detecting and responding to such threats.

We review the processes of our third-party vendors and consider their ability to adhere to relevant industry practices and maintain adequate technology risk programs. In addition, we maintain cyber and cyber-related crime insurance coverage policies as part of our overall risk management strategy, however, our policies may not be sufficient to cover against all potential future claims, if any.

In the last two fiscal years, we have not identified cybersecurity threats that have materially affected, or are reasonably likely to materially affect, our business, results of operations, or financial condition. Although we proactively attempt to prevent all threats, we are unable to eliminate all risk from cybersecurity threats or provide assurance that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see Item 1A. Risk Factors "Our business and operations would suffer in the event of computer system failures".

Cybersecurity Governance

While our board of directors is responsible for oversight and risk management in general, our Audit Committee provides oversight of our technology management strategy to ensure that cybersecurity threats and risks are identified, evaluated, and managed. The Audit Committee receives periodic updates from our management team regarding the overall state of our technology management strategy and any relevant risks from cybersecurity threats and cybersecurity incidents.

Our management team is responsible for assessing and managing the material risks from cybersecurity threats. Our management team members have expertise in information systems, compliance and corporate governance, which we believe are disciplines that are effective in the management of the Company's cybersecurity risk. Our management team is informed of and monitors the prevention, detection, and mitigation of cybersecurity threats and incidents.

Item 2. Properties

Our corporate and executive office is located at 95 Sawyer Road, Suite 110, Waltham, MA, 02453. We are not currently under a lease agreement at 95 Sawyer Road. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

Item 3. Legal Proceedings

We and James Oliviero have been named as defendants in a consolidated putative stockholder class action lawsuit pending in the United States District Court for the Southern District of New York (the "Court"), which was filed on April 5, 2024. The action is styled In re Checkpoint Therapeutics, Inc. Securities Litigation, No. 1:24-cv-02613-PAE (the "Securities Class Action"). On June 21, 2024, the Court appointed a lead plaintiff for the putative class and approved his choice of lead counsel. The lead plaintiff filed his amended complaint (the "Amended Complaint") on August 23, 2024, which alleges that defendants violated the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions, and that James Oliviero is named as a control person under Section 20(a) of the Exchange Act. The Amended Complaint was filed on behalf of stockholders who purchased shares of our common stock between March 10, 2021 and December 15, 2023, and seeks, among other things, monetary damages on behalf of the purported class. Defendants moved to dismiss the Amended Complaint on October 23, 2024, and the motion was fully briefed in February 2025.

We have been named as a nominal defendant and certain of our current and former directors and executive officers have been named as defendants in derivative lawsuits pending in the United States District Court for the Southern District of New York. The actions are styled Geary v. Oliviero, et al., No. 1:24-cv-03471 (the "Geary Action") and Mehr v. Oliviero, et al., No. 1:25-cv-00331 (the "Mehr Action" and together with the Geary Action, the "Derivative Actions"). The Complaints in the Geary and Mehr Actions, which were filed on May 6, 2024 and January 13, 2025, respectively, assert claims against all defendants under Delaware law for, among other things, breach of fiduciary duty, claims against all defendants under Section 14(a) of the Exchange Act, and claims for contribution under the federal securities laws against certain of the defendants. On June 20, 2024 and March 17, 2025, the Geary and Mehr Actions, respectively, were stayed pending final resolution of the anticipated motion to dismiss in the Securities Class Action, including any appeals therefrom.

We intend to defend ourselves and our directors and executive officers vigorously.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market information

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol "CKPT."

Equity Compensation Plans

On March 21, 2017, November 9, 2017, November 27, 2020, December 9, 2022, November 17, 2023, and May 24, 2024 we filed registration statements on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our Amended and Restated 2015 Incentive Plan ("2015 Plan"). The registration statements became effective immediately upon filing, and shares covered by the registration statements are eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 limitations applicable to our affiliates.

Holders

As of March 25, 2025, there were approximately 63 holders of record for our common stock and 1 holder of record for our Class A common stock. The number of beneficial holders of our common stock does not reflect stockholders who hold shares in street name through brokerage accounts or other nominees.

Dividends

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

Securities Authorized for Issuance under Equity Compensation Plans

Subject to adjustment as provided in the 2015 Plan, the total aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 18,000,000. The following table provides information as of December 31, 2024, regarding the securities authorized for issuance under our equity compensation plan, the 2015 Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 1)
Equity compensation plans approved by security holders	127,000	$ 8.88	8,010,406
Equity compensation plans not approved by security holders	—	—	—
Total	127,000		8,010,406

Item 6. RESERVED

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

Forward-Looking Statements

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

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

Overview

We are a commercial-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. On December 13, 2024, we announced that the U.S. Food and Drug Administration ("FDA") granted approval of cosibelimab-ipdl, now referred to as UNLOXCYT™, for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("CSCC") or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The approval was granted for this indication based upon data from an ongoing multi-regional, 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 CSCC.

Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, the manufacturing costs of UNLOXCYT were expensed to research and development in the period incurred prior to receipt of FDA approval.

Recent Developments

On March 9, 2025, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sun Pharmaceutical Industries, Inc., a Delaware corporation ("Sun Pharma" or "Parent"), and Snoopy Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"). The Merger Agreement provides that, on the terms and subject to the conditions set forth in the Merger Agreement, Parent, Merger Sub and us will effect a merger of Merger Sub with and into us (the "Merger"), with us continuing as the surviving corporation of the Merger and a wholly owned subsidiary of Parent. The Merger Agreement contains customary representations, warranties and covenants made by each of Parent, us and Merger Sub, including, among others, customary covenants regarding the operation of our business prior to the effective time of the Merger. For a more detailed description of the Merger Agreement, see Note 11 to our financial statements.

We have also entered into various collaboration agreements with TGTX, a related party, to develop and commercialize certain assets in connection with our licenses in the field of hematological malignancies, while we retain the right to develop and commercialize these assets in solid tumors. Effective September 30, 2023, TGTX agreed to mutually terminate these collaborations, with full rights reverting back to us.

To date, we have not generated any product sales from any products. 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, 2024, we have an accumulated deficit of $370.6 million.

We are a majority-controlled subsidiary of Fortress.

Checkpoint Therapeutics, Inc. was incorporated in Delaware on November 10, 2014 and commenced principal operations in March 2015. Our executive offices are located at 95 Sawyer Road, Suite 110, Waltham, MA 02453. Our telephone number is (781) 652-4500 and our email address is ir@checkpointtx.com.

Critical Accounting Policies and Use of Estimates

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

Our significant accounting policies are described in the notes to our financial statements appearing elsewhere in this Form 10-K. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development

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

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

Accrued Research and Development Expense

We record accruals for estimated costs of research, preclinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers such as contract research organizations in connection with our clinical studies, contract manufacturing organizations, trial sites in connection with our clinical studies and vendors associated with licenses/milestones. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs through the reviewing of open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly for services performed or when contractual milestones are met. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We expense stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures, which are recorded upon occurrence. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved. We estimate the fair value of stock option grants using the Black-Scholes Model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

We will continue to use judgment in evaluating the expected volatility, expected terms and interest rates utilized for our stock-based compensation expense calculations on a prospective basis. The assumptions underlying these valuations represent management's best estimate, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. We expect to continue to grant options and other stock-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Common Stock Warrant Liabilities

We have issued freestanding warrants to purchase shares of our common stock in connection with financing activities. Our outstanding common stock warrants issued in connection with the registered direct financing completed in December 2022 (the "December 2022 Registered Direct Offering") are classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside our control. We estimate the fair value of warrants using the Black-Scholes Model. The assumptions used in calculating the fair value of warrants represent management's best estimates and involve inherent uncertainties and the application of management's judgment. We will continue to use judgment in evaluating the expected volatility, expected terms and interest rates utilized for our common stock warrant liability calculations on a prospective basis. The assumptions underlying these valuations represent management's best estimate, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our common stock warrant liabilities could be materially different.

The fair value of common stock warrant liabilities is re-measured at each financial reporting date and upon exercise with any changes in fair value being recognized in gain (loss) on common stock warrant liabilities, a component of other income (loss), in the Statements of Operations. We will continue to re-measure the fair value of the warrant liabilities until exercise or expiration of the related warrant.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2024 compared to the year ended December 31, 2023. For a discussion of the year ended December 31, 2023 compared to the year ended December 31, 2022, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Comparison of the Years Ended December 31, 2024 and 2023

Revenue

For the year ended December 31, 2024, revenue was approximately $41,000 compared to approximately $103,000 for the year ended December 31, 2023, a decrease of approximately $62,000. The current and prior period revenue primarily consisted of the reimbursement of patent costs related to the collaboration agreement with TGTX.

Research and Development Expenses

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

For the year ended December 31, 2024, research and development expenses were approximately $36.2 million, compared to approximately $43.6 million for the year ended December 31, 2023, a decrease of $7.4 million. The current period research and development expenses primarily consisted of $10.8 million related to commercial manufacturing costs and inventory build, which is expensed prior to approval, to support a potential launch of UNLOXCYT, $3.9 million related to clinical costs, primarily for the CK-301-101 study, $0.3 million related to regulatory costs, $7.6 million related to the non-cash annual equity fee in connection with the Founders Agreement with Fortress, $5.9 million related to salary expenses and $5.2 million related to non-cash stock compensation expense, including $3.1 million of expense recognized in relation to the achievement of FDA approval of UNLOXCYT. For the year ended December 31, 2023, research and development expenses primarily consisted of $19.0 million related to commercial manufacturing costs and inventory build, which is expensed prior to approval, to support a potential launch of UNLOXCYT, $7.0 million related to clinical costs for our product candidates, $3.6 million related to regulatory costs, including $3.2 million for the PDUFA fee to the FDA for the BLA filing for UNLOXCYT in the first quarter of 2023, $2.3 million in license fees due upon the FDA filing acceptance of the BLA, $3.4 million related to the non-cash annual equity fee in connection with the Founders Agreement with Fortress, $5.1 million related to salary expenses and $1.2 million related to non-cash stock compensation expense.

We anticipate research and development expenses in 2025 to decrease as compared to 2024 due primarily to the capitalization of inventory costs for UNLOXCYT following regulatory approval in December 2024 and decreased clinical costs for our products.

General and Administrative Expenses

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

For the year ended December 31, 2024, general and administrative expenses were approximately $20.1 million, compared to approximately $8.7 million for the year ended December 31, 2023, an increase of $11.4 million. The current period general and administrative expenses primarily consisted of non-cash stock compensation expense of $10.0 million, including $7.1 million of expense recognized in relation to the achievement of FDA approval of UNLOXCYT, $2.0 million related to salary expenses, $1.0 million related to our issuance of shares to Fortress pursuant to the Founders Agreement in connection with the sale of shares of our common stock, $4.1 million related to legal and accounting fees, with legal fees increasing due to costs to respond to litigation filed in 2024 as well as costs to explore corporate development transactions, $0.2 million related to marketing costs and $0.3 million related to investor relation fees. The prior period general and administrative expenses primarily consisted of non-cash stock compensation expense of $1.7 million, $1.6 million related to salary expenses, $1.0 million related to our issuance of shares to Fortress pursuant to the Founders Agreement in connection with the sale of shares of our common stock, $1.8 million related to legal and accounting fees, $0.3 million related to marketing costs and $0.3 million related to investor relation fees.

We anticipate general and administrative expenses in 2025 will increase compared to 2024, pending the outcome of the Merger.

Other Income (loss)

For the year ended December 31, 2024, interest income was approximately $11,000 compared to approximately $84,000 for the year ended December 31, 2023, a decrease of approximately $73,000. The decrease was primarily due to a decrease in interest earned from money in interest bearing accounts between the periods.

For the year ended December 31, 2024, the loss on common stock warrant liabilities were approximately $73,000, compared to a gain of approximately $217,000 for the year ended December 31, 2023. The loss on common stock warrant liabilities in the current period is the net loss resulting from the fair value remeasurement of the common stock warrant liabilities at each reporting period in 2024. The gain on common stock warrant liabilities as of December 31, 2023 is comprised of net gains of approximately $7.9 million resulting from the fair value remeasurement of the common stock warrant liabilities at each reporting period in 2023 and upon exercise of a portion of the warrants associated with the December 2022 Registered Direct Offering. This gain was partially offset by a loss of approximately $7.7 million recorded on October 4, 2023 as part of the October 2023 warrant exercise inducement associated with a portion of the warrants issued in the December 2022 Registered Direct Offering as a result of offering additional warrants to the holder as part of the inducement. We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether

the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For the year ended December 31, 2024, foreign currency exchange loss was approximately $4,000, which is comprised of the currency fluctuation when purchasing goods and services in another currency relative to the United States dollar.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2024, we had an accumulated deficit of $370.6 million.

In February 2023, we closed on a registered direct offering (the "February 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,428,572 shares of our common stock at a purchase price of $5.25 per share. In addition, the offering included 248,572 shares of common stock in the form of pre-funded warrants at a price of $5.2499. In a concurrent private placement, we issued and sold Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to 1,428,572 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $5.00 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $7.5 million with net proceeds of approximately $6.7 million after deducting approximately $0.8 million in commissions and other transaction costs. In February 2023, the pre-funded warrants from the February 2023 Registered Direct Offering were fully exercised. In October 2023, the Series A and Series B warrants from the February 2023 Registered Direct Offering were fully exercised at a reduced exercise price of $1.76 per share as part of the October 2023 inducement offer letter agreement (see below).

In April 2023, we closed on a registered direct offering (the "April 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,700,000 shares of our common stock at a purchase price of $3.60 per share. In a concurrent private placement, we issued and sold Series A warrants to purchase up to 1,700,000 shares of common stock and Series B warrants to purchase up to 1,700,000 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $3.35 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $6.1 million with net proceeds of approximately $5.5 million after deducting approximately $0.6 million in commissions and other transaction costs. The Series B warrants expired in October 2024 without being exercised.

In May 2023, we closed on a registered direct offering (the "May 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,650,000 shares of our common stock at a purchase price of $3.071 per share. In addition, the offering included 1,606,269 shares of common stock in the form of pre-funded warrants at a price of $3.0709. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,256,269 shares of common stock and Series B warrants to purchase up to 3,256,269 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.821 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. In August 2023, the pre-funded warrants from the May 2023 Registered Direct Offering were fully exercised. The Series B warrants were exercised in full in November 2024 (see below).

In July 2023, we closed on a registered direct offering (the "July 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 2,427,186 shares of our common stock at a purchase price of $3.09 per share. In addition, the offering included 809,062 shares of common stock in the form of pre-funded warrants at a price of $3.0899. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,236,248 shares of common stock and Series B warrants to purchase up to 3,236,248 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.84 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. In September 2023,

the pre-funded warrants from the July 2023 Registered Direct Offering were fully exercised. In January 2025, warrants representing 740,000 shares of the Series B warrants were exercised, with the remainder of the Series B warrants expiring (see below).

In October 2023, we entered into an inducement offer letter agreement (the "October 2023 Inducement") with a certain holder of our existing warrants to exercise for cash an aggregate of 6,325,354 shares of our common stock at a reduced exercise price of $1.76 per share. The warrants were issued to the holder on December 16, 2022 with an exercise price of $4.075 per share and on February 22, 2023 with an exercise price of $5.00 per share as part of registered direct offerings. As part of the inducement, we agreed to issue new unregistered Series A warrants to purchase up to 6,325,354 shares of Common Stock and new unregistered Series B warrants to purchase up to 6,325,354 shares of Common Stock (collectively, the "October 2023 Common Stock Warrants"). The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants will expire five years following the issuance date and the Series B warrants will expire twenty-four months following the issuance date. The total gross proceeds from the exercise were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs. Upon the close of the transaction, we issued the holder 110,000 of the 6,325,354 shares of common stock that were issuable upon exercise of the existing warrants. Due to the beneficial ownership limitation provisions in the inducement offer letter agreement, the remaining 6,215,354 shares were initially unissued, and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2024, 1,134,000 shares remained in abeyance. These shares were fully issued to the holder in January 2024.

As a result of the October 2023 Inducement, we presented a deemed dividend for the modification of certain of its existing warrants and issuance of the October 2023 Common Stock Warrants of $0 and $7.5 million for the years ended December 31, 2024 and 2023, respectively. The deemed divided was included in net loss attributable to common stockholders in the calculation of net loss per share in the consolidated statements of operations.

In January 2024, we closed on a registered direct offering (the "January 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,275,000 shares of our common stock at a purchase price of $1.805 per share of common stock. In addition, the offering included 6,481,233 shares of common stock in the form of pre-funded warrants at a price of $1.8049. The common stock and the pre-funded warrants were sold together with common warrants (the "January 2024 Common Stock Warrants") to purchase up to 7,756,233 shares of common stock. The January 2024 Common Stock Warrants are exercisable immediately upon issuance with an exercise price of $1.68 per share and will expire five years following the issuance date. The total gross proceeds from the January 2024 Registered Direct Offering were approximately $14.0 million with net proceeds of approximately $12.6 million after deducting approximately $1.4 million in commissions and other transaction costs. In July 2024, the pre-funded warrants from the January 2024 Registered Direct Offering were fully exercised.

In July 2024, we closed on a registered direct offering (the "July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of $2.05 per share of common stock. In addition, the offering includes 4,623,659 shares of common stock in the form of pre-funded warrants at a price of $2.0499. The common stock and the pre-funded warrants were sold together with common warrants (the "July 2024 Common Stock Warrants") to purchase up to 5,853,659 shares of common stock. The July 2024 Common Warrants have an exercise price of $2.05 per share, will be exercisable after requisite approval of our stockholders is received, and have a term of exercise of five years from the issuance date. The total gross proceeds from the July 2024 Registered Direct Offering were approximately $12.0 million with net proceeds of approximately $11.0 million after deducting approximately $1.0 million in commissions and other transaction costs. In November 2024, the pre-funded warrants from the July 2024 Registered Direct Offering were fully exercised.

In November 2024, we received approximately $9.2 million from the full exercise of existing Series B warrants for the issuance of 3,256,269 shares of common stock from the May 2023 Registered Direct Offering with an exercise price of $2.821 per share. Due to the beneficial ownership limitation provisions in the securities purchase agreement, the shares were initially unissued and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2024, 1,437,000 shares remained in abeyance. These shares were fully issued to the holder in February 2025.

In January 2025, we received approximately $2.1 million from the partial exercise of existing Series B warrants for the issuance of 740,000 shares of common stock from the July 2023 Registered Direct Offering with an exercise price of $2.84 per share. The remainder of the Series B warrants from the July 2023 Registered Direct Offering expired on January 31, 2025 without exercise.

In connection with the Company's entry into the Merger Agreement, the Company entered into a letter agreement (the "Warrant Amendment"), dated as of March 9, 2025, with Armistice Capital Master Fund Ltd., a Cayman Islands exempted company ("Armistice"). Pursuant to the Warrant Amendment, the Company and Armistice agreed (i) to, immediately prior to the effective time of the Merger, amend all outstanding Company Warrants held by or issued to Armistice or any of its affiliates other than the Specified Warrant (the "Armistice Warrants") to provide that each such Armistice Warrant that remains outstanding and unexercised as of the effective time of the Merger will automatically be converted into the right to receive the Warrant Consideration (as defined in the Merger Agreement), and (ii) that at the effective time of the Merger, to the extent that any portion of that certain warrant to purchase 5,853,659 Shares, dated as of July 2, 2024 (the "Specified Warrant"), remains outstanding and unexercised as of the effective time of the Merger, the Specified Warrant will be converted into the right of Armistice to receive, for each Share underlying the Specified Warrant, a cash payment equal to $3.62. The Warrant Amendment also provides that Armistice will not be entitled to transfer the Armistice Warrants prior to the effective time of the Merger unless the Merger Agreement is validly terminated in accordance with its terms prior to the effective time of the Merger.

In March 2025, we received approximately $36.0 million from the exercise of warrants for the issuance of 21,691,003 shares of common stock with an average exercise price of $1.66 per share.

Our major sources of cash have been proceeds from the sale of equity securities and the exercise of warrants. We expect to use these proceeds primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments.

We believe that our cash and cash equivalents are only sufficient to fund our operating expenses into the fourth quarter of 2025. We will need to secure additional funds through equity or debt offerings, or other potential sources such as partnerships to fully develop and commercialize, if approved, our product candidates. Our estimate as to how long we expect our existing cash to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We cannot be certain that additional funding will be available on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

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

Cash Flows for the Years Ended December 31, 2024 and 2023

Operating Activities

Net cash used in operating activities was $31.1 million for the year ended December 31, 2024, compared to $47.6 million for the year ended December 31, 2023. The decrease in net cash used in operating activities was due primarily to greater manufacturing costs to support the BLA filing of cosibelimab and commercial inventory build in the prior period as well as a reduction in clinical costs between the two periods.

Investing Activities

There were no investing activities for the years ended December 31, 2024 and 2023.

Financing Activities

Net cash provided by financing activities was $32.8 million for the year ended December 31, 2024, which related to net proceeds of $23.6 million from the issuance of common shares and warrants from the January 2024 Registered Direct Offering and the July 2024 Registered Direct Offering, as well as $9.2 million received from the exercise of common stock warrants. Net cash provided by financing activities was $40.5 million for the year ended December 31, 2023, which related to net proceeds of $30.3 million from the issuance of common shares and warrants from the February 2023 Registered Direct Offering, April 2023 Registered Direct Offering, May 2023 Registered Direct Offering and July 2023 Registered Direct Offering, as well as $10.1 million from the October 2023 Inducement.

Recently Issued Accounting Standards

See Note 2 to our Financial Statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of December 31, 2024, our portfolio of financial instruments consists of cash equivalents, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

As of December 31, 2024, management carried out, under the supervision and with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting.

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

Limitations on the Effectiveness of Controls.

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

Item 9B. Other Information

During the three months ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act of 1933).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our Board of Directors

Our Bylaws provide that our Board of Directors ("Board") shall consist of between one and nine directors, and such number of directors within this range may be determined from time to time by resolution of our Board or our stockholders. Currently, we have seven directors. The following individuals are being nominated to serve on our Board:

Name	Age	Position	Director Since
Michael S. Weiss	59	Chairman of the Board of Directors	2015
Christian Béchon	65	Director	2018
Neil Herskowitz	68	Director	2015
James F. Oliviero, III	49	Chief Executive Officer, President, and Director	2018
Lindsay A. Rosenwald, M.D.	69	Director	2014
Barry Salzman	62	Director	2016
Amit Sharma, M.D.	56	Director	2024

Our Board does not have a formal policy regarding the separation of the roles of Chief Executive Officer and Chairman, as our Board believes that it is in the best interests of the Company to make that determination based on the direction of the Company and the current

membership of our Board. Our Board has determined that at present having a director who is an executive officer serve as the Chairman is not in the best interest of our stockholders at this time.

We have a risk management program overseen by James Oliviero, our President and Chief Executive Officer, and our Board. Mr. Oliviero and management identify material risks and prioritize them for our Board. Our Board regularly reviews information regarding our credit, liquidity, operations, and compliance as well as the risks associated with each.

The following biographies set forth the names of our directors and director nominees, the year in which they first became directors, their positions with us, their principal occupations and employers for at least the past five years, any other directorships held by them during the past five years in companies that are subject to the reporting requirements of the Exchange Act, or any company registered as an investment company under the Investment Company Act of 1940, as well as additional information, all of which we believe sets forth each director nominee's qualifications to serve on our Board. There is no family relationship between and among any of our executive officers or directors. There are no arrangements or understandings between any of our executive officers or directors and any other person pursuant to which any of them are elected as an officer or director, except as disclosed below.

We adhere to the corporate governance standards adopted by The Nasdaq Stock Market ("Nasdaq"). Nasdaq rules require our Board to make an affirmative determination as to the independence of each director. Consistent with these rules, our Board undertook its annual review of director independence on March 21, 2024. During the review, our Board considered relationships and transactions during 2023 and since inception between each director or any member of his immediate family, on the one hand, and the Company and our subsidiaries and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our Board determined that Christian Béchon, Neil Herskowitz, Barry Salzman, and Amit Sharma, M.D., are independent under the criteria established by Nasdaq and our Board.

Michael S. Weiss - Chairman of the Board of Directors

Mr. Weiss has served as Chairman of our Board of Directors since March 2015. Effective January 1, 2017, the services of Mr. Weiss as Chairman are provided under an Advisory Agreement (the "Advisory Agreement") with Caribe BioAdvisors, LLC (see below). He also served as Interim Chief Executive Officer and President from August 2015 until October 2015 and Executive Chairman from March 2015 to December 2016. Mr. Weiss also serves as a director and Executive Vice Chairman, Strategic Development of Fortress Biotech, Inc., as Chairman of the Board of Directors and Executive Chairman of Mustang Bio, Inc., and as Chairman, President and Chief Executive Officer of TG Therapeutics, Inc., a company he founded in 2011. Mr. Weiss was also a board member of Avenue Therapeutics, Inc. from March 2015 to February 2018 and the Chairman of the Board of National Holding Corporation from September 2016 to June 2018. From 2002 to 2009, Mr. Weiss was the Chairman and Chief Executive Officer of Keryx Biopharmaceuticals, Inc., where he helped the company acquire and develop its lead drug, Auryxia®, as well as executed a strategic alliance for Auryxia with Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd. worth more than $100 million. Mr. Weiss began his professional career as a lawyer with Cravath, Swaine & Moore LLP. He earned his J.D. from Columbia Law School and his B.S. in Finance from The University at Albany. Based on Mr. Weiss' biotechnology and pharmaceutical industry experience, as well as his extensive management experience, our Board of Directors believes that Mr. Weiss has the appropriate set of skills to serve as a member of the Board.

Effective January 1, 2017, our Board of Directors approved and authorized the execution of an advisory agreement (the "Advisory Agreement") with Caribe BioAdvisors, LLC (the "Advisor"), which is owned by Michael S. Weiss, to provide our Board with the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the Advisory Agreement, the Advisor is paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of our Board. In June 2023, Mr. Weiss assigned the agreement to Hawkins BioVentures, LLC.

Christian Béchon

Mr. Béchon joined our Board of Directors in October 2018. He is currently Chairman and Chief Executive Officer of ChB Consultants, a privately held life science consultancy company. From 2006 to 2017, Mr. Béchon was Chairman and Chief Executive Officer of LFB S.A., a French biopharmaceutical company with more than €500M in annual revenue. Previously, he was Senior Advisor for the Boston Consulting Group in 2005 and 2006. Earlier in his career, he held various positions in the French government, including Chief of Staff to the Minister for Public Health and Health Insurance. From 2000 to 2004, he was Deputy Chief of Staff to the Minister of the Economy, Finance and Industry. He is a graduate of the Ecole Centrale des Arts et Manufactures engineering school, Institut d'Etudes Politiques

de Paris and Ecole Nationale d'Administration. Mr. Béchon is a member of Quantum Genomics' (ALQGC) Board of Directors and has been a board member of private companies in the USA, Mexico and Europe. He has received numerous awards and medals, including the Knight of the French Legion of Honor and the French National Order of Merit. Based on Mr. Béchon's biotechnology and pharmaceutical industry experience, as well as his extensive management experience, our Board of Directors believes that Mr. Béchon has the appropriate set of skills to serve as a member of our Board.

Neil Herskowitz

Mr. Herskowitz joined our Board of Directors in August 2015 and has served as the Chairman of our Audit Committee since September 2016. Mr. Herskowitz has served as the managing member of the ReGen Group of companies, located in New York, since 1998, which include ReGen Capital Investments LLC and Riverside Claims Investments LLC. He has also served as the President of its affiliate, Riverside Claims LLC, since June 2004. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978. Based on Mr. Herskowitz's financial industry experience and in-depth understanding of our business, our Board of Directors believes that Mr. Herskowitz has the appropriate set of skills to serve as a member of our Board.

James F. Oliviero, III

Mr. Oliviero joined our Board of Directors in October 2018 and has served as our Chief Executive Officer and President since October 2015. Mr. Oliviero has twenty-five years of operational experience in the biotechnology industry. From May 2003 to September 2015, Mr. Oliviero served in a variety of leadership capacities at Keryx Biopharmaceuticals, Inc., a publicly traded biotechnology company, most recently as its Chief Financial Officer since April 2009, where he was instrumental in the growth of the company to a market capitalization over $1 billion. During his tenure at Keryx, Mr. Oliviero oversaw all finance, accounting, investor relations, corporate governance, business development and legal matters, as well as a leading member of the design of several clinical studies and the regulatory oversight of Keryx's new drug application for Auryxia®, which successfully obtained FDA marketing approval in 2014 and also gained EMA marketing approval. Also while at Keryx, Mr. Oliviero completed over $500 million in various public financings for the company. Prior to Keryx, from August 1999 to May 2003, Mr. Oliviero was Director of Finance for ACCESS Oncology, Inc., a privately held biotechnology company. Mr. Oliviero began his professional career as an investment banker at Furman Selz LLC in New York City. Since July 2021, Mr. Oliviero has also served on the Board of Directors for Nuvectis Pharma, Inc. Mr. Oliviero is a CFA charterholder and holds a B.B.A. in Finance with Highest Distinction from Emory University's Goizueta Business School. Based on Mr. Oliviero's biotechnology and pharmaceutical industry experience, as well as his extensive management experience, our Board of Directors believes that Mr. Oliviero has the appropriate set of skills to serve as a member of our Board.

Lindsay A. Rosenwald, M.D.

Dr. Rosenwald has served as a member of our Board of Directors since inception. From November 2014 to August 2015, he also was our Chief Executive Officer and President. Dr. Rosenwald also serves as Chairman, President and Chief Executive Officer of Fortress Biotech, Inc., as a director of Mustang Bio, Inc., and as Chairman of the Board of Directors of Avenue Therapeutics, Inc. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 23 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine. Based on Dr. Rosenwald's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, our Board of Directors believes that Dr. Rosenwald has the appropriate set of skills to serve as a member of our Board.

Barry Salzman

Mr. Salzman joined our Board of Directors in January 2016. Mr. Salzman is currently a Managing Director for Compass Partners LLC, a merchant banking and financial advisory firm that specializes in middle market companies and corporate restructuring. Mr. Salzman joined Compass Partners LLC in July 2007, the same time at which he became a Board Member and Principal owner of BP Gamma Medical Supply Company, which he sold in 2021. Prior to July 2007, Mr. Salzman served as Board Chairman, President and Principal owner of Becker-Parkin Dental Supply Company. After 20 years at Becker-Parkin, Mr. Salzman sold the company to Henry Schein Inc. (NASDAQ: HSIC). Five months after selling Becker-Parkin, Mr. Salzman served as President of Surgery Works, LLC, formed by Compass Partners LLC to provide financial management services for Ambulatory Surgery Centers until the centers sold a controlling interest to Amsurg (NASDAQ: AMSG). Mr. Salzman has maintained a Board seat at both Surgery Works, LLC centers and continues

to work in a consulting and advisory role to Amsurg. In 2014, Mr. Salzman founded and became President of Practice Management Works LLC and also accepted a board seat at Vivex Corporation, a private research driven Biomedical Company. Since January 2022, Mr. Salzman has also served as Co-President of Vivex Corporation. Mr. Salzman is a 1987 graduate of Brooklyn Law School and is a member in good standing of the New York Bar Association. Based on Mr. Salzman's financial industry experience and in-depth understanding of our business, as well as his extensive management experience, our Board of Directors believes that Mr. Salzman has the appropriate set of skills to serve as a member of our Board.

Amit Sharma, M.D.

Dr. Sharma joined our Board of Directors in March of 2024. Dr. Sharma currently serves as Executive Vice President, Clinical Research and Medical Affairs at Vera Therapeutics, a clinical-stage biotechnology company focused on developing treatments for immunological diseases that improve patients' lives. He previously served as Vice President of Clinical Development and Therapeutic Head for Nephrology and Hematology at Alexion, AstraZeneca Rare Disease, where he guided and executed the strategic direction of development products and programs within Alexion's nephrology franchise across all stages of development. From June 2020 until December 2023, he served as Vice President of Medical Affairs for the Cardiovascular and Renal Division of Bayer Pharmaceuticals. Prior to joining Bayer Pharmaceuticals, he served as Vice President of Akebia Pharmaceuticals from June 2015 to May 2020. As a widely recognized physician, Dr. Sharma has held numerous senior leadership industry positions in various roles at both biotechnology companies as well as larger pharmaceutical companies. Dr. Sharma received his medical degree from Louisiana State University Medical Center in New Orleans and completed his nephrology and hypertension fellowship at the University of California in San Diego. He is board certified by the American Board of Internal Medicine for internal medicine, nephrology, and also has an additional certification as a hypertension specialist by the American Society of Hypertension. Based on Dr. Sharma's pharmaceutical industry experience and various leadership positions, our Board of Directors believes that Dr. Sharma has the appropriate set of skills to serve as a member of our Board.

Meetings of our Board of Directors

Our Board held four meetings and took five actions by unanimous written consent during the fiscal year ended December 31, 2024. During 2024, each incumbent director standing for election attended at least 75% of the meetings of our Board of Directors and the meetings of those committees on which each incumbent director served, in each case during the period that such person was a director. The permanent committees established by our Board of Directors are the Audit Committee and the Compensation Committee, descriptions of which are set forth in more detail below . Our directors are expected to attend each Annual Meeting of Stockholders.

Audit Committee

The Audit Committee currently consists of Neil Herskowitz, Christian Béchon, and Barry Salzman.

The Audit Committee held four meetings during the fiscal year ended December 31, 2024. The duties and responsibilities of the Audit Committee are set forth in the Charter of the Audit Committee which was recently reviewed by our Audit Committee. Our Audit Committee determined that no revisions needed to be made to the charter at this time. A copy of the Charter of the Audit Committee is available on our website, located at www.checkpointtx.com. Among other matters, the duties and responsibilities of the Audit Committee include reviewing and monitoring our financial statements and internal accounting procedures, the selection of our independent registered public accounting firm and consulting with and reviewing the services provided by our independent registered public accounting firm. Our Audit Committee has sole discretion over the retention, compensation, evaluation and oversight of our independent registered public accounting firm.

The SEC and Nasdaq have established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. Our Board of Directors has examined the composition of our Audit Committee and the qualifications of our Audit Committee members in light of the current rules and regulations governing audit committees. Based upon this examination, our Board of Directors has determined that each member of our Audit Committee is independent and is otherwise qualified to be a member of our Audit Committee in accordance with the rules of the SEC and Nasdaq.

Additionally, the SEC requires that at least one member of the Audit Committee have a "heightened" level of financial and accounting sophistication. Such a person is known as the "audit committee financial expert" under the SEC's rules. Our Board has determined that Mr. Herskowitz is an "audit committee financial expert," as the SEC defines that term, and is an independent member of our Board of

Directors and our Audit Committee. Please see Mr. Herskowitz's biography in Item 10. Directors, Executive Officers and Corporate Governance for a description of his relevant experience.

Compensation Committee

The Compensation Committee did not hold any meetings and took one action by unanimous written consent during the fiscal year ended December 31, 2024. The Compensation Committee currently consists of Neil Herskowitz and Barry Salzman, with Mr. Salzman serving as chairman. The duties and responsibilities of the Compensation Committee are set forth in the Charter of the Compensation Committee. A copy of the Charter of the Compensation Committee is available on our website, located at www.checkpointtx.com. As discussed in its charter, among other things, the duties and responsibilities of the Compensation Committee include the following (unless such duties and responsibilities are undertaken by our Board of Directors): evaluating the performance of our Chief Executive Officer and our Chief Financial Officer, determining the overall compensation of our Chief Executive Officer and our Chief Financial Officer and administering all executive compensation programs, including, but not limited to, our incentive and equity-based plans. The Compensation Committee evaluates the performance of our Chief Executive Officer and our Chief Financial Officer on an annual basis and reviews and approves on an annual basis all compensation programs and awards relating to such officers. The Compensation Committee applies discretion in the determination of individual executive compensation packages to ensure compliance with the Company's compensation philosophy. Our Chief Executive Officer makes recommendations to the Compensation Committee with respect to the compensation packages for officers other than himself. The Compensation Committee may delegate its authority to grant awards to certain employees, and within specified parameters under the Company's Amended and Restated 2015 Incentive Plan, to a special committee consisting of one or more directors who may but need not be officers of the Company. The Committee did not engage a compensation consultant in 2024.

Nasdaq has established rules and regulations regarding the composition of compensation committees and the qualifications of compensation committee members. Our Board of Directors has examined the composition of our Compensation Committee and the qualifications of our Compensation Committee members in light of the current rules and regulations governing compensation committees. Based upon this examination, our Board of Directors has determined that each member of our Compensation Committee is independent and is otherwise qualified to be a member of our Compensation Committee in accordance with such rules.

Nominating Process

We do not currently have a nominating committee or any other committee serving a similar function. Director nominations are approved by a vote of a majority of our independent directors as required under the Nasdaq rules and regulations. Although we do not have a written charter in place to select director nominees, our Board of Directors has adopted resolutions regarding the director nomination process. We believe that the current process in place functions effectively to select director nominees who will be valuable members of our Board of Directors.

We identify potential nominees to serve as directors through a variety of business contacts, including current executive officers, directors, community leaders and stockholders. We may, to the extent they deem appropriate, retain a professional search firm and other advisors to identify potential nominees.

We will also consider candidates recommended by stockholders for nomination to our Board. A stockholder who wishes to recommend a candidate for nomination to our Board must submit such recommendation to our Corporate Secretary, Garrett Gray, at our offices located at 95 Sawyer Road, Suite 110, Waltham, MA 02453. Any recommendation must be received not less than 50 calendar days nor more than 90 calendar days before the anniversary date of the previous year's annual meeting. All stockholder recommendations of candidates for nomination for election to our Board must be in writing and must set forth the following: (i) the candidate's name, age, business address, and other contact information, (ii) the number of shares of common stock beneficially owned by the candidate, (iii) a complete description of the candidate's qualifications, experience, background and affiliations, as would be required to be disclosed in the proxy statement pursuant to Schedule 14A under the Exchange Act, (iv) a sworn or certified statement by the candidate in which he or she consents to being named in the proxy statement as a nominee and to serve as director if elected, and (v) the name and address of the stockholder(s) of record making such a recommendation.

We believe that our Board as a whole should encompass a range of talent, skill, and expertise enabling it to provide sound guidance with respect to our operations and interests. Our independent directors evaluate all candidates to our Board by reviewing their biographical information and qualifications. If the independent directors determine that a candidate is qualified to serve on our Board, such candidate

is interviewed by at least one of the independent directors and our Chief Executive Officer. Other members of our Board also have an opportunity to interview qualified candidates. The independent directors then determine, based on the background information and the information obtained in the interviews, whether to recommend to our Board that the candidate be nominated for approval by the stockholders to fill a directorship. With respect to an incumbent director whom the independent directors are considering as a potential nominee for re-election, the independent directors review and consider the incumbent director's service during his or her term, including the number of meetings attended, level of participation, and overall contribution to our Board. The manner in which the independent directors evaluate a potential nominee will not differ based on whether the candidate is recommended by our directors or stockholders.

We consider the following qualifications, among others, when making a determination as to whether a person should be nominated to our Board: the independence of the director nominee; the nominee's character and integrity; financial literacy; level of education and business experience, including experience relating to biopharmaceutical companies; whether the nominee has sufficient time to devote to our Board; and the nominee's commitment to represent the long-term interests of our stockholders. We review candidates in the context of the current composition of our Board and the evolving needs of our business. We believe that each of the current members of our Board has the requisite business, biopharmaceutical, financial or managerial experience to serve as a member of our Board, as described above in their biographies under the heading "Our Board of Directors." We also believe that each of the current members of our Board has other key attributes that are important to an effective board, including integrity, high ethical standards, sound judgment, analytical skills, and the commitment to devote significant time and energy to service on our Board and its committees.

We do not have a formal policy regarding board diversity.

Code of Business Conduct and Ethics

We have adopted a Code of Ethics ("the Code") which applies to all of our directors and employees, including our principal executive officer and principal financial officer. The Code includes guidelines dealing with the ethical handling of conflicts of interest, compliance with federal and state laws, financial reporting, and our proprietary information. The Code also contains procedures for dealing with and reporting violations of the Code. We have posted the Code on our website, located at www.checkpointtx.com. If we ever were to amend or waive any provision of the Code that applies to our principal executive officer or principal financial officer or any person performing similar functions, we intend to satisfy our disclosure obligations, if any, with respect to any such waiver or amendment by posting such information on our website set forth above rather than by filing a Current Report on Form 8-K. In the case of a waiver for an executive officer or a director, the disclosure required under applicable Nasdaq listing standards also will be made available on our website.

Policy Prohibiting Hedging and Pledging

Pursuant to our Insider Trading Policy, our officers, directors, and employees are prohibited from engaging in speculative trading, including hedging transactions or short sale transactions with respect to Company securities. A copy of our Insider Trading Policy is filed as exhibit 19.1 to this Annual Report on Form 10-K.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors and executive officers and persons who beneficially own more than ten percent of a registered class of the Company's equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of equity securities of the Company. To the Company's knowledge, based solely on a review of the copies of such filings on file with the SEC and written representations from the Company's directors and executive officers, we believe that during 2024, all transactions were reported on a timely basis.

Executive Officers

Our current executive officers are as follows:

Name	Age	Position
James F. Oliviero, III	49	President, Chief Executive Officer and Director
Garrett Gray	37	Chief Financial Officer, Corporate Secretary and Treasurer

No executive officer is related by blood, marriage or adoption to any other director or executive officer. The biography of Mr. Oliviero is presented in connection with his service as a member of our Board of Directors in Item 10. Directors, Executive Officers and Corporate Governance.

Garrett Gray - Chief Financial Officer, Corporate Secretary and Treasurer

Mr. Gray has served as our Chief Financial Officer since December 2020, as our Principal Financial Officer since December 2016, and as our Corporate Secretary and Treasurer since January 2018. Mr. Gray served as our Vice President, Finance and Accounting from February 2016 until December 2020. Mr. Gray joined us from Keryx Biopharmaceuticals, Inc., a publicly traded biotechnology company, which he joined in 2013, and where he most recently served as Corporate Controller, helping grow the finance and accounting department during Keryx's transition from a development-stage company to a fully integrated commercial organization. Prior to joining Keryx, Mr. Gray began his professional career with Deloitte & Touche, LLP, where he served as a senior auditor. Mr. Gray has a Bachelor of Science degree in Accounting from Lehigh University and is a Certified Public Accountant in the State of New York.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets forth information concerning compensation paid by us to our named executive officers ("NEOs") for their services rendered to us in all capacities during the years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)[2]	Total ($)
James F. Oliviero III	2024	661,003	—	8,635,711	479,230	—	9,775,944
President, Chief Executive Officer and Director	2023	635,580	—	720,000	286,011	—	1,641,591
Garrett Gray	2024	350,000	—	2,249,325	152,250	9,235	2,760,810
Chief Financial Officer, Corporate Secretary and Treasurer	2023	315,000	—	303,750	85,050	9,075	712,875

(1) Reflects the aggregate grant date fair value of restricted stock granted during the fiscal year calculated in accordance with FASB ASC Topic 718. The grant date fair value of the stock awards is based on the fair market value of the underlying shares on the date of grant and does not take into account any estimated forfeitures. The grant date fair value of the stock awards also does not take into account any stock awards which vest upon certain corporate milestones when the "measurement date" for accounting purposes for such awards has not yet occurred and the fair value is uncertain. For such awards, stock-based compensation is measured and recorded if and when a milestone occurs, and the compensation for such awards is reflected in the table in such year the compensation is recorded.

(2) Reflects 401(k) company contributions for Mr. Gray.

Narrative to Summary Compensation Table

Employment Agreement with Mr. Oliviero

On October 13, 2015, we entered into an employment agreement with Mr. Oliviero (the "Oliviero Employment Agreement"). As part of his 2024 annual review, the Compensation Committee raised his base salary from $661,003 to $694,050 effective as of January 1, 2025. The Oliviero Employment Agreement provides for an incentive bonus linked to the realization of goals and objectives to be established annually by agreement between Mr. Oliviero and our Chairman. The achievement of these goals and objectives (as determined by the Chairman) may result in a target annual award of up to fifty percent (50%) of Mr. Oliviero's annual salary, with a maximum annual award of up to seventy-five percent (75%). Mr. Oliviero's incentive award for 2024 is described under "Annual Incentive Bonus" below. The Oliviero Employment Agreement provides Mr. Oliviero with severance benefits upon certain terminations of employment, as described below. In each case, the severance benefits are conditioned upon Mr. Oliviero's execution and non-revocation of a release of claims against the Company.

Equity Awards. In connection with the execution of the Oliviero Employment Agreement, Mr. Oliviero received 100,000 restricted shares (the "Restricted Shares"), which remaining unvested Restricted Shares are subject to a repurchase right in favor of the Company that lapses as such Restricted Shares vest, as described in footnote (2) to the Outstanding Equity Awards table. The Company has issued additional awards to Mr. Oliviero in subsequent years, as described under "Equity Awards" below.

Termination without Cause; Resignation for Good Reason (Not in Connection with a Change in Control). If we terminate Mr. Oliviero's employment without "cause" or Mr. Oliviero resigns for "good reason" (as such terms are defined in the Oliviero Employment Agreement), at any time other than at the time of, or within 18 months following, a change in control, then he will receive: (i) continuation of his then-current base salary for 12 months, payable in accordance with our normal payroll practices; and (ii) reimbursement for COBRA premiums for 12 months. He will also be entitled to acceleration of vesting with respect to his equity awards, as described below under "Acceleration of Vesting of Equity Awards."

Termination without Cause; Resignation for Good Reason (In Connection with a Change in Control). If we terminate Mr. Oliviero's employment without "cause" or Mr. Oliviero resigns for "good reason" upon the occurrence of, or within 18 months following, a change in control, then he will receive: (i) a lump sum payment equal to the sum of (A) 150% of his then-current base salary, plus (B) 150% of the actual amount (if any) of the annual bonus paid or payable to him for the year immediately preceding the year in which the termination occurs, payable in a single lump sum; and (ii) reimbursement for COBRA premiums for 12 months. He will also be entitled to acceleration of vesting with respect to his equity awards, as described below under "Acceleration of Vesting of Equity Awards."

Termination due to Death or Disability. If Mr. Oliviero's employment terminates as a result of his death or "disability" (as defined in the Oliviero Employment Agreement), then he (or his estate, if applicable) will receive continuation of his then-current base salary for 4 months, payable in accordance with our normal payroll practices.

Employment Agreement with Mr. Gray

On January 7, 2025, we entered into an employment agreement with Mr. Gray (the "Gray Employment Agreement"). As part of his 2024 annual review, the Compensation Committee raised his base salary to $400,000. Mr. Gray is also eligible for an annual performance-based cash bonus based on attainment of certain financial, clinical development, and/or business milestones to be established annually by our Board (or a committee thereof). The achievement of goals as determined by our Board (or committee thereof) may result in a target annual award of up to thirty percent (30%) of Mr. Gray's base salary, with a maximum annual award of up to forty-five percent (45%). Mr. Gray will also be eligible to receive grants of long-term incentive awards under and subject to the terms of the Company's equity or other long-term incentive plans in effect from time to time. Mr. Gray's incentive award for 2024 is described under "Annual Incentive Bonus" below. The Gray Employment Agreement provides Mr. Gray with severance benefits upon certain terminations of employment, as described below. In each case, the severance benefits are conditioned upon Mr. Gray's execution and non-revocation of a release of claims against the Company.

Termination without Cause; Resignation for Good Reason (Not in Connection with a Change in Control). If we terminate Mr. Gray's employment without "cause" or Mr. Gray resigns for "good reason" (as such terms are defined in the Gray Employment Agreement), at any time other than at the time of, or within 18 months following, a change in control, then he will receive: (i) continuation of his then-current base salary for 12 months, payable in accordance with our normal payroll practices; and (ii) reimbursement for COBRA premiums for 12 months. He will also be entitled to acceleration of vesting with respect to his equity awards, as described below under "Acceleration of Vesting of Equity Awards."

Termination without Cause; Resignation for Good Reason (In Connection with a Change in Control). If we terminate Mr. Gray's employment without "cause" or Mr. Gray resigns for "good reason" upon the occurrence of, or within 18 months following, a change in control, then he will receive: (i) a lump sum payment equal to the sum of (A) 150% of his then-current base salary, plus (B) 150% of the actual amount (if any) of the annual bonus paid or payable to him for the year immediately preceding the year in which the termination occurs, payable in a single lump sum; and (ii) reimbursement for COBRA premiums for 12 months. He will also be entitled to acceleration of vesting with respect to his equity awards, as described below under "Acceleration of Vesting of Equity Awards."

Termination due to Death or Disability. If Mr. Gray's employment terminates as a result of his death or "disability" (as defined in the Gray Employment Agreement), then he (or his estate, if applicable) will receive continuation of his then-current base salary for 4 months, payable in accordance with our normal payroll practices.

Annual Incentive Bonus

In 2024, Mr. Oliviero was eligible to earn a target annual cash incentive equal to 50% of his base salary, with a maximum incentive of 75% of his base salary, as per the terms of the Oliviero Employment Agreement, and Mr. Gray was eligible to earn a target annual cash incentive equal to 30% of his base salary, with a maximum incentive of 45% of his base salary, as per the terms of the Gray Employment Agreement.

Both executives' annual cash incentive awards were based upon the Company's performance against pre-established corporate goals and objectives, which included a combination of clinical and regulatory goals related to our lead product (weighted at an aggregate of 100% of the target awards), and each executive's individual performance based upon subjective performance reviews. Also, certain corporate development goals were designated as reach goals to provide additional opportunities of obtaining an annual incentive award, with a maximum of 150% of the target awards eligible for achievement. The goals were achieved at an aggregate level of 145% of target

awards (97% of maximum awards) reflecting the successful achievement of clinical and regulatory goals and partial achievement of manufacturing development goals and all of our reach goals. Accordingly, the executives were paid 145% of their target bonus amounts for 2024. The actual amounts paid to the executives pursuant to their annual cash incentive awards and bonuses are reported in the "Summary Compensation Table" as non-equity incentive plan compensation.

Equity Awards

The Compensation Committee has granted each of Messrs. Oliviero and Gray equity awards under our Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, (the "2015 Incentive Plan"). In 2024, Mr. Oliviero received an award of 1,660,000 restricted shares, and Mr. Gray received an award of 540,000 restricted shares, both of which vest as described in footnote (6) to the Outstanding Equity Awards table below. Additionally, Mr. Oliviero previously received 1,660,000 restricted stock units and Mr. Gray received 540,000 restricted stock units that vested upon approval by the U.S. Food and Drug Administration of the Company's Biologics License Application for cosibelimab in December 2024. For such awards, stock-based compensation was measured and recorded in 2024, when the milestone occurred.

Outstanding Equity Awards at 2024 Fiscal Year End

Name	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)[1]
Mr. Oliviero	—	—	22,222 [2]	71,110
	13,475 [3]	43,120	—	—
	22,750 [4]	72,800	—	—
	187,500 [5]	600,000	—	—
	1,660,000 [6]	5,312,000	—	—
Mr. Gray	3,775 [3]	12,080	—	—
	6,850 [4]	21,920	—	—
	75,000 [5]	240,000	—	—
	540,000 [6]	1,728,000	—	—

(1) Market value is based on $3.20 per share, the closing price of our common stock on the Nasdaq Capital Market on December 31, 2024, the last trading day of the fiscal year.

(2) The restricted shares vest as follows: (i) 11,111 shares will vest on the Company's achievement of fully-diluted "market capitalization" (as defined in the Oliviero Employment Agreement") of $500,000,000; and, (ii) 11,111 shares will vest on the Company's achievement of a fully-diluted market capitalization of $750,000,000.

(3) The restricted shares vest as follows: 100% on January 6, 2025, subject to Messrs. Oliviero and Gray's continued employment with us on the vesting date.

(4) The restricted shares vest as follows: 50% each on January 31, 2025 and January 31, 2026, subject to Messrs. Oliviero and Gray's continued employment with us on each vesting date.

(5) The restricted shares vest as follows: 33% each on March 31, 2025, March 31, 2026 and March 31, 2027 subject to Messrs. Oliviero and Gray's continued employment with us on each vesting date.

(6) The restricted shares vest as follows: 33% each on January 31, 2025, January 31, 2026, and January 31, 2027, subject to Messrs. Oliviero and Gray's continued employment with us on each vesting date.

Potential Payments upon Termination or Change in Control

As detailed above, we have employment agreements with Messrs. Oliviero and Gray that provide certain compensation and benefits in the event of a termination of their employment or change in control under certain conditions. In addition, the employment agreements with Messrs. Oliviero and Gray and our equity plan provide certain equity award benefits in connection with a termination or change in control.

Acceleration of Vesting of Equity Awards

Mr. Oliviero's Equity Awards

- If we terminate Mr. Oliviero's employment without "cause" or Mr. Oliviero resigns for "good reason," at any time other than at the time of, or within 18 months following, a change in control, then (i) his unvested equity awards that would have vested if he had continued employment for one year after his date of termination will become fully vested and he will have 12 months following his date of termination to exercise any outstanding stock options; and (ii) his restricted shares subject to the market capitalization milestones, to the extent outstanding as of the date of termination, will remain outstanding for a period of 6 months following the date of termination and to the extent that such milestones are achieved during such 6-month period, such Restricted Shares will vest.
- If we terminate Mr. Oliviero's employment without "cause" or Mr. Oliviero resigns for "good reason" upon the occurrence of, or within 18 months following, a change in control, then all of his unvested equity awards will become fully vested and he will have 12 months following the date of termination to exercise any outstanding stock options.
- If Mr. Oliviero's employment terminates as a result of his death or "disability," then (i) his unvested equity awards that would have vested if he had continued employment for one year after his date of termination will become fully vested and he will have 12 months following his date of termination to exercise any outstanding stock options; and (ii) his restricted shares subject to the market capitalization milestones, to the extent outstanding as of the date of termination, will remain outstanding for a period of 4 months following the date of termination and to the extent that such milestones are achieved during such 4-month period, such restricted shares will vest.
- All of the restricted shares provided for in the Employment Agreement also will vest upon the occurrence of a "change in our control" of the Company, as defined in the Employment Agreement, in which the company is valued in excess of $500,000,000 (on a fully diluted basis).

Mr. Gray's Equity Awards

- If we terminate Mr. Gray's employment without "cause" or Mr. Gray resigns for "good reason," at any time other than at the time of, or within 18 months following, a change in control, then (i) his unvested equity awards that would have vested if he had continued employment for one year after his date of termination will become fully vested and he will have 12 months following his date of termination to exercise any outstanding stock options.
- If we terminate Mr. Gray's employment without "cause" or Mr. Gray resigns for "good reason" upon the occurrence of, or within 18 months following, a change in control, then all of his unvested equity awards will become fully vested and he will have 12 months following the date of termination to exercise any outstanding stock options.
- If Mr. Gray's employment terminates as a result of his death or "disability," then (i) his unvested equity awards that would have vested if he had continued employment for one year after his date of termination will become fully vested and he will have 12 months following his date of termination to exercise any outstanding stock options.

Other Awards Granted under the Amended and Restated 2015 Incentive Plan

- Unless otherwise provided in an award certificate or any special plan document governing an award, upon the occurrence of a change in control of our company, as defined in the Amended and Restated 2015 Incentive Plan, (i) all outstanding options, SARs and other awards in the nature of rights that may be exercised will become fully exercisable; (ii) all time-based vesting restrictions on outstanding awards will lapse; and (iii) the payout opportunities attainable under all outstanding performance-based awards will vest based on target performance and the awards will pay out on a pro rata basis, based on the time elapsed prior to the change in control.

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

Clawback Policy

Pursuant to Nasdaq listing requirements, we have adopted a policy providing for the recovery of erroneously awarded incentive-based compensation received by our executive officers during an applicable recovery period (the "Clawback Policy"). Under the Clawback Policy, in the event that financial results upon which a cash or equity-based incentive award was based becomes the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the Clawback Policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate award reflects the financial results as restated. The Clawback Policy covers any cash or equity-based incentive compensation award that was paid, earned or granted to covered executive officers during the last completed three fiscal years immediately preceding the date on which we are required to prepare the accounting restatement.

Director Compensation Program

Our non-employee directors receive the following compensation pursuant to our Non-Employee Directors Compensation Plan, which is a subplan of our Amended and Restated 2015 Incentive Plan:

Cash Compensation:

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

Equity Compensation:

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

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

2024 Director Compensation Table

The following table sets forth the cash and other compensation we paid to the non-employee members of our Board of Directors for all services in all capacities during 2024.

In addition, in 2024 the Board formed a Special Committee to review and evaluate potential strategic alternatives involving the Company. The Special Committee consisted of Barry Salzman (Chair), Christian Béchon, and Amit Sharma, M.D. In consideration for their services on the Special Committee, the Chair received a one-time retainer of $50,000, and a monthly retainer of $10,000 (not to exceed $50,000), and the other members received a one-time retainer of $30,000 and a monthly retainer of $5,000 (not to exceed $20,000).

Name	Fees Earned or Paid in Cash ($)[1]	Stock Awards ($)[2]	Total ($)
Neil Herskowitz	60,000	167,685	227,685
Barry Salzman	120,000	167,685	287,685
Scott Boilen[3]	4,167	—	4,167
Christian Béchon	90,000	161,736	251,736
Michael S. Weiss[4]	60,000	156,435	216,435
Lindsay A. Rosenwald	50,000	156,435	206,435
Amit Sharma[5]	80,278	150,000	230,278

(1) Represents cash retainer for serving on our Board and committees of our Board.

(2) Reflects the aggregate grant date fair value of restricted stock granted during the fiscal year calculated in accordance with FASB ASC Topic 718.

(3) Mr. Boilen resigned from our Board effective January 31, 2024.

(4) Reflects the compensation paid under an Advisory Agreement with Caribe BioAdvisors, LLC for the service of Mr. Weiss as Chairman of our Board. In June 2023, Mr. Weiss assigned the agreement to Hawkins BioVentures, LLC.

(5) Dr. Sharma was appointed to our Board effective March 12, 2024.

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

The following table shows information, as of March 25, 2025, concerning the beneficial ownership of our common stock by:

- each person we know to be the beneficial owner of more than 5% of our common stock;
- each of our current directors; and
- each of our NEOs shown in our Summary Compensation Table.

ALL CURRENT DIRECTORS AND NEOS AS A GROUP

As of March 25, 2025, there were 83,063,733 shares of our common stock outstanding and 700,000 shares of our Class A common stock outstanding. In order to calculate a stockholder's percentage of beneficial ownership, we include in the calculation those shares underlying options or warrants beneficially owned by that stockholder that are vested or that will vest within 60 days of March 25, 2025. Shares of restricted stock are deemed to be outstanding. Options or warrants held by other stockholders that are not attributed to the named beneficial owner are disregarded in this calculation. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of our common stock. Unless we have indicated otherwise, each person named in the table below has sole voting power and investment power for the shares listed opposite such person's name, except to the extent authority is shared by spouses under community property laws.

	Common Stock Beneficially Owned	
Name and Address of Beneficial Owner(1)	**Amount and Nature of Beneficial Ownership**	**Percentage of Total Common Stock**
Michael S. Weiss	174,812 (2)	0.2 %(2)
James F. Oliviero	3,775,019	4.5 %
Garrett Gray	1,458,644	1.8 %
Lindsay A. Rosenwald, M.D.	194,812 (2)	0.2 %(2)
Neil Herskowitz	134,812	0.2 %
Christian Béchon	129,523	0.2 %
Barry Salzman	134,812	0.2 %
Amit Sharma, M.D.	82,051	0.1 %
All executive officers and directors as a group	5,984,485 (3)	7.2 %(3)
5% or Greater Stockholders:		
Fortress Biotech, Inc.	6,222,249 (4)	7.5 %
Beryl Capital Management LLC	6,074,216 (5)	7.3 %
Armistice Capital, LLC	5,216,445 (6)	6.3 %

(1) The address of each of the directors and officers listed is c/o Checkpoint Therapeutics, Inc., 95 Sawyer Road, Suite 110, Waltham, MA 02453.

(2) Includes 50,000 warrants issued by Fortress to each of Mr. Weiss and Dr. Rosenwald that cover shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.

(3) The total calculation for all executive officers and directors as a group does not include Mr. Weiss' and Dr. Rosenwald's warrants, which have not yet been exercised. The shares underlying the warrants are currently held by Fortress and are included in the 6,222,249 shares of common stock shown as held by Fortress.

(4) The address of Fortress Biotech is 1111 Kane Concourse, Suite 301, Bay Harbor Islands, FL 33154. Includes 100,000 shares of common stock underlying the warrants granted by Fortress to Mr. Weiss and Dr. Rosenwald.

(5) Share ownership reported above is based on a Schedule 13G filed by Beryl Capital Management LLC on March 17, 2025. The address of Beryl Capital Management LLC is 225 Avenue I, Suite 205, Redondo Beach, California 90277.

(6) Share ownership reported above is based on a Schedule 13G/A filed by Armistice Capital, LLC on February 14, 2025. Armistice Capital, LLC holds certain warrants which are exercisable for shares of common stock of the Company. These warrants provide that the holder may not exercise the warrants to the extent such exercise would cause the holder, together with its affiliates, to beneficially own a number of common shares which would exceed 4.99% of the then-outstanding common shares following such exercise. Since Armistice Capital, LLC's ownership was above 4.99% as of March 25, 2025, no warrants were assumed exercised given the ownership limitations set forth above. The address of Armistice Capital, LLC is 510 Madison Avenue, 7th Floor, New York, New York 10022.

	Class A Common Stock Beneficially Owned	
Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Total Class A Common Stock
Fortress Biotech, Inc.	700,000	100 %

The Company is authorized to issue 175,000,000 common shares with a par value of $0.0001 per share, of which 700,000 shares are designated as "Class A common stock". Dividends are to be distributed pro-rata to the Class A and common stockholders. The holders of common stock are entitled to one vote per share of common stock held. The Class A common stockholders are entitled to a number of votes per share equal to 1.1 times a fraction the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of Class A common stock. Accordingly, the holder of shares of Class A common stock will be able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Each share of Class A common stock is convertible, at the option of the holder thereof, into one fully paid and non-assessable share of common stock subject to adjustment for stock splits and combinations.

All outstanding and issued Class A common stock is presently held by Fortress. As such, the following table shows information, as of March 25, 2025, concerning the aggregated beneficial ownership on an as-converted basis of Fortress, inclusive of both its common stock and Class A common stock:

	Common Stock Beneficially Owned Assuming Conversion of Class A Common to Common	
Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Total Common Stock
Fortress Biotech, Inc.	6,922,249 (1)	8.3 %(2)

(1) Assumes one-for-one conversion of 700,000 shares of Class A common stock to 700,000 shares of common stock.

(2) Calculated by aggregating 6,222,249 shares of common stock outstanding plus 700,000 shares of Class A common stock outstanding (Fortress' aggregated ownership on an as-converted basis), divided by 83,763,733.

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

The following is a summary of each transaction or series of similar transactions since the beginning of the 2023 fiscal year to which we were or are a party and that:

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

Effective March 17, 2015, we entered into a Founders Agreement with Fortress, which was amended in July 2016 and October 2017 (the "Founders Agreement"). The Founders Agreement provides, that in exchange for the time and capital expended in the formation of the Company and the identification of specific assets the acquisition of which resulted in the formation of a viable emerging growth life science company, we assumed $2.8 million in debt that Fortress accumulated under a promissory note through National Securities

Corporation for expenses and costs of forming the Company. Further, we shall also: (i) issue annually to Fortress, on January 1 of each year, shares of common stock equal to two and one-half percent (2.5%) of the fully-diluted outstanding equity of the Company at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for the Company or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in our voting equity, equal to two and one-half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of our annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), we will pay a one-time change in control fee equal to five times (5x) the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%). The Founders Agreement has a term of fifteen years, after which it automatically renews for one-year periods unless Fortress gives us notice of termination. The Founders Agreement will also automatically terminate upon a change of control.

Effective March 17, 2015, we entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). We are obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, we are not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of our actions or inactions based upon their advice. Fortress and its affiliates, including all members of its Board of Directors, have been contractually exempt from fiduciary duties to us relating to corporate opportunities. In consideration for the Services, we will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which we have net assets in excess of $100 million at the beginning of the calendar year. The MSA shall be automatically extended for additional five-year periods unless Fortress or we provide notice to the other party of its desire not to automatically extend the term. For the years ended December 31, 2024 and 2023, we recognized $0.5 million in expense in our Statements of Operations related to the MSA.

Michael S. Weiss, our Chairman of the Board of Directors, is currently Executive Vice Chairman of Fortress and Lindsay A. Rosenwald, M.D, a member of our Board of Directors, is currently Chairman, President and Chief Executive Officer of Fortress.

In December 2016, our Board of Directors approved and authorized the execution of an advisory agreement effective as of January 1, 2017 (the "Advisory Agreement") with Caribe BioAdvisors, LLC (the "Advisor"), owned by Michael S. Weiss, the Chairman of our Board, to provide our Board advisory services of Mr. Weiss as Chairman of our Board. Pursuant to the Advisory Agreement, the Advisor will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of our Board. In June 2023, Mr. Weiss assigned the agreement to Hawkins BioVentures, LLC. For the years ended December 31, 2024 and 2023, we recognized approximately $153,000 and $110,000, respectively, in expenses in our Statements of Operations related to the advisory agreement, including $93,000 and $50,000 in expenses related to equity incentive grants.

In connection with our license agreement with Dana-Farber, in March 2015 we entered into a collaboration agreement with TG Therapeutics ("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 retained the right to develop and commercialize these antibodies in solid tumors. Michael Weiss, Chairman of our Board of Directors 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, TGTX agreed to mutually terminate the collaboration agreement, with full rights reverting back to us. For the years ended December 31, 2024 and 2023, we recognized approximately $41,000 and $58,000 respectively, in revenue from our collaboration agreement with TGTX in the Statements of Operations.

In connection with the license agreement with Jubilant, we entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while we retained the right to develop and commercialize these compounds in the field of solid tumors. Effective September 30, 2023, TGTX agreed to mutually terminate the sublicense agreement, with full rights reverting back to us. For the year ended December 31, 2023, we recognized $46,000 in revenue related to the sublicense agreement in our Statements of Operations.

Concurrently with the execution of the Merger Agreement, we entered into a Support Agreement (the "Support Agreement") with Parent and Fortress. Under the terms of the Support Agreement, Fortress has agreed to, among other things, during the term of the Support Agreement, (i) vote its Shares that it owns of record or beneficially, as well as any additional Shares it may acquire (the "Covered Shares") in favor of the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement, and against any acquisition proposal or any action, proposal, agreement, transaction or arrangement that is intended, or would reasonably expected, to result in a material breach of a covenant, representation or warranty or any obligation of ours under the Merger Agreement or any of the conditions to our obligations under the Merger Agreement not being fulfilled or satisfied, (ii) not transfer any of its Covered Shares (subject to certain exceptions) and (iii) waive and not to exercise any appraisal rights in respect of such Covered Shares that may arise with respect to the Merger and not to commence or participate in, any class action or legal action (a) challenging the validity of, or seeking to enjoin or delay the operation of any provision of the Merger Agreement or (b) with respect to claims against our Board, or any committee thereof, Parent of Merger Sub relating to the Merger Agreement or the transactions contemplated thereby.

Under the Support Agreement, subject to the occurrence of the effective time of the Merger, Fortress also agreed to forgo any further payment, dividend or distribution, or issuance or transfer of securities by us on or after the date of the Support Agreement pursuant to the Amended and Restated Founders Agreement, dated as of July 11, 2016, as amended (the "Founders Agreement") between Fortress and us and certain other agreements between Fortress and us. The Support Agreement further provides that effective immediately prior to, but conditioned upon the closing of the Merger, the Founders Agreement shall be terminated.

Concurrently with the execution of the Merger Agreement, we entered into a Royalty Agreement (the "Royalty Agreement") with Parent and Fortress pursuant to which following, and subject to the occurrence of, the effective time of the Merger, Fortress will receive a royalty interest right based on worldwide net sales of certain products of ours and Parent. The royalty interest right represents the right to receive quarterly cash payments of 2.5% of net sales of such products during the time period set forth in the Royalty Agreement.

Pursuant to the Merger Agreement, as of or prior to the effective time of the Merger, the Company and Fortress will enter into a Transition Services Agreement (the "Transition Services Agreement"), pursuant to which, from and after the effective time of the Merger, Fortress would provide the Company with certain transition services as set forth in the Transition Services Agreement, for the period of time and in exchange for the compensation set forth therein.

Item 14. Principal Accounting Fees and Services

Audit Fees

For the fiscal years ended December 31, 2024 and 2023, KPMG billed us an aggregate of approximately $424,760 and $417,000, respectively, in fees for the professional services rendered in connection with the audit of our annual financial statements included in our Annual Report on Form 10-K for those two fiscal years, the review of our financial statements included in our Quarterly Reports on Form 10-Q during those two fiscal years, and other services provided in connection with registration statements.

Audit-Related Fees

During the fiscal years ended December 31, 2024 and 2023, we were not billed by KPMG for any fees for audit-related services reasonably related to the performance of the audits and reviews for those two fiscal years, in addition to the fees described above under the heading "Audit Fees."

Tax Fees

During the fiscal years ended December 31, 2024 and 2023, we were billed approximately $31,576 and $26,750, respectively, by KPMG for fees for professional services rendered for tax compliance, tax advice, and tax planning services.

All Other Fees

During the fiscal years ended December 31, 2024 and 2023, we were not billed by KPMG for any fees for services, other than those described above, rendered to us for those two fiscal years.

Pre-Approval of Services

Our Audit Committee has established a policy setting forth the procedures under which services provided by our independent registered public accounting firm will be pre-approved by our Audit Committee. The potential services that might be provided by our independent registered public accounting firm fall into two categories:

- Services that are permitted, including the audit of our annual financial statements, the review of our quarterly financial statements, related attestations, benefit plan audits and similar audit reports, financial and other due diligence on acquisitions, and federal, state, and non-US tax services; and
- Services that may be permitted, subject to individual pre-approval, including compliance and internal-control reviews, indirect tax services such as transfer pricing and customs and duties, and forensic auditing.

Services that our independent registered public accounting firm are prohibited from providing include such services as bookkeeping, certain human resources services, internal audit outsourcing, and investment or investment banking advice.

All proposed engagements of our independent registered public accounting firm, whether for audit services or permissible non-audit services, are pre-approved by the Audit Committee. We jointly prepare a schedule with our independent registered public accounting firm that outlines services which we reasonably expect we will need from our independent registered public accounting firm and categorize them according to the classifications described above. Each service identified is reviewed and approved or rejected by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)Financial Statements.

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

(b)Exhibits.

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of March 9, 2025, by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc., and Snoopy Merger Sub, Inc., filed as Exhibit 2.1 to Form 8-K filed on March 10, 2025 (File No. 001-38128) and incorporated herein by reference. **
3.1	Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.2.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 7, 2018 (File No. 001-38128) and incorporated herein by reference.
3.2.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 4, 2020 (File No. 001-38128) and incorporated herein by reference.
3.2.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 11, 2021 (File No. 001-38128) and incorporated herein by reference.
3.2.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on December 5, 2022 (File No. 001-38128) and incorporated herein by reference.
3.2.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 13, 2023 (File No. 001-38128) and incorporated herein by reference.
3.2.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Checkpoint Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on May 14, 2024 (File No. 001-38128) and incorporated herein by reference.
3.3	Bylaws of Checkpoint Therapeutics, Inc., filed as Exhibit 3.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
3.3.1	Bylaw Amendment, dated as of March 9, 2025, filed as Exhibit 3.1 to Form 8-K filed on March 10, 2025 (File No. 001-38128) and incorporated herein by reference.
4.1	Specimen certificate evidencing shares of common stock, filed as Exhibit 4.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.2	Form of warrant agreement, filed as Exhibit 4.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
4.3	Form of pre-funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8-K filed on December 16, 2022 (File No. 001-38128) and incorporated herein by reference.
4.4	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.2 to Form 8-K filed on December 16, 2022 (File No. 001-38128) and incorporated herein by reference.
4.5	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8-K filed on December 15, 2022 (File No. 001-38128) and incorporated herein by reference.
4.6	Description of Securities of Checkpoint Therapeutics, Inc. *
4.7	Form of pre - funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8 - K filed on February 22, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.8	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.2 to Form 8 - K filed on February 22, 2023 (File No. 001 - 38128) and incorporated herein by reference.

Exhibit No.	Description
4.9	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8 - K filed on February 22, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.10	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.1 to Form 8 - K filed on April 4, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.11	Form of placement agent warrant, filed as Exhibit 4.2 to Form 8 - K filed on April 4, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.12	Form of pre - funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8 - K filed on May 24, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.13	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.2 to Form 8 - K filed on May 24, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.14	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8 - K filed on May 24, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.15	Form of pre - funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8 - K filed on July 31, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.16	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.2 to Form 8 - K filed on July 31, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.17	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8 - K filed on July 31, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.18	Form of Series A/B common stock purchase warrant, filed as Exhibit 4.1 to Form 8 - K filed on October 3, 2023 (File No. 001 - 38128) and incorporated herein by reference.
4.19	Form of placement agent warrant, filed as Exhibit 4.2 to Form 8-K filed on October 3, 2023 (File No. 001-38128) and incorporated herein by reference.
4.20	Form of pre-funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8-K filed on January 30, 2024 (File No. 001-38128) and incorporated herein by reference.
4.21	Form of common stock purchase warrant, filed as Exhibit 4.2 to Form 8-K filed on January 30, 2024 (File No. 001-38128) and incorporated herein by reference.
4.22	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8-K filed on January 30, 2024 (File No. 001-38128) and incorporated herein by reference.
4.23	Form of pre-funded common stock purchase warrant, filed as Exhibit 4.1 to Form 8-K filed on July 3, 2024 (File No. 001-38128) and incorporated herein by reference.
4.24	Form of common stock purchase warrant, filed as Exhibit 4.2 to Form 8-K filed on July 3, 2024 (File No. 001-38128) and incorporated herein by reference.
4.25	Form of placement agent warrant, filed as Exhibit 4.3 to Form 8-K filed on July 3, 2024 (File No. 001-38128) and incorporated herein by reference.
4.26	Form of Indenture, filed as Exhibit 4.4 to Form S-3 filed on March 24, 2023 (File No. 001-38128) and incorporated herein by reference.
4.27	Letter Agreement, dated as of March 9, 2025, by and between Checkpoint Therapeutics, Inc. and Armistice Capital Master Fund Ltd., filed as Exhibit 4.1 to Form 8-K filed on March 10, 2025 (File No. 001-38128) and incorporated herein by reference.

Exhibit No.	Description
10.1	Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.1 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.2	Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated July 11, 2016 and effective as of March 17, 2015, filed as Exhibit 10.2 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.3	Amendment 1 to Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc., dated October 5, 2017 filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 3, 2017 (File No. 001-38128) and incorporated herein by reference.
10.4	Management Services Agreement between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.3 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.5	Common Stock Warrant issued by Checkpoint Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC dated July 30, 2015, filed as Exhibit 10.5 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference.
10.6	License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute, Inc. dated March 2, 2015, filed as Exhibit 10.6 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.7	Amendment 1 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 5, 2015, filed as Exhibit 10.7 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.8	Amendment 2 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated April 12, 2016, filed as Exhibit 10.8 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.9	Amendment 3 to License Agreement by and between Checkpoint Therapeutics, Inc. and Dana-Farber Cancer Institute dated October 24, 2016, filed as Exhibit 10.9 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.10	License Agreement by and between NeuPharma Inc. and Coronado Biosciences, Inc. (Fortress' predecessor) dated March 17, 2015 (assigned to Checkpoint Therapeutics, Inc. under the Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015), filed as Exhibit 10.8 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.11	Amendment 1 to License Agreement by and between NeuPharma Inc. and Checkpoint Therapeutics, Inc. dated February 21, 2017, filed as Exhibit 10.11 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.12	Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated March 3, 2015, filed as Exhibit 10.9 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.12.1	Amended and Restated Collaboration Agreement by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated June 19, 2019, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 8, 2019 (File No. 001-38128) and incorporated herein by reference. **
10.12.2	Mutual Termination Agreement (Sublicense) by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated September 30, 2023, filed as Exhibit 10.12.2 to Form 10 - K filed on March 22, 2024 (File No. 001 - 38128) and incorporated herein by reference.

Exhibit No.	Description
10.12.3	Mutual Termination Agreement (Collaboration) by and between Checkpoint Therapeutics, Inc. and TG Therapeutics, Inc. dated September 30, 2023, filed as Exhibit 10.12.3 to Form 10 - K filed on March 22, 2024 (File No. 001 - 38128) and incorporated herein by reference.
10.13	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.10 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.13.1	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 9, 2017 (File No. 001-38128) and incorporated herein by reference. #
10.14	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Form 8-K filed on June 4, 2020 (File No. 001-38128) and incorporated herein by reference. #
10.14.1	Amendment to Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Form 8-K on December 5, 2022 (File No. 001-38128) and incorporated herein by reference. #
10.15	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Form 8 - K filed on June 13, 2023 (File No. 001 - 38128) and incorporated herein by reference. #
10.15.1	Checkpoint Therapeutics, Inc. Amended and Restated 2015 Incentive Plan, filed as Exhibit 10.1 to Form 8-K filed on May 14, 2024 (File No. 001-38128) and incorporated herein by reference. #
10.16	Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated October 13, 2015, filed as Exhibit 10.11 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.17	Amendment to Executive Employment Agreement by and between James F. Oliviero III and Checkpoint Therapeutics, Inc. dated September 27, 2016, filed as Exhibit 10.1 to Form 8-K filed on October 3, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.18	Amendment No. 2, dated December 15, 2016, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.16 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.19	Amendment No. 3, dated January 30, 2018, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.16.1 to Annual Report on Form 10-K filed on March 16, 2018 (File No. 001-38128) and incorporated herein by reference. #
10.20	Amendment No. 4, dated October 7, 2019, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 12, 2019 (File No. 001-38128) and incorporated herein by reference. #
10.21	Amendment No. 5, dated September 24, 2020, to the Executive Employment Agreement dated October 13, 2015, by and between Checkpoint Therapeutics, Inc. and James F. Oliviero III, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 6, 2020 (File No. 001-38128) and incorporated herein by reference. #
10.22	Executive Employment Agreement by and between William Garrett Gray and Checkpoint Therapeutics, Inc. dated January 7, 2025, filed as Exhibit 10.1 to Form 8-K filed on January 10, 2025 (File No. 001-38128) and incorporated herein by reference. #
10.23	Non-Employee Directors Compensation Plan, filed as Exhibit 10.13 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. #
10.24	Amended and Restated Non-Employee Directors Compensation Plan, filed as Exhibit 10.2 to Quarterly Report on Form 10-Q filed on August 9, 2017 (File No. 001-38128) and incorporated herein by reference. #

Exhibit No.	Description
10.25	Amended and Restated Non-Employee Directors Compensation Plan, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 14, 2023 (File No. 001-38128) and incorporated herein by reference. #
10.26	Amended and Restated Non-Employee Directors Compensation Plan, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on May 10, 2024 (File No. 001-38128) and incorporated herein by reference. #
10.27	Board Advisory Services Agreement by and between Caribe BioAdvisors, LLC and Checkpoint Therapeutics, Inc. dated January 1, 2017, filed as Exhibit 10.19 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference. #
10.28	License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.18 to Form 10-12G filed on July 11, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.29	Amendment 1 to License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc. dated December 13, 2016, filed as Exhibit 10.26 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.30	Amendment 2 to License Agreement by and between Jubilant Biosys Limited and Checkpoint Therapeutics, Inc. dated March 31, 2017, filed as Exhibit 10.2 to Quarterly Report on Form 10-Q filed on May 10, 2017 (File No. 000-55506) and incorporated herein by reference.
10.31	Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated May 26, 2016, filed as Exhibit 10.19 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference. **
10.32	Amendment 1 to Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc. dated December 13, 2016, filed as Exhibit 10.28 to Annual Report on Form 10-K filed on March 17, 2017 (File No. 000-55506) and incorporated herein by reference.
10.33	Amendment 2 to Sublicense Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2017, filed as Exhibit 10.1 to Quarterly Report on Form 10-Q filed on May 10, 2017 (File No. 000-55506) and incorporated herein by reference.
10.34	Assignment and Assumption Agreement by and between Fortress Biotech, Inc. and Checkpoint Therapeutics, Inc. dated March 17, 2015, filed as Exhibit 10.21 to Form 10-12G/A filed on August 19, 2016 (File No. 000-55506) and incorporated herein by reference.
10.35	Collaboration Agreement by and between Adimab, LLC and Checkpoint Therapeutics, Inc., dated January 22, 2019, filed as exhibit 10.31 to Annual Report on Form 10-K filed on March 18, 2019 (File No. 001-38128) and incorporated herein by reference. **
10.36	Master Services Agreement, dated November 8, 2017, between Checkpoint Therapeutics, Inc. and Samsung Biologics Co., Ltd., filed as Exhibit 10.2 to Quarterly Report on Form 10-Q filed on November 6, 2020 (File No. 001-38128) and incorporated herein by reference. **
10.37	Securities Purchase Agreement, dated December 14, 2022, between Checkpoint Therapeutics, Inc. and the Purchaser named therein, filed as Exhibit 10.1 to Form 8-K filed on December 16, 2022 (File No. 001-38128) and incorporated herein by reference.
10.38	Securities Purchase Agreement, dated February 20, 2023, between Checkpoint Therapeutics, Inc. and the Purchaser named therein, filed as Exhibit 10.1 to Form 8-K filed on February 22, 2023 (File No. 001-38128) and incorporated herein by reference.
10.39	Securities Purchase Agreement, dated March 30, 2023, between Checkpoint Therapeutics, Inc. and the Purchasers named therein, filed as Exhibit 10.1 to Form 8-K filed on April 4, 2023 (File No. 001-38128) and incorporated herein by reference.

Exhibit No.	Description
10.40	Securities Purchase Agreement, dated May 23, 2023, between Checkpoint Therapeutics, Inc. and the Purchaser named therein, filed as Exhibit 10.1 to Form 8-K filed on May 24, 2023 (File No. 001-38128) and incorporated herein by reference.
10.41	Securities Purchase Agreement, dated July 28, 2023, between Checkpoint Therapeutics, Inc. and the Purchasers named therein, filed as Exhibit 10.1 to Form 8-K filed on July 31, 2023 (File No. 001-38128) and incorporated herein by reference.
10.42	Securities Purchase Agreement, dated January 27, 2024, between Checkpoint Therapeutics, Inc. and the Purchasers named therein, filed as Exhibit 10.1 to Form 8-K filed on January 30, 2024 (File No. 001-38128) and incorporated herein by reference.
10.43	Securities Purchase Agreement, dated July 2, 2024, between Checkpoint Therapeutics, Inc. and the Purchasers named therein, filed as Exhibit 10.1 to Form 8-K filed on July 3, 2024 (File No. 001-38128) and incorporated herein by reference.
10.44	Inducement Offer to Exercise Warrants Issued in December 2022 and February 2023, filed as Exhibit 10.1 to Form 8-K filed on October 3, 2023 (File No. 001-38128) and incorporated herein by reference.
10.45	Support Agreement, dated as of March 9, 2025, by and among Checkpoint Therapeutics, Inc., Sun Pharmaceutical Industries, Inc. and Fortress Biotech, Inc., filed as Exhibit 10.1 to Form 8-K filed on March 10, 2025 (File No. 001-38128) and incorporated herein by reference. **
10.46	Change in Control Severance Plan. *
19.1	Insider Trading Plan. *
23.1	Consent of Independent Registered Public Accounting Firm, KPMG, LLP. *
24.1	Power of Attorney (included on signature page). *
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
97.1	Policy Related to Recovery of Erroneously Awarded Compensation, filed as Exhibit 97.1 to Form 10-K filed on March 22, 2024 (File No. 001-38128) and incorporated herein by reference.
101	The following financial information from the Company's Annual Report on Form 10-K for the period ended December 31, 2024, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statement of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.
104	Cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL.

* Filed herewith.
** Certain portions of this exhibit have been omitted pursuant to Item 601(b) of Regulation S-K.
# Management Compensation Arrangement.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Checkpoint Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

KPMG LLP

We have served as the Company's auditor since 2022.

Boston, Massachusetts
March 28, 2025

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

	December 31,	
	2024	**2023**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,604	$ 4,928
Prepaid expenses and other assets	867	450
Total current assets	7,471	5,378
Total Assets	**$ 7,471**	**$ 5,378**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 17,465	$ 15,485
Accounts payable and accrued expenses - related party	2,433	2,815
Common stock warrant liabilities	198	125
Total current liabilities	20,096	18,425
Total Liabilities	**20,096**	**18,425**
Commitments and Contingencies (Note 5)		
Stockholders' Equity (Deficit)		
Common Stock ($0.0001 par value), 175,000,000 and 80,000,000 shares authorized as of December 31, 2024 and 2023, respectively		
Class A common shares, 700,000 shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common shares, 53,640,422 and 27,042,035 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	5	3
Common stock issuable, 2,386,808 and 1,492,915 shares as of December 31, 2024 and December 31, 2023, respectively	7,638	3,419
Additional paid-in capital	350,305	297,864
Accumulated deficit	(370,573)	(314,333)
Total Stockholders' Equity (Deficit)	(12,625)	(13,047)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 7,471**	**$ 5,378**

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

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

	For the year ended December 31,	
	2024	**2023**
Revenue - related party	$ 41	$ 103
Operating expenses:		
Research and development	36,152	43,566
General and administrative	20,063	8,685
Total operating expenses	56,215	52,251
Loss from operations	(56,174)	(52,148)
Other income (loss):		
Interest income	11	84
Gain (loss) on common stock warrant liabilities	(73)	217
Foreign currency exchange loss	(4)	—
Total other income (loss)	(66)	301
Net Loss	**$ (56,240)**	**$ (51,847)**
Loss per Share:		
Basic and diluted net loss per Class A common share and common share outstanding	$ (1.42)	$ (3.17)
Basic and diluted weighted average number of Class A common shares and common shares outstanding	39,674,444	18,742,494

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

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

	Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	**700,000**	**$ —**	**9,586,683**	**$ 1**	**$ 1,885**	**$ 241,117**	**$ (262,486)**	**$ (19,483)**
Stock-based compensation expense	—	—	1,091,098	—	—	2,897	—	2,897
Issuance of common shares, net of offering costs - Registered direct offerings	—	—	6,957,186	1	—	30,124	—	30,125
Issuance of common shares - Founders Agreement	—	—	767,567	—	(1,885)	2,837	—	952
Common shares issuable - Founders Agreement	—	—	—	—	3,419	—	—	3,419
Exercise of prefunded and common stock warrants, including inducement	—	—	8,639,501	1	—	20,889	—	20,890
Net loss	—	—	—	—	—	—	(51,847)	(51,847)
Balances at December 31, 2023	**700,000**	**$ —**	**27,042,035**	**$ 3**	**$ 3,419**	**$ 297,864**	**$ (314,333)**	**$ (13,047)**
Stock-based compensation expense	—	—	8,120,658	—	—	15,252	—	15,252
Issuance of common shares, net of offering costs - Registered direct offerings	—	—	2,505,000	2	—	23,590	—	23,592
Issuance of common shares - Founders Agreement	—	—	1,914,568	—	(3,419)	4,414	—	995
Common shares issuable - Founders Agreement	—	—	—	—	7,638	—	—	7,638
Exercise of prefunded and common stock warrants	—	—	14,058,161	—	—	9,185	—	9,185
Net loss	—	—	—	—	—	—	(56,240)	(56,240)
Balances at December 31, 2024	**700,000**	**$ —**	**53,640,422**	**$ 5**	**$ 7,638**	**$ 350,305**	**$ (370,573)**	**$ (12,625)**

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

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

	For the year ended December 31,	
	2024	**2023**
Cash Flows from Operating Activities:		
Net loss	$ (56,240)	$ (51,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	15,252	2,897
Issuance of common shares - Founders Agreement	995	952
Common shares issuable - Founders Agreement	7,638	3,419
Loss (gain) on common stock warrant liabilities	73	(217)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(417)	699
Other receivables - related party	—	73
Accounts payable and accrued expenses	1,980	(5,075)
Accounts payable and accrued expenses - related party	(382)	1,509
Net cash used in operating activities	(31,101)	(47,590)
Cash Flows from Financing Activities:		
Issuance of common shares - Registered direct offerings	26,000	33,621
Payment of offering costs for the issuance of common shares – Registered direct offerings	(2,408)	(3,289)
Cash received for exercise of warrants	9,185	11,134
Payment of transactional costs for exercise of warrants	—	(1,016)
Net cash provided by financing activities	32,777	40,450
Net increase (decrease) in cash and cash equivalents	1,676	(7,140)
Cash and cash equivalents at beginning of period	4,928	12,068
Cash and cash equivalents at end of period	**$ 6,604**	**$ 4,928**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 3,419	$ 1,885
Issuance of common shares - Registered direct offerings (offering costs incurred but not paid)	$ —	$ 207
Warrant inducement (transactional costs incurred but not paid)	$ —	$ 56

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

Note 1 - Organization and Description of Business Operations

Checkpoint Therapeutics, Inc. (the "Company" or "Checkpoint") was incorporated in Delaware on November 10, 2014. Checkpoint is a commercial-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. On December 13, 2024, Checkpoint announced that the U.S. Food and Drug Administration ("FDA") granted approval of cosibelimab-ipdl, now referred to as UNLOXCYT™, for the treatment of adults with metastatic cutaneous squamous cell carcinoma ("CSCC") or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The Company may acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

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

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

Liquidity, Capital Resources and Going Concern

The Company has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2024, the Company had an accumulated deficit of $370.6 million.

In February 2023, the Company closed on a registered direct offering (the "February 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,180,000 shares of its common stock at a purchase price of $5.25 per share in a registered direct offering. In addition, the offering includes 248,572 shares of common stock in the form of pre-funded warrants at a price of $5.2499. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to1,428,572 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $5.00 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $7.5 million with net proceeds of approximately $6.7 million after deducting approximately $0.8 million in commissions and other transaction costs.

In April 2023, the Company closed on a registered direct offering (the "April 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,700,000 shares of its common stock at a purchase price of $3.60 per share of common stock in a registered direct offering. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,700,000 shares of common stock and Series B warrants to purchase up to 1,700,000 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $3.35 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $6.1 million with net proceeds of approximately $5.5 million after deducting approximately $0.6 million in commissions and other transaction costs.

In May 2023, the Company closed on a registered direct offering (the "May 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 1,650,000 shares of its common stock at a purchase price of $3.071 per share of common stock in a registered direct offering. In addition, the offering includes 1,606,269 shares of common stock in the form of pre-funded warrants at a price of $3.0709. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,256,269 shares of common stock and Series B warrants to purchase up to3,256,269 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.821 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs.

In July 2023, the Company closed on a registered direct offering (the "July 2023 Registered Direct Offering") for the issuance and sale of an aggregate of 2,427,186 shares of its common stock at a purchase price of $3.09 per share of common stock in a registered direct offering. In addition, the offering includes 809,062 shares of common stock in the form of pre-funded warrants at a price of $3.0899. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,236,248 shares of common stock and Series B warrants to purchase up to3,236,248 shares of common stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.84 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The total gross proceeds from the offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs.

In October 2023, the Company entered into an inducement offer letter agreement (the "October 2023 Inducement") with a certain holder of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of the Company's common stock at a reduced exercise price of $1.76 per share. The warrants were issued to the holder as part of the December 2022 Registered Direct Offering with an exercise price of $4.075 per share and as part of the February 2023 Registered Direct Offering with an exercise price of $5.00 per share. As part of the October 2023 Inducement, the Company agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Common Stock (collectively, the "October 2023 Common Stock Warrants"). The October 2023 Common Stock Warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire twenty-four months following the issuance date. The total gross proceeds from the exercise were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs.

In January 2024, the Company closed on a registered direct offering (the "January 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,275,000 shares of its common stock at a purchase price of $1.805 per share of common stock. In addition, the offering includes6,481,233 shares of common stock in the form of pre-funded warrants at a price of $1.8049. In a concurrent private placement, the Company issued and sold common warrants to purchase up to 7,756,233 shares of common stock. The common warrants are exercisable immediately upon issuance with an exercise price of $1.68 per share and expire five years following the issuance date. The total gross proceeds from the January 2024 Registered Direct Offering were approximately $14.0 million with net proceeds of approximately $12.6 million after deducting approximately $1.4 million in commissions and other transaction costs.

In July 2024, the Company closed on a registered direct offering (the "July 2024 Registered Direct Offering") for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of $2.05 per share of common stock. In addition, the offering includes4,623,659 shares of common stock in the form of pre-funded warrants at a price of $2.0499. In a concurrent private placement, the Company issued and sold common warrants to purchase up to 5,853,659 shares of common stock. The common warrants will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise with an exercise price of $2.05 per share and expire five years following the issuance date. The total gross proceeds from the July 2024 Registered Direct Offering were approximately $12.0 million with net proceeds of approximately $11.0 million after deducting approximately $1.0 million in commissions and other transaction costs.

In November 2024, the Company received approximately $9.2 million from the full exercise of existing Series B warrants for the issuance of3,256,269 shares of common stock from the May 2023 Registered Direct Offering with an exercise price of $2.821 per share. Due to the beneficial ownership limitation provisions in the securities purchase agreement, the shares were initially unissued and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2024, 1,437,000 shares remained in abeyance. These shares were fully issued to the holder in February 2025.

The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, which may include financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments.

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these financial statements are issued. This evaluation initially does not take into consideration the potential

mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future equity or debt issuances and other potential sources such as partnerships cannot be considered probable at this time because these plans are not entirely within the Company's control nor have these plans been approved by the Board as of the date of these financial statements.

The Company believes that its cash and cash equivalents are only sufficient to fund its operating expenses into the fourth quarter of 2025. The Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that these financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include reduced 2025 spending, including projected savings through delaying the development timelines of certain programs and the pursuit of additional cash resources through public or private equity or debt financings and potential partnerships. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements. The Company's estimate as to how long it expects its existing cash to be able to continue to fund its operations is based on assumptions that may prove to be wrong, and it could use its available capital resources sooner than it currently expects. Further, changing circumstances, some of which may be beyond its control, could cause the Company to consume capital faster than it currently anticipates, and it may need to seek additional funds sooner than planned. The Company cannot be certain that additional funding will be available to it on acceptable terms, or at all.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Note 2 - Significant Accounting Policies

Basis of Presentation

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

Segments

Operating segments are defined as components of an enterprise that engage in business activities from which it may recognize revenues and incur expenses, and for which discrete financial information is available that is evaluated regularly by the chief operating decision maker ("CODM") to allocate resources and assess performance. The Company operates in one reportable segment, immunotherapy and targeted oncology therapy, which includes all activities related to the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, including UNLOXCYT (see Note 10).

Use of Estimates

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

Cash and Cash Equivalents

The Company considers highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Other Receivables - Related Party

Other receivables consist of amounts due to the Company from TG Therapeutics, Inc. ("TGTX"), a related party, and are recorded at the invoiced amount. Effective September 30, 2023, TGTX agreed to mutually terminate the collaboration agreements.

Inventory

Prior to regulatory approval, the Company expenses costs relating to the production of inventory as research and development expense in the period incurred. Following regulatory approval, costs to manufacture those approved products will be capitalized. Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in-first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the approval of UNLOXCYT, all manufacturing and other potential costs related to the potential commercial launch of UNLOXCYT were expensed to research and development expense in the period incurred.

Research and Development Costs

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

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

Annual Equity Fee

Under the Founders Agreement with Checkpoint dated March 17, 2015 and amended and restated in July 2016 and October 2017 (the "Founders Agreement"), Fortress is entitled to an annual equity fee on January 1 of each year equal to 2.5% of fully diluted outstanding equity of the Company, payable in Checkpoint common shares ("Annual Equity Fee"). The Annual Equity Fee was part of the consideration payable for formation of the Company, identification of certain assets, including the license contributed to Checkpoint by Fortress (see Note 4).

The Company records the Annual Equity Fee in connection with the Founders Agreement with Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. Due to the nature of the Company's assets and stage of development, future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee. Due to these uncertainties, the Company has concluded that it is unable to reasonably estimate the contingent consideration until shares are actually issued on January 1 of each year.

Pursuant to the Founders Agreement, the Company issued 1,492,915 shares of common stock to Fortress on May 16, 2024 for the Annual Equity Fee, representing 2.5% of the fully diluted outstanding equity of Checkpoint on January 1, 2024. The Company did not have enough unreserved authorized shares under its certificate of incorporation on January 1, 2024 to issue the shares for the Annual Equity Fee. Therefore, in December 2023, Fortress and Checkpoint mutually agreed to defer the issuance until such time as certificate

of incorporation has been amended in order to increase the number of authorized that may be issued thereunder. At the Company's 2024 Annual Meeting of Stockholders held on May 13, 2024, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue. Because the number of outstanding shares issuable to Fortress was determinable on January 1, 2024 prior to the issuance of the December 31, 2023 financial statements, the Company recorded approximately $3.4 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2023.

Pursuant to the Founders Agreement, the Company issued 2,386,808 shares of common stock to Fortress for the Annual Equity Fee, representing 2.5% of the fully diluted outstanding equity of Checkpoint on January 1, 2025. Because the number of outstanding shares issuable to Fortress was determinable on January 1, 2025 prior to the issuance of the December 31, 2024 financial statements, the Company recorded approximately $7.6 million in research and development expense and a credit to Common shares issuable - Founders Agreement during the year ended December 31, 2024.

Stock-Based Compensation Expenses

The Company expenses stock-based compensation over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. The Company accounts for forfeitures as they occur.

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

In addition, because some of the restricted stock, restricted stock units and options issued to employees, directors and consultants vest upon achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestones is probable.

Common Stock Warrant Liability

The Company has issued freestanding warrants to purchase shares of its common stock in connection with its financing activities and accounts for them in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreements. Warrants classified as liabilities are remeasured each period they are outstanding. Any resulting gain or loss related to the change in the fair value of the warrant liability is recognized in gain (loss) on common stock warrant liabilities, a component of other income (loss), in the Statements of Operations.

The Company estimates the fair value of common stock warrant liabilities using the Black-Scholes Model. The assumptions used in calculating the fair value represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Fair Value Measurement

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

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

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

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

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

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable and accrued expenses.

Revenue from Contracts with Customers

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

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

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

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

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

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

- variable consideration;
- constraining estimates of variable consideration;
- the existence of a significant financing component in the contract;
- noncash consideration; and
- consideration payable to a customer

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

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

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

a. the subsequent sale or usage occurs; and
b. the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

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

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not to be sustained upon audit, the Company recognizes the largest amount with a greater than 50% likely of being realized. The Company does not recognize any portion of the benefit for tax positions that are not more likely than not to be sustained upon audit. As of December 31, 2024 and December 31, 2023, the Company determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset.

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of Class A common shares and common shares outstanding during the period. Net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends. The Company recorded a deemed dividend for the modification of certain of its existing warrants and issuance of the October 2023 Common Stock Warrants of $7.5 million during the year ended December 31, 2023 (see Notes 1 and 6). Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The following table summarizes potentially dilutive securities outstanding at December 31, 2024 and 2023 that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	December 31,	
	2024	2023
Warrants (Note 6)	39,567,888	30,097,671
Stock options (Note 6)	127,000	127,000
Unvested restricted stock awards (Note 6)	4,887,499	1,316,120
Unvested restricted stock units (Note 6)	—	615,884
Total	44,582,387	32,156,675

The 1,437,000 shares held in abeyance from the November 2024 warrant exercise as of December 31, 2024 were included in the December 31, 2024 computation of basic and diluted net loss per share since no additional consideration is due upon issuance of the shares. The 1,134,000 shares held in abeyance from the October 2023 Inducement (see Note 6) as of December 31, 2023 were included in the December 31, 2023 computation of basic and diluted net loss per share since no additional consideration is due upon issuance of the shares.

Comprehensive Loss

The Company has no components of comprehensive loss other than net loss. Thus, comprehensive loss is the same as net loss for the periods presented.

Recently Issued Accounting Standards

In October 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Updated and Simplification Initiative*, which amends the disclosure or presentation requirements related to various subtopics in the FASB Accounting Standards Codification. ASU 2023-06 was issued in response to the SEC's August 2018 final rule that updated and simplified disclosure requirements and is intended to align U.S. GAAP requirements with those of the SEC and to facilitate the application of U.S. GAAP for all entities. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC removes that related disclosure from its rules. However, if by June 30, 2027, the SEC has not removed the related disclosure from its regulations, the amendments will be removed from the Codification and not become effective for any entity. The Company is currently evaluating the impact of the new standard on its disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which will require public entities to disclose on an annual basis a tabular reconciliation using both percentages and amounts, broken out into specific categories with certain reconciling items at or above 5% of the statutory (i.e. expected) tax further broken out by nature and/or jurisdiction. The ASU requires all entities to disclose on an annual basis the amount of income taxes paid (net of refunds received), disaggregated between federal (national), state/local and foreign, and amounts paid to an individual jurisdiction when 5% or more of the total income taxes paid. The guidance is required to be applied on a prospective basis; retrospective application is permitted. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. Although the guidance only requires additional disclosures, the Company is in the process of determining the impact of this guidance to its income tax disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which will require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. The guidance is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of the new standard on its disclosures.

Recently Adopted Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which amends ASC 280, *Segment Reporting* to require public entities to disclose significant segment expenses and other segment items that are regularly provided to the CODM and included in each reported measure of a reportable segment's profit or loss, on an annual and interim basis, and provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The ASU permits entities to report multiple measures of a reportable segment's profit or loss if the CODM uses those measures to allocate resources and assess performance. The guidance is required to be applied retrospectively to all periods presented in the financial statements, unless impracticable. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted the new standard as of January 1, 2024, and the adoption of this guidance did not have a material impact on its financial statements (see Note 10).

Note 3 - License Agreements

Dana-Farber Cancer Institute

In March 2015, the Company entered into an exclusive license agreement with Dana-Farber Cancer Institute ("Dana Farber") to develop a portfolio of fully human immuno-oncology targeted antibodies targeting PD-L1, Glucocorticoid-induced TNFR-related protein ("GITR") and Carbonic anhydrase IX ("CAIX"). Under the terms of the license agreement, the Company paid Dana-Farber an up-front licensing fee of $1.0 million and, on May 11, 2015, granted Dana-Farber 50,000 shares, valued at $32,500 or $0.65 per share. The license agreement included an anti-dilution clause that maintained Dana-Farber's ownership at 5% until such time that the Company raised $10 million in cash in exchange for common shares. Pursuant to this provision, on September 30, 2015, the Company granted to Dana-Farber an additional 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 the Company's successful achievement of certain clinical development and first commercial sale milestones. As of December 31, 2024, $5.0 million of these milestones have been expensed for the antibody targeting PD-L1. In addition, Dana-Farber is eligible to receive up to an aggregate of $60.0 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Dana-Farber also receives an annual license maintenance fee of $50,000, which is creditable against future milestone payments or royalties.

In connection with the license agreement with Dana-Farber, in March 2015 the Company 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. The Company 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, TGTX agreed to mutually terminate the collaboration agreement. For the years ended December 31, 2024 and 2023, the Company recognized approximately $41,000 and $58,000 respectively, in revenue related to the collaboration agreement with TGTX in the Statements of Operations.

Adimab, LLC

In October 2015, Fortress entered into a collaboration agreement with Adimab, LLC ("Adimab") to discover and optimize antibodies using their proprietary core technology platform. Under this agreement, Adimab optimized UNLOXCYT, the Company's anti-PD-L1 antibody which it originally licensed from Dana-Farber. In January 2019, Fortress transferred the rights to the optimized antibody to the Company, and Checkpoint entered into a collaboration agreement directly with Adimab on the same day. Under the terms of the agreement, Adimab is eligible to receive additional payments from the Company up to an aggregate of approximately $2.5 million upon various filings for regulatory approvals to commercialize the product. In addition, Adimab is eligible to receive royalty payments from the Company based on a tiered low single digit percentage of net sales.

In February 2023, the Company expensed a non-refundable milestone payment of $2.2 million to research and development expenses upon the United States Food and Drug Administration's filing acceptance of the Company's Biologics License Application for UNLOXCYT.

NeuPharma, Inc.

In March 2015, Fortress entered into an exclusive license agreement with NeuPharma, Inc. ("NeuPharma") to develop and commercialize novel irreversible, 3rd generation EGFR inhibitors, including 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 the Company. Under the terms of the license agreement, the Company paid NeuPharma an up-front licensing fee of $1.0 million, and NeuPharma is eligible to receive additional payments of up to an aggregate of approximately $39.0 million upon the Company's successful achievement of certain clinical development and regulatory milestones 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 the Company's 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.

Jubilant Biosys Limited

In May 2016, the Company entered into a license agreement with Jubilant Biosys Limited ("Jubilant"), whereby the Company obtained an exclusive, worldwide license to Jubilant's family of patents covering compounds that inhibit BET proteins such as BRD4, including CK-103. Under the terms of the license agreement, the Company 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 the Company's successful achievement of certain clinical development and regulatory milestones, of which $59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of $89.3 million upon the Company's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales.

In connection with the license agreement with Jubilant, the Company entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retained the right to develop and commercialize these compounds in the field of solid tumors. Effective September 30, 2023, TGTX agreed to mutually terminate the sublicense agreement, with full rights reverting back to the Company. For the year ended December 31, 2023, the Company recognized $46,000 in revenue related to the sublicense agreement in the Statements of Operations.

The collaborations with TGTX each contained single material performance obligations under Topic 606, which was the granting of a license that is functional intellectual property. The Company's performance obligations were satisfied at the point in time when TGTX had the ability to use and benefit from the right to use the intellectual property. The performance obligations of the original agreements were satisfied prior to the adoption of Topic 606. The performance obligation of the amendment to the collaboration agreement was satisfied in June 2019.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 17, 2015, the Company entered into a Founders Agreement with Fortress, which was amended in July 2016 and October 2017. The Founders Agreement provides, that in exchange for the time and capital expended in the formation of Checkpoint and the identification of specific assets the acquisition of which resulted in the formation of a viable emerging growth life science company, the Company shall: (i) issue annually to Fortress, on January 1 of each year, shares of common stock equal to two and one-half percent (2.5)% of the fully diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Checkpoint's voting equity, equal to two and one-half percent (2.5)% of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5)% of Checkpoint's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Checkpoint will pay a one-time change in control fee equal to five times (5x) the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5)%. The Founders Agreement has a term of fifteen years, after which it automatically renews for one-year periods unless Fortress gives the Company notice of termination. The Founders Agreement will also automatically terminate upon a change of control.

Effective March 17, 2015, the Company entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Checkpoint's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of the Company's actions or inactions based upon their advice. Fortress and its affiliates, including all members of its Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will

pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $ 1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. The MSA shall be automatically extended for additional five-year periods unless Fortress or the Company provides notice to the other party of its desire not to automatically extend the term. For the years ended December 31, 2024 and 2023, the Company recognized $0.5 million in expense in its Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all equity incentive grants paid to members of the board. In June 2023, Mr. Weiss assigned the agreement to Hawkins BioVentures, LLC. For the years ended December 31, 2024 and 2023, the Company recognized approximately $153,000 and $110,000, respectively, in expenses in its Statements of Operations related to the advisory agreement, including $93,000 and $50,000 in expenses related to equity incentive grants.

Note 5 - Commitments and Contingencies

Leases

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

License Agreements

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

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company accrues the most likely amount of such loss, and if such amount is not determinable, then the Company accrues the minimum of the range of probable loss. The Company expenses legal costs as they are incurred.

The Company and James Oliviero have been named as defendants in a consolidated putative stockholder class action lawsuit pending in the United States District Court for the Southern District of New York (the "Court"), which was filed on April 5, 2024. The action is styled In re Checkpoint Therapeutics, Inc. Securities Litigation, No. 1:24-cv-02613-PAE (the "Securities Class Action"). On June 21, 2024, the Court appointed a lead plaintiff for the putative class and approved his choice of lead counsel. The lead plaintiff filed his amended complaint (the "Amended Complaint") on August 23, 2024, which alleges that defendants violated the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions, and that James Oliviero is named as a control person under Section 20(a) of the Exchange Act. The Amended Complaint was filed on behalf of stockholders who purchased shares of the Company's common stock between March 10, 2021, and December 15, 2023, and seeks, among other things, monetary damages on behalf of the purported class. Defendants moved to dismiss the Amended Complaint on October 23, 2024, and the motion was fully briefed in February 2025.

The Company has been named as a nominal defendant and certain of its current and former directors and executive officers have been named as defendants in derivative lawsuits pending in the United States District Court for the Southern District of New York. The actions are styled Geary v. Oliviero, et al., No. 1:24-cv-03471 (the "Geary Action") and Mehr v. Oliviero, et al., No. 1:25-cv-00331 (the "Mehr Action" and together with the Geary Action, the "Derivative Actions"). The Complaints in the Geary and Mehr Actions, which were filed on May 6, 2024 and January 13, 2025, respectively, assert claims against all defendants under Delaware law for, among other things, breach of fiduciary duty, claims against all defendants under Section 14(a) of the Exchange Act, and claims for contribution

under the federal securities laws against certain of the defendants. On June 20, 2024 and March 17, 2025, the Geary and Mehr Actions, respectively, were stayed pending final resolution of the anticipated motion to dismiss in the Securities Class Action, including any appeals therefrom.

The Company believes that the allegations in the Securities Class Action and the Derivative Actions are without merit and intends to defend itself and its directors and executive officers vigorously. There is no assurance, however, that the Company or the other defendants will be successful in their defense of either of these allegations or that the Company's insurance policy coverage will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, the Company is unable to predict the outcome or reasonably estimate a range of possible losses at this time.

Note 6 - Stockholders' Equity

Common Stock

At the Company's 2024 Annual Meeting of Stockholders held on May 13, 2024, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue by 95,000,000 to 175,000,000 with a par value of $0.0001 per share, of which 700,000 shares are designated as "Class A common stock." The amendment was filed with the Secretary of State of the State of Delaware on May 13, 2024.

As of December 31, 2024 and 2023, there were700,000 shares of Class A common stock issued and outstanding to Fortress. Dividends are to be distributed pro-rata to the Class A and common stockholders. The holders of common stock are entitled to one vote per share of common stock held. The Class A common stockholders are entitled to a number of votes per share equal to 1.1 times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of Class A common stock. Accordingly, the holder of shares of Class A common stock will be able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Each share of Class A common stock is convertible, at the option of the holder thereof, into one (1) fully paid and non-assessable share of common stock subject to adjustment for stock splits and combinations.

Registered Direct Offerings

In November 2020, the Company filed a shelf registration statement on Form S - 3 (the "November 2020 S – 3"), which was declared effective in December 2020 (File No. 333 - 251005). Under the S - 3, the Company may sell up to a total of $100 million of its securities.

In February 2023, the Company closed on the February 2023 Registered Direct Offering for the issuance and sale of an aggregate of1,180,000 shares of its common stock at a purchase price of $5.25 per share of common stock. In addition, the offering includes248,572 shares of common stock in the form of pre-funded warrants at a price of $5.2499. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such pre-funded warrants are exercised in full. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,428,572 shares of common stock and Series B warrants to purchase up to1,428,572 shares of common stock (collectively, the "February 2023 Common Stock Warrants"). The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $5.00 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The Company also issued the placement agent warrants to purchase up to85,714 shares of common stock with an exercise price of $6.5625 per share. The total gross proceeds from the February 2023 Registered Direct Offering were approximately $7.5 million with net proceeds of approximately $6.7 million after deducting approximately $0.8 million in commissions and other transaction costs. The shares of common stock and the shares underlying the prefunded warrants were registered for sale under the November 2020 S-3. In March 2023, the Company filed a registration statement on Form S-3 to register the February 2023 Common Stock Warrants and placement agent warrants, which was declared effective May 5, 2023 (File No. 333-270474). In February 2023, the pre-funded warrants from the February 2023 Registered Direct Offering were fully exercised. The February 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification. In October 2023, the February 2023 Common Stock Warrants were fully exercised at a reduced exercise price of $1.76 per share as part of the October 2023 Inducement (see below).

In April 2023, the Company closed on the April 2023 Registered Direct Offering for the issuance and sale of an aggregate of 1,700,000 shares of its common stock at a purchase price of $3.60 per share of common stock. In a concurrent private placement, Checkpoint issued and sold Series A warrants to purchase up to 1,700,000 shares of common stock and Series B warrants to purchase up to 1,700,000 shares of common stock (collectively, the "April 2023 Common Stock Warrants"). The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $3.35 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The Company also issued the placement agent warrants to purchase up to 102,000 shares of common stock with an exercise price of $4.50 per share. The total gross proceeds from the April 2023 Registered Direct Offering were approximately $6.1 million with net proceeds of approximately $5.5 million after deducting approximately $0.6 million in commissions and other transaction costs. The shares of common stock were registered for sale under the November 2020 S-3. In April 2023, the Company filed a registration statement on Form S-3 to register the April 2023 Common Stock Warrants and placement agent warrants, which was declared effective May 5, 2023 (File No. 333-271171). The April 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification. The Series B warrants expired in October 2024 without being exercised.

The November 2020 Form S-3 expired in December 2023.

In March 2023, the Company filed a shelf registration statement on Form S-3 (the "March 2023 S-3"), which was declared effective May 5, 2023 (File No. 333-270843). Under the March 2023 S-3, the Company may sell up to a total of $150 million of its securities.

In May 2023, the Company closed on the May 2023 Registered Direct Offering for the issuance and sale of an aggregate of 1,650,000 shares of its common stock at a purchase price of $3.071 per share of common stock. In addition, the offering includes 1,606,269 shares of common stock in the form of pre-funded warrants at a price of $3.0709. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such pre-funded warrants are exercised in full. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,256,269 shares of common stock and Series B warrants to purchase up to 3,256,269 shares of common stock (collectively, the "May 2023 Common Stock Warrants"). The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.821 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The Company also issued the placement agent warrants to purchase up to 195,376 shares of common stock with an exercise price of $3.8388 per share. The total gross proceeds from the May 2023 Registered Direct Offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. The shares of common stock and the shares underlying the prefunded warrants, May 2023 Common Stock Warrants, and placement agent warrants were registered for sale under the March 2023 S-3. In August 2023, the pre-funded warrants from the May 2023 Registered Direct Offering were fully exercised. The May 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification. The Series B warrants were exercised in full in November 2024 (see below).

In July 2023, the Company closed on the July 2023 Registered Direct Offering for the issuance and sale of an aggregate of 2,427,186 shares of its common stock at a purchase price of $3.09 per share of common stock. In addition, the offering includes 809,062 shares of common stock in the form of pre-funded warrants at a price of $3.0899. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001 and are exercisable commencing on the closing date and will terminate when such pre-funded warrants are exercised in full. The common stock and the pre-funded warrants were sold together with Series A warrants to purchase up to 3,236,248 shares of common stock and Series B warrants to purchase up to 3,236,248 shares of common stock (collectively, the "July 2023 Common Stock Warrants"). The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $2.84 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire eighteen months following the issuance date. The Company also issued the placement agent warrants to purchase up to 194,175 shares of common stock with an exercise price of $3.8625 per share. The total gross proceeds from the July 2023 Registered Direct Offering were approximately $10.0 million with net proceeds of approximately $9.1 million after deducting approximately $0.9 million in commissions and other transaction costs. The shares of common stock and the shares underlying the prefunded warrants, July 2023 Common Stock Warrants, and placement agent warrants were registered for sale under the March 2023 S-3. In September 2023, the pre-funded warrants from the July 2023 Registered Direct Offering were fully exercised. The July 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

In January 2024, the Company closed on the January 2024 Registered Direct Offering for the issuance and sale of an aggregate of 1,275,000 shares of its common stock at a purchase price of $1.805 per share of common stock. In addition, the offering includes 6,481,233 shares of common stock in the form of pre-funded warrants at a price of $1.8049. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001, are exercisable commencing on the closing date, and will terminate when such pre-funded warrants are exercised in full. In a concurrent private placement, the Company issued and sold common warrants to purchase up to 7,756,233 shares of common stock (the "January 2024 Common Stock Warrants"). The January 2024 Common Stock Warrants are exercisable immediately upon issuance with an exercise price of $1.68 per share and expire five years following the issuance date. The Company also issued the placement agent warrants to purchase up to 465,374 shares of common stock with an exercise price of $2.2563 per share. The total gross proceeds from the January 2024 Registered Direct Offering were approximately $14.0 million with net proceeds of approximately $12.6 million after deducting approximately $1.4 million in commissions and other transaction costs. The shares of common stock and the shares underlying the pre-funded warrants were registered for sale under the March 2023 S-3. In March 2024, the Company filed a registration statement on Form S-3 to register the January 2024 Common Stock Warrants and placement agent warrants, which was declared effective April 5, 2024 (File No. 333-278397). In July 2024, the pre-funded warrants from the January 2024 Registered Direct Offering were fully exercised. The January 2024 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

In July 2024, the Company closed on the July 2024 Registered Direct Offering for the issuance and sale of an aggregate of 1,230,000 shares of its common stock at a purchase price of $2.05 per share of common stock. In addition, the offering includes 4,623,659 shares of common stock in the form of pre-funded warrants at a price of $2.0499. The pre-funded warrants were funded in full at closing except for a nominal exercise price of $0.0001, are exercisable commencing on the closing date, and will terminate when such pre-funded warrants are exercised in full. In a concurrent private placement, the Company issued and sold common warrants to purchase up to 5,853,659 shares of common stock (the "July 2024 Common Stock Warrants"). The July 2024 Common Stock Warrants have an exercise price of $2.05 per share, will be exercisable after requisite approval of our stockholders is received, and have a term of exercise of five years from the issuance date. The Company also issued the placement agent warrants to purchase up to 351,220 shares of common stock with an exercise price of $2.5625 per share. The total gross proceeds from the July 2024 Registered Direct Offering were approximately $12.0 million with net proceeds of approximately $11.0 million after deducting approximately $1.0 million in commissions and other transaction costs. The shares of common stock and the shares underlying the pre-funded warrants were registered for sale under the March 2023 S-3. In August 2024, the Company filed a registration statement on Form S-3 to register the July 2024 Common Stock Warrants and placement agent warrants, which was declared effective August 30, 2024 (File No. 333-281650). In November 2024, the pre-funded warrants from the July 2024 Registered Direct Offering were fully exercised. The July 2024 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

In November 2024, the Company received approximately $9.2 million from the exercise of existing Series B warrants for the issuance of 3,256,269 shares of common stock from the May 2023 Registered Direct Offering with an exercise price of $2.821 per share. Due to the beneficial ownership limitation provisions in the securities purchase agreement, the shares were initially unissued and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2024, 1,437,000 shares remained in abeyance. These shares were fully issued to the holder in February 2025.

As of December 31, 2024, approximately $65.7 million of securities remain available for sale under the March 2023 S-3.

Warrant Inducement

In October 2023, the Company entered into the October 2023 Inducement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of the Company's common stock at a reduced exercise price of $1.76 per share. The exercised warrants included Series A warrants to purchase up to 1,734,105 shares of common stock and Series B warrants to purchase up to 1,734,105 shares of common stock (collectively, the "December 2022 Common Stock Warrants") with an original exercise price of $4.075 per share, which were issued as part of a registered direct offering the Company closed on in December 2022 (the "December 2022 Registered Direct Offering"), and the February Common Stock Warrants with an original exercise price of $5.00 per share,. which were issued as part of the February 2023 Registered Direct Offering. As part of the October 2023 Inducement, the Company agreed to issue new unregistered Series A Warrants to purchase up to 6,325,354 shares of Common Stock and new unregistered Series B Warrants to purchase up to 6,325,354 shares of Common Stock. The Series A and B warrants are exercisable immediately upon issuance with an exercise price of $1.51 per share. The Series A warrants expire five years following the issuance date and the Series B warrants expire

twenty-four months following the issuance date. The Company also issued the placement agent warrants to purchase up to379,521 shares of common stock with an exercise price of $2.20 per share. The total gross proceeds from the October 2023 Inducement were approximately $11.1 million with net proceeds of approximately $10.0 million after deducting approximately $1.1 million in commissions and other transaction costs. In November 2023, the Company filed a registration statement on Form S-3 to register the October 2023 Common Stock Warrants and placement agent warrants, which was declared effective November 24, 2023 (File No. 333-275644). The October 2023 Common Stock Warrants and placement agent warrants met the criteria for equity classification.

The December 2022 Common Stock Warrants, which were liability classified, were revalued on October 4, 2023 using Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $1.2 million was recorded as a loss on common stock warrant liabilities in the Statements of Operations. The issuance of the October 2023 Common Stock Warrants was also considered as part of the cost of the inducement and were valued using Black-Scholes Model and allocated between the December 2022 Common Stock Warrants and the February 2023 Common Stock Warrants on a weighted basis. The approximately $7.7 million allocated to the December 2022 Common Stock Warrants was recorded as loss on common stock warrant liabilities in the Statements of Operations with a corresponding offset to additional paid-in-capital (see Note 7).

The February 2023 Common Stock Warrants, which were equity classified and treated under ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity*, were revalued using Black-Scholes Model to calculate the difference in fair value as a result of the change in exercise price. The difference in fair value of $1.1 million was deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The approximately $6.3 million allocated to the February 2023 Common Stock Warrants from the issuance of the October 2023 Common Stock Warrants was also deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. As a result, the Company presents a deemed dividend for the modification of the February 2023 Common Stock Warrants and issuance of the October 2023 Common Stock Warrants of $7.5 million for the year ended December 31, 2023. The deemed divided was included in net loss attributable to common stockholders in the calculation of net loss per share in the consolidated statements of operations (see Note 2).

Upon the close of the transaction, the Company issued the holder110,000 of the 6,325,354 shares of common stock that were issuable upon exercise of the existing warrants. Due to the beneficial ownership limitation provisions in the inducement offer letter agreement, the remaining 6,215,354 shares were initially unissued, and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2023, 1,134,000 shares remained in abeyance. These shares were fully issued to the holder in January 2024.

Shares Issued Under the Founders Agreement

Pursuant to the Founders Agreement, the Company issued to Fortress2.5% of the aggregate number of shares of common stock issued in the offerings and warrant exercises noted above. Accordingly, the Company issued 421,653 and 398,660 shares to Fortress for the years ended December 31, 2024 and 2023, respectively, and recorded expenses of approximately $1.0 million each year related to these stock grants, which is included in general and administrative expenses in the Company's Statements of Operations for the years ended December 31, 2024 and 2023, respectively.

Pursuant to the Founders Agreement, the Company issued2,386,808 shares of common stock to Fortress for the Annual Equity Fee, representing2.5% of the fully diluted outstanding equity of the Company on January 1, 2025. Because the number of outstanding shares issuable to Fortress was determinable on January 1, 2025 prior to the issuance of the December 31, 2024 financial statements, the Company recorded approximately $7.6 million in research and development expense and a credit to Common shares issuable-Founders Agreement during the year ended December 31, 2024.

Pursuant to the Founders Agreement, the Company issued1,492,915 shares of common stock to Fortress on May 16, 2024 for the Annual Equity Fee, representing 2.5% of the fully diluted outstanding equity of the Company on January 1, 2024. The Company did not have enough unreserved authorized shares under its certificate of incorporation on January 1, 2024 to issue the shares for the Annual Equity Fee. Therefore, in December 2023, Fortress and Checkpoint mutually agreed to defer the issuance until such time as the certificate of incorporation has been amended in order to increase the number of authorized shares that may be issued thereunder (see Notes 2 and 4). At the Company's 2024 Annual Meeting of Stockholders held on May 13, 2024, its stockholders approved an amendment to its certificate of incorporation to increase the number of authorized shares of common stock available to issue. Because the number of

outstanding shares issuable to Fortress was determinable on January 1, 2024 prior to the issuance of the December 31, 2023 financial statements, the Company recorded approximately $3.4 million in research and development expense and a credit to Common shares issuable-Founders Agreement during the year ended December 31, 2023.

The Company may offer the securities under the S-3 from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders.

Equity Incentive Plan

The Company has in effect the Amended and Restated 2015 Incentive Plan ("2015 Incentive Plan"). The 2015 Incentive Plan was adopted in March 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. At the Company's 2024 Annual Meeting of Stockholders held on May 13, 2024, its stockholders approved an amendment to the 2015 Incentive Plan to increase the shares available for issuance to 18,000,000 shares. The plan expires 10 years from the effective date of the amendment and limits the term of each option to no more than 10 years from the date of grant.

On May 24, 2024, the Company filed a registration statement on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our 2015 Incentive Plan. The registration statement became effective immediately upon filing, and shares covered by the registration statement are eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 imitations applicable to our affiliates.

As of December 31, 2024, 8,010,406 shares are available for issuance under the 2015 Incentive Plan.

Restricted Stock Awards

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activity for the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2022	378,897	$ 26.15
Granted	1,103,698	2.33
Forfeited	(55,100)	11.34
Vested	(111,375)	25.07
Nonvested at December 31, 2023	1,316,120	$ 6.88
Granted	5,346,306	1.89
Forfeited	(23,894)	6.28
Vested	(1,751,033)	3.95
Non-vested at December 31, 2024	4,887,499	$ 2.48

As of December 31, 2024, there was $4.8 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 1.7 years. In December 2024, the Company announced that the FDA granted approval of UNLOXCYT for the treatment of adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Approximately 1.5 million shares of restricted stock vested upon this achievement and the Company recorded expense of $4.4 million in the Company's Statements of Operations for the year ended December 31, 2024.

Restricted Stock Units

Certain employees and directors have been awarded restricted stock units. The following table summarizes restricted stock units activity for the years ended December 31, 2024 and 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2022	85,000	$ 10.50
Granted	577,384	2.25
Forfeited	(4,000)	10.50
Vested	(42,500)	10.50
Non-vested at December 31, 2023	615,884	2.77
Granted	2,200,000	1.84
Forfeited	(17,638)	2.25
Vested	(2,798,246)	2.04
Non-vested at December 31, 2024	—	$ —

All restricted stock units were performance-based with vesting upon the achievement of certain corporate milestones. In December 2024, the Company announced that the FDA granted approval of UNLOXCYT for the treatment of adults with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Approximately 2.8 million restricted stock units vested upon this achievement and the Company recorded expense of $5.7 million in the Company's Statements of Operations for the year ended December 31, 2024.

Stock Options

The following table summarizes stock option award activity for the years ended December 31, 2024 and 2023:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	27,000	$ 31.35	6.44
Granted	100,000	2.81	
Outstanding as of December 31, 2023	127,000	$ 8.88	8.60
Outstanding as of December 31, 2024	127,000	$ 8.88	7.60
Vested and exercisable as of December 31, 2024	120,250	$ 6.50	7.88

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

The Company used the Black-Scholes Model for determining the estimated fair value of stock-based compensation related to stock options. The table below summarizes the assumptions used:

	For the Years Ended December 31,	
	2024	2023
Risk-free interest rate	—	3.7 %
Expected dividend yield	—	—
Expected term in years	—	10.0
Expected volatility	—	83.5 %

Warrants

A summary of warrant activities for year ended December 31, 2024 and 2023 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	4,357,597	$ 3.37	3.26
Granted	35,513,575	2.30	
Exercised	(9,773,501)	1.76	
Outstanding as of December 31, 2023	30,097,671	$ 2.36	3.00
Granted	25,531,378	1.87	
Exercised	(14,361,161)	0.64	
Expired	(1,700,000)	3.35	
Outstanding as of December 31, 2024	39,567,888	$ 2.10	3.09

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

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the years ended December 31, 2024 and 2023 (in thousands).

	For the year ended December 31,	
	2024	2023
Research and development	$ 5,248	$ 1,169
General and administrative	10,004	1,728
Total stock-based compensation expense	$ 15,252	$ 2,897

Note 7 – Common Stock Warrant Liabilities

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity*. For warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter.

On December 16, 2022, the Company closed on an offering for the sale of shares of its common stock and pre-funded warrants as part of the December 2022 Registered Direct Offering. The common stock and the pre-funded warrants were sold together with December 2022 Common Stock Warrants. The Company also issued the placement agent warrants to purchase up to 104,046 shares of common stock with an exercise price of $5.406 per share (the "December 2022 Placement Agent Warrants"). The Company deemed the December 2022 Common Stock Warrants and December 2022 Placement Agent Warrants to be classified as liabilities on the balance sheet as they contain terms for redemption of the underlying security that are outside its control. The December 2022 Common Warrants and December 2022 Placement Agent Warrants were recorded at the time of closing at a fair value, determined by using the Black-Scholes Model.

In October 2023, the Company entered into the October 2023 Inducement with a holder of certain of its existing warrants to exercise for cash an aggregate of 6,325,354 shares of the Company's common stock at a reduced exercise price of $1.76 per share (see Note 6). Included in the exercise were the entirety of the December 2022 Common Stock Warrants. The Company revalued the December 2022 Common Stock Warrants on October 4, 2023, resulting in a fair value of $3.1 million. The Company also revalued the December 2022 Common Stock Warrants and December 2022 Placement Agent Warrants at each reporting period in 2023, and the decrease in the fair value of the common stock warrant liability throughout the year resulted in an offsetting gain on common stock warrant liabilities in the Statements of Operations. Since the December 2022 Placement Agent Warrants issued in the December 2022 Registered Direct Offering were not included in the October 2023 Inducement and have not been exercised, they will continue to be revalued at each reporting period for as long as they remain outstanding. The Company revalued the warrants at December 31, 2024 and 2023, resulting in a fair value of approximately $198,000 and $125,000, respectively.

	Warrant Liabilities
Common Stock Warrant liabilities at December 31, 2022	$ 11,170
Change in fair value of Common Stock Warrant liabilities	(7,924)
Exercise of December 2022 Common Stock Warrants	(3,121)
Common Stock Warrant liabilities at December 31, 2023	$ 125
Change in fair value of Common Stock Warrant liabilities	73
Common Stock Warrant liabilities at December 31, 2024	$ 198

The Company used the Black-Scholes Model for determining the estimated fair value of the common stock warrant liabilities. A summary of the weighted average (in aggregate) significant unobservable inputs used in measuring the warrant liability is determined using Level 3 inputs as follows:

Placement Agent Warrants	December 31, 2024	December 31, 2023
Exercise price	$ 5.41	$ 5.41
Volatility	111.1 %	96.4 %
Expected life	3.0	4.0
Risk-free rate	4.3 %	3.8 %
Dividend yield	—	—

Note 8 - Income Taxes

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit during the years ended December 31, 2024 and 2023.

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

	For the Year Ended December 31,	
	2024	2023
Percentage of pre-tax income:		
Statutory federal income tax rate	21 %	21 %
State taxes, net of federal tax benefit	4 %	11 %
Credits	3 %	2 %
Change in state tax rate	(15)%	12 %
Provision to return	(4)%	— %
Stock based compensation	1 %	(1)%
162(m) limitation	(4)%	— %
Other	(2)%	(1)%
Change in valuation allowance	(4)%	(43)%
Income taxes provision (benefit)	— %	— %

The components of the net deferred tax asset as of December 31, 2024 and 2023 are the following (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryovers	$ 51,309	$ 45,000
Stock compensation and other	1,547	1,384
Amortization of license	9,352	11,126
Accruals and reserves	629	825
Tax credits	6,768	5,105
Start Up Costs	15	24
Section 174 Capitalization	19,783	23,793
Total deferred tax assets	89,403	87,257
Less valuation allowance	(89,403)	(87,257)
Deferred tax asset, net of valuation allowance	$ —	$ —

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset. A valuation allowance of approximately $ 89.4 million and $87.3 million was recorded for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company had federal and state net operating loss carryforwards of approximately $196.6 million and $152.4 million, respectively. Approximately $165.5 million of the federal net operating loss carryforwards and $1.5 million of the state net operating loss carryforwards can be carried forward indefinitely. The remaining $31.2 million of federal and $150.9 million of state net operating loss carryforwards will begin to expire, if not utilized, by2034 and 2034, respectively. The Company has $5.3 million of research and development credit carryforwards and $1.5 million of orphan drug credit carryforwards, which will begin to expire, if not utilized, by 2034. Utilization of the net operating loss and credit carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions. The Company has not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2024. The Company has no income tax affect due to the recognition of a full valuation allowance on the expected tax benefits of future loss carry forwards based on uncertainty surrounding realization of such assets.

There are no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740, which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the years ended December 31, 2024 and 2023.

The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There wereno interest or penalties related to income taxes that have been accrued or recognized as of and for the period ended December 31, 2024 and 2023. The Company would classify interest and penalties related to uncertain tax positions as income tax expense, if applicable.

The federal and state tax returns for the periods ended December 31, 2021, 2022 and 2023 are currently open for examination under the applicable federal and state income tax statues of limitations.

Beginning with the 2022 tax year, the Company is required to capitalize research and development expenses for tax purposes as defined under Internal Revenue Code Section 174. For expenses that are incurred for research and development in the U.S., the amounts will be amortized over 5 years, and for expenses that are incurred for research and development outside the U.S., the amounts will be amortized over 15 years.

Note 9 - Accounts Payable and Accrued Expenses

At December 31, 2024 and 2023, accounts payable and accrued expenses consisted of the following (in thousands):

	December 31,	
	2024	2023
Accounts payable	$ 6,091	$ 6,570
Accrued compensation	1,877	1,206
Research and development	8,036	7,123
Other	1,461	586
Total accounts payable and accrued expenses	$ 17,465	$ 15,485

Note 10 – Segment Information

Operating segments are defined as components of an enterprise that engage in business activities from which it may recognize revenues and incur expenses, and for which discrete financial information is available that is evaluated regularly by the CODM to allocate resources and assess performance.

The Company operates in one reportable segment, immunotherapy and targeted oncology therapy, which includes all activities related to the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, including UNLOXCYT. The determination of a single reportable segment is consistent with the financial information regularly provided to the Company's CODM, which is its chief executive officer, who reviews and evaluates net loss, as reported on the Company's Statements of Operations, for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. Net loss is also used to monitor budget versus actual results. The measure of segment assets is reported on the Company's Balance Sheets as total assets.

For the years ended December 31, 2024 and 2023, the significant expense categories regularly provided to the CODM consisted of the following (in thousands):

	For the year ended December 31,	
	2024	2023
Revenue - related party	$ 41	$ 103
Operating expenses:		
Employee Expenses	8,624	7,285
Stock-based Compensation	15,252	2,897
Fortress Founder's Agreement and MSA Expenses	9,133	4,871
Manufacturing and Development Expenses	10,755	19,013
Clinical Expenses	3,901	6,981
Regulatory Expenses	334	3,615
License Fees	152	2,300
Legal & Accounting Expense	4,123	1,814
R&D Other Expense [1]	1,629	1,439
G&A Other Expense [2]	2,312	2,036
Total Operating Expenses	56,215	52,251
Other Segment Items [3]	(66)	301
Net Loss	**$ (56,240)**	**$ (51,847)**

(1) R&D Other Expense includes travel, consulting, and outside service expenses.

(2) G&A Other Expense includes travel, consulting, marketing, business development, investor relations and outside services expenses.

(3) Other Segment Items include interest income, foreign currency exchange loss, and gain (loss) on common stock warrant liabilities.

Note 11 – Subsequent Events

In January 2025, the Company received approximately $2.1 million from the partial exercise of existing Series B warrants for the issuance of740,000 shares of common stock from the July 2023 Registered Direct Offering with an exercise price of $2.84 per share. The remainder of the Series B warrants from the July 2023 Registered Direct Offering expired without exercise.

On March 9, 2025, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Sun Pharmaceutical Industries, Inc., a Delaware corporation (“Sun Pharma” or “Parent”), and Snoopy Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent (“Merger Sub”). The Merger Agreement provides that, on the terms and subject to the conditions set forth in the Merger Agreement, Parent, Merger Sub and the Company will effect a merger of Merger Sub with and into the Company (the “Merger”), with the Company continuing as the surviving corporation of the Merger and a wholly owned subsidiary of Parent.

Pursuant to the Merger Agreement, at the effective time of the Merger (the “Effective Time”), each share of common stock and each share of Class A common stock of the Company (collectively, the “Shares”) (including each Unvested Company Restricted Share (as defined in the Merger Agreement)) outstanding immediately prior to the Effective Time will be canceled and cease to exist and be converted into the right to receive (i) $4.10 in cash, without interest, and (ii) one non-tradable contingent value right (a “CVR”), which will represent the right to receive a contingent cash payment of up to $0.70 upon the achievement of a specified milestone, subject to and in accordance with the terms and conditions set forth in a Contingent Value Rights Agreement, substantially in the form attached as Exhibit B to the Merger Agreement (the “CVR Agreement”), in each case subject to applicable withholding taxes. This implies a total transaction value of up to approximately $416 million as of the date hereof. The Merger is expected to close in the second quarter of 2025.

Pursuant to the Merger Agreement, as of or prior to the Effective Time, Parent and a rights agent (the "Rights Agent") will enter into the CVR Agreement governing the terms of the CVRs issued in connection with the Merger. The Rights Agent will maintain an up-to-date register of the holders of CVRs (the "Holders"). Holders shall not be permitted to transfer the CVRs (subject to certain limited exceptions as set forth in the CVR Agreement).

Concurrently with the execution of the Merger Agreement, the Company entered into a Support Agreement (the "Support Agreement") with Parent and Fortress. Under the terms of the Support Agreement, Fortress has agreed to, among other things, during the term of the Support Agreement, (i) vote its Shares that it owns of record or beneficially, as well as any additional Shares it may acquire (the "Covered Shares") in favor of the adoption of the Merger Agreement and the approval of the Merger and the other transactions contemplated by the Merger Agreement, and against any acquisition proposal or any action, proposal, agreement, transaction or arrangement that is intended, or would reasonably expected, to result in a material breach of a covenant, representation or warranty or any obligation of the Company under the Merger Agreement or any of the conditions to the Company's obligations under the Merger Agreement not being fulfilled or satisfied, (ii) not transfer any of its Covered Shares (subject to certain exceptions) and (iii) waive and not to exercise any appraisal rights in respect of such Covered Shares that may arise with respect to the Merger and not to commence or participate in, any class action or legal action (a) challenging the validity of, or seeking to enjoin or delay the operation of any provision of the Merger Agreement or (b) with respect to claims against the Company Board, or any committee thereof, Parent of Merger Sub relating to the Merger Agreement or the transactions contemplated thereby.

Under the Support Agreement, subject to the occurrence of the Effective Time, Fortress also agreed to forgo any further payment, dividend or distribution, or issuance or transfer of securities by the Company on or after the date of the Support Agreement pursuant to the Amended and Restated Founders Agreement, dated as of July 11, 2016, as amended (the "Founders Agreement") between Fortress and the Company and certain other agreements between Fortress and the Company. The Support Agreement further provides that effective immediately prior to, but conditioned upon the closing of the Merger, the Founders Agreement shall be terminated.

Additionally, in connection with the Company's entry into the Merger Agreement, the Company entered into a letter agreement (the "Warrant Amendment"), dated as of March 9, 2025, with Armistice Capital Master Fund Ltd., a Cayman Islands exempted company ("Armistice"). Pursuant to the Warrant Amendment, the Company and Armistice agreed (i) to, immediately prior to the Effective Time, amend all outstanding Company Warrants held by or issued to Armistice or any of its affiliates other than the Specified Warrant (the "Armistice Warrants") to provide that each such Armistice Warrant that remains outstanding and unexercised as of the Effective Time will automatically be converted into the right to receive the Warrant Consideration, and (ii) that at the Effective Time, to the extent that any portion of that certain warrant to purchase 5,853,659 Shares, dated as of July 2, 2024 (the "Specified Warrant"), remains outstanding and unexercised as of the Effective Time, the Specified Warrant will be converted into the right of Armistice to receive, for each Share underlying the Specified Warrant, a cash payment equal to $3.62. The Warrant Amendment also provides that Armistice will not be entitled to transfer the Armistice Warrants prior to the Effective Time unless the Merger Agreement is validly terminated in accordance with its terms prior to the Effective Time.

Concurrently with the execution of the Merger Agreement, the Company entered into a Royalty Agreement (the "Royalty Agreement") with Parent and Fortress pursuant to which following, and subject to the occurrence of, the Effective Time, Fortress will receive a royalty interest right based on worldwide net sales of certain products of the Company and Parent. The royalty interest right represents the right to receive quarterly cash payments of 2.5% of net sales of such products during the time period set forth in the Royalty Agreement.

Pursuant to the Merger Agreement, as of or prior to the Effective Time, the Company and Fortress will enter into a Transition Services Agreement (the "Transition Services Agreement"), pursuant to which, from and after the Effective Time, Fortress would provide the Company with certain transition services as set forth in the Transition Services Agreement, for the period of time and in exchange for the compensation set forth therein.

In March 2025, the Company received approximately $36.0 million from the exercise of warrants for the issuance of21,691,003 shares of common stock with an average exercise price of $1.66 per share.

SIGNATURES

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

Checkpoint Therapeutics, Inc.
By: /s/ James F. Oliviero
Name: James F. Oliviero
Title: President, Chief Executive Officer and Director
March 28, 2025

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ James F. Oliviero James F. Oliviero	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2025
/s/ Garrett Gray Garrett Gray	Chief Financial Officer (Principal Financial Officer)	March 28, 2025
/s/ Michael S. Weiss Michael S. Weiss	Chairman of the Board	March 28, 2025
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 28, 2025
/s/ Neil Herskowitz Neil Herskowitz	Director	March 28, 2025
/s/ Barry Salzman Barry Salzman	Director	March 28, 2025
/s/ Christian Béchon Christian Béchon	Director	March 28, 2025
/s/ Amit Sharma Amit Sharma, MD	Director	March 28, 2025

DESCRIPTION OF SECURITIES

When used herein, the terms "we," "our," and "us" refer to Checkpoint Therapeutics, Inc.

DESCRIPTION OF CAPITAL STOCK

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

Common Stock

Our common stock is traded on The Nasdaq Capital Market, or the Exchange, under the symbol "CKPT."

The authorized capital stock of Checkpoint consists of 175,000,000 shares of common stock, of which 700,000 shares have been designated as Class A common stock. The description of our Class A Common Stock in this item is for information purposes only. All of the Class A common stock has been issued to Fortress. Class A common stock is identical to common stock other than as to voting rights, the election of directors for a definite period, and conversion rights. On any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A common stock will be entitled to cast for each share of Class A common stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of the shares of outstanding common stock and the denominator of which is the number of shares of outstanding Class A common stock. Thus, the Class A common stock will at all times constitute a voting majority. For a period of ten (10) years from the date of the first issuance of shares of Class A common stock expiring in 2025 (the "Class A Director Period"), the holders of record of the shares of Class A common stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A common stock), exclusively and as a separate class, will be entitled to appoint or elect the majority of the directors of Checkpoint (the "Class A Directors"). Finally, each share of Class A common stock is convertible, at the option of the holder, into one fully paid and nonassessable share of common stock (the "Conversion Ratio"), subject to certain adjustments.

If Checkpoint at any time effects a subdivision of the outstanding common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) by any stock split, stock dividend, recapitalization or otherwise, the applicable Conversion Ratio in effect immediately before that subdivision will be proportionately decreased so that the number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) issuable on conversion of each share of Class A common stock will be increased in proportion to such increase in the aggregate number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) outstanding. If Checkpoint at any time combines the outstanding shares of common stock, the applicable Conversion Ratio in effect immediately before the combination will be proportionately increased so that the number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) issuable on conversion of each share of Class A common stock will be decreased in proportion to such decrease in the aggregate number of shares of common stock (or other capital stock or securities at the time issuable upon conversion of the Class A common stock) outstanding. Additionally, if any reorganization, recapitalization, reclassification, consolidation or merger involving Checkpoint occurs in which the common stock (but not the Class A common stock) is converted into or exchanged for securities, cash or other property (other than a transaction involving the subdivision or combination of the common stock), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Class A common stock becomes convertible into the kind and amount of securities, cash or other property which such Class A Stockholder would have been entitled to receive had he or she

converted the Class A Shares immediately before said transaction. In such case, appropriate adjustment (as determined in good faith by the Board of Directors of Checkpoint) will be made in the application of the provisions of Checkpoint's Amended and Restated Certificate of Incorporation relating the subdivision or combination of the common stock with respect to the rights and interests thereafter of the holders of the Class A common stock, such that the provisions set forth in of Checkpoint's Amended and Restated Certificate of Incorporation relating to the subdivision or combination of the common stock (including the provisions with respect to changes in and other adjustments of the applicable Conversion Ratio) will thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Class A common stock. Checkpoint is not authorized to issue preferred stock.

Dividends

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

Voting Rights

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

Liquidation and Dissolution

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

Other

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

All of the outstanding shares of our common stock, including Class A common stock, are duly issued, fully paid and non-assessable.

DESCRIPTION OF WARRANTS

We may issue warrants to purchase shares of our common stock in one or more series together with other securities or separately, as described in each applicable prospectus supplement.

The prospectus supplement relating to any warrants we offer will include specific terms relating to the offering. These terms will include some or all of the following:

- the title of the warrants;
- the aggregate number of warrants offered;
- the designation, number and terms of the shares of common stock purchasable upon exercise of the warrants and procedures by which those numbers may be adjusted;
- the exercise price of the warrants;

- the dates or periods during which the warrants are exercisable;
- the designation and terms of any securities with which the warrants are issued;
- if the warrants are issued as a unit with another security, the date on and after which the warrants and the other security will be separately transferable;
- if the exercise price is not payable in U.S. dollars, the foreign currency, currency unit or composite currency in which the exercise price is denominated;
- any minimum or maximum amount of warrants that may be exercised at any one time;
- any terms relating to the modification of the warrants;
- any terms, procedures and limitations relating to the transferability, exchange or exercise of the warrants; and
- any other specific terms of the warrants.

DESCRIPTION OF DEBT SECURITIES

We may offer debt securities which may be senior, subordinated or junior subordinated and may be convertible. Unless otherwise specified in the applicable prospectus supplement, our debt securities will be issued in one or more series under an indenture to be entered into between us and a trustee. We will issue the debt securities offered by any applicable prospectus supplement under an indenture to be entered into between us and the trustee identified in the applicable prospectus supplement. The terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as in effect on the date of the indenture. The indenture will be subject to and governed by the terms of the Trust Indenture Act of 1939.

The following description briefly sets forth certain general terms and provisions of the debt securities that we may offer. The particular terms of the debt securities offered by any prospectus supplement and the extent, if any, to which these general provisions may apply to the debt securities, will be described in the related prospectus supplement. Accordingly, for a description of the terms of a particular issue of debt securities, reference must be made to both the related prospectus supplement and to the following description.

The aggregate principal amount of debt securities that may be issued under the indenture is unlimited. The debt securities may be issued in one or more series as may be authorized from time to time pursuant to a supplemental indenture entered into between us and the trustee or an order delivered by us to the trustee. For each series of debt securities we offer, a prospectus supplement will describe the following terms and conditions of the series of debt securities that we are offering, to the extent applicable:

- title and aggregate principal amount;
- whether the debt securities will be senior, subordinated or junior subordinated;
- applicable subordination provisions, if any;
- provisions regarding whether the debt securities will be convertible or exchangeable into other securities or property of the Company or any other person;
- percentage or percentages of principal amount at which the debt securities will be issued;
- maturity date(s);

- interest rate(s) or the method for determining the interest rate(s);
- whether interest on the debt securities will be payable in cash or additional debt securities of the same series;
- dates on which interest will accrue or the method for determining dates on which interest will accrue and dates on which interest will be payable;
- whether the amount of payment of principal of, premium, if any, or interest on the debt securities may be determined with reference to an index, formula or other method;
- redemption, repurchase or early repayment provisions, including our obligation or right to redeem, purchase or repay debt securities under a sinking fund, amortization or analogous provision;
- if other than the debt securities' principal amount, the portion of the principal amount of the debt securities that will be payable upon declaration of acceleration of the maturity;
- authorized denominations;
- form;
- amount of discount or premium, if any, with which the debt securities will be issued, including whether the debt securities will be issued as "original issue discount" securities;
- the place or places where the principal of, premium, if any, and interest on the debt securities will be payable;
- where the debt securities may be presented for registration of transfer, exchange or conversion;
- the place or places where notices and demands to or upon the Company in respect of the debt securities may be made;
- whether the debt securities will be issued in whole or in part in the form of one or more global securities;
- if the debt securities will be issued in whole or in part in the form of a book-entry security, the depository or its nominee with respect to the debt securities and the circumstances under which the book-entry security may be registered for transfer or exchange or authenticated and delivered in the name of a person other than the depository or its nominee;
- whether a temporary security is to be issued with respect to such series and whether any interest payable prior to the issuance of definitive securities of the series will be credited to the account of the persons entitled thereto;
- the terms upon which beneficial interests in a temporary global security may be exchanged in whole or in part for beneficial interests in a definitive global security or for individual definitive securities;
- the guarantors, if any, of the debt securities, and the extent of the guarantees and any additions or changes to permit or facilitate guarantees of such debt securities;
- any covenants applicable to the particular debt securities being issued;
- any defaults and events of default applicable to the debt securities, including the remedies available in connection therewith;
- currency, currencies or currency units in which the purchase price for, the principal of and any premium and any interest on, such debt securities will be payable;

- time period within which, the manner in which and the terms and conditions upon which the Company or the purchaser of the debt securities can select the payment currency;
- securities exchange(s) on which the debt securities will be listed, if any;
- whether any underwriter(s) will act as market maker(s) for the debt securities;
- extent to which a secondary market for the debt securities is expected to develop;
- provisions relating to defeasance;
- provisions relating to satisfaction and discharge of the indenture;
- any restrictions or conditions on the transferability of the debt securities;
- provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- any addition or change in the provisions related to compensation and reimbursement of the trustee;
- provisions, if any, granting special rights to holders upon the occurrence of specified events;
- whether the debt securities will be secured or unsecured, and, if secured, the terms upon which the debt securities will be secured and any other additions or changes relating to such security; and
- any other terms of the debt securities that are not inconsistent with the provisions of the Trust Indenture Act (but may modify, amend, supplement or delete any of the terms of the indenture with respect to such series of debt securities).

General

One or more series of debt securities may be sold as "original issue discount" securities. These debt securities would be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at the time of issuance is below market rates. One or more series of debt securities may be variable rate debt securities that may be exchanged for fixed rate debt securities.

United States federal income tax consequences and special considerations, if any, applicable to any such series will be described in the applicable prospectus supplement.

Debt securities may be issued where the amount of principal and/or interest payable is determined by reference to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount or a payment of interest that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending upon the value of the applicable currencies, commodities, equity indices or other factors. Information as to the methods for determining the amount of principal or interest, if any, payable on any date, the currencies, commodities, equity indices or other factors to which the amount payable on such date is linked and certain additional United States federal income tax considerations will be set forth in the applicable prospectus supplement.

The term "debt securities" includes debt securities denominated in U.S. dollars or, if specified in the applicable prospectus supplement, in any other freely transferable currency or units based on or relating to foreign currencies.

We expect most debt securities to be issued in fully registered form without coupons and in denominations of $2,000 and any integral multiples thereof. Subject to the limitations provided in the indenture and in the prospectus supplement, debt securities that are issued in registered form may be transferred or exchanged at the principal corporate trust office of the trustee, without the payment of any service charge, other than any tax or other governmental charge payable in connection therewith.

Global Securities

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depositary identified in the prospectus supplement. Global securities will be issued in registered form and in either temporary or definitive form. Unless and until it is exchanged in whole or in part for the individual debt securities, a global security may not be transferred except as a whole by the depositary for such global security to a nominee of such depositary or by a nominee of such depositary to such depositary or another nominee of such depositary or by such depositary or any such nominee to a successor of such depositary or a nominee of such successor. The specific terms of the depositary arrangement with respect to any debt securities of a series and the rights of and limitations upon owners of beneficial interests in a global security will be described in the applicable prospectus supplement.

Governing Law

The indenture and the debt securities shall be construed in accordance with and governed by the laws of the State of New York.

DESCRIPTION OF UNITS

We may issue, in one more series, units comprised of shares of our common stock, warrants to purchase common stock, debt securities or any combination of those securities. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We may evidence units by unit certificates that we issue under a separate agreement. We may issue the units under a unit agreement between us and one or more unit agents. If we elect to enter into a unit agreement with a unit agent, the unit agent will act solely as our agent in connection with the units and will not assume any obligation or relationship of agency or trust for or with any registered holders of units or beneficial owners of units. We will indicate the name and address and other information regarding the unit agent in the applicable prospectus supplement relating to a particular series of units if we elect to use a unit agent.

We will describe in the applicable prospectus supplement the terms of the series of units being offered, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described herein; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The other provisions regarding our common stock, warrants and debt securities as described in this section will apply to each unit to the extent such unit consists of shares of our common stock, warrants and/or debt securities.

Exhibit 10.46

CHECKPOINT THERAPEUTICS, INC.
CHANGE IN CONTROL SEVERANCE PLAN
April 26, 2022

Checkpoint Therapeutics, Inc., a Delaware corporation (the "Company"), has adopted this Change in Control Severance Plan (the "Plan"), dated as of April 26, 2022, and effective upon the consummation of a Change in Control (as defined herein), for the benefit of its employees, on the terms and conditions hereinafter stated.

1. **Defined Terms**. For purposes of the Plan, the following terms shall have the meanings indicated below:

1.1 "Annual Base Salary" means a Participant's annual base salary at the rate in effect immediately prior to a Qualifying Termination or, if higher, at the rate in effect immediately prior to a Change in Control.

1.2 "Board" means the Board of Directors of the Company.

1.3 "Cause" means (a) a material breach of the terms of the Participant's Proprietary Information and Inventions Agreement or any provisions relating to non-competition or non-solicitation in any other agreement; (b) a material breach by the Participant of any other provision of his or her employment arrangement, which is not cured by the Participant within fifteen (15) days after receiving written notice thereof from the Company containing a description of the breach or breaches alleged to have occurred; (c) the habitual neglect or gross failure by the Participant to adequately perform the duties of his or her position; (d) any act of the Participant involving moral turpitude; (e) the Participant's commission or conviction of, or pleading guilty or no lo contendere to, a felony or criminal action involving dishonesty or other moral turpitude or that is connected to the Participant's employment with the Company or his or her place of employment; (f) the Participant's use of illegal drugs, abuse of other controlled substances, working under the influence of alcohol or other controlled substances, or knowing neglect of reasonably assigned duties; or (g) the Participant's repetitive refusal to comply with or the Participant's violation of lawful instructions of the Chief Executive Officer, Chief Financial Officer or the Board of Directors, unless cured within fifteen (15) days after receiving written notice thereof from the Company.

1.4 "COBRA Payment" shall have the meaning provided in Section 4 hereof.

1.5 "Code" means the Internal Revenue Code of 1986, as amended from time to time.

1.6 "Committee" means the Compensation Committee of the Board.

1.7 "Company" means Checkpoint Therapeutics, Inc., a Delaware corporation.

1.8 "Change in Control" means and includes the occurrence of any one of the following events:

(i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially

owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 30% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (A) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (B) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (C) any acquisition by any corporation pursuant to a Business Combination (as defined in subsection (iii) below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or

(ii) such time as the Continuing Directors (as defined below) do not constitute a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board who was a member of the Board on the date of the initial adoption of this Plan by the Board or (x) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or

(iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding the Acquiring Corporation or any employee benefit plan (or related

trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 30% or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination).

1.9 "Date of Termination" shall have the meaning provided in Section 7 hereof.

1.10 "Disability" means a Participant's inability to perform the essential functions of his or her job for more than twelve (12) workweeks in any one (1) year period, with or without reasonable accommodation).

1.11 "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time.

1.12 "Good Reason" means any of the following, without the Participant's written consent: (i) a material diminution in the Participant's Annual Base Salary in effect as of the date of the Change in Control; (ii) a material diminution in the Participant's authority, duties, or responsibilities as of the date of the Change in Control; or (iii) the relocation of Participant's principal office to a facility or location that is more than fifty (50) miles away from the location of the Participant's primary place of business as of the Effective Date; provided, however, that a termination by the Participant shall not constitute termination for Good Reason unless the Participant shall first have delivered to the Company written notice setting forth with specificity the occurrence deemed to give rise to a right to terminate for Good Reason (which notice must be given no later than sixty (60) days after the initial occurrence of such event). Good Reason shall not include the Participant's death or Disability. The Participant's employment must be terminated by the Participant for Good Reason within ninety (90) days after the occurrence of an event of Good Reason. A resignation by the Participant for Good Reason effectively constitutes an involuntary separation from service within the meaning of Section 409A of the Code and Treas. Reg. Section 1.409A-1(n)(2).

1.13 "Participant" means an individual who is an employee of the Company on the effective date of a Change in Control; provided, however, that the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, and any other employee of the Company that is or may become entitled to cash separation payments or benefits under any employment, consulting or severance agreement or other plan, program or arrangement of the Company, shall not be Participants in this Plan. For the purposes of the Plan, an individual is an "employee" of the Company if, on the effective date of a Change in Control, that individual was either (i) on authorized leave of absence from the Company or (ii) providing services for the Company under the Company's direction and control, including any individual performing services for the Company under a leasing arrangement or other agreement with a professional employment organization.

1.14 "Plan" means this Change in Control Severance Plan.

1.15 "Qualifying Termination" means the Participant's termination of employment with the Company or the Successor Entity either by the Company or the Successor Entity without Cause or by the Participant for Good Reason, in each case, on, or within eighteen months after, the effective date of a Change in Control. For the avoidance of doubt, in no event shall a Participant be deemed to have experienced a Qualifying Termination as a result of the Participant's death or Disability.

1.16 "Severance Payment" shall have the meaning provided in Section 4 hereof.

1.17 "Successor Entity" means any entity that acquires or otherwise succeeds to all or substantially all of the business or assets of the Company following a Change in Control.

2. **Effectiveness of the Plan**. This Plan shall become effective upon the consummation of a Change in Control and shall be of no force or effect prior to a Change in Control. In the event that a Change in Control does not occur on or prior to the fourth anniversary of the date on which this Plan is adopted, the Plan shall thereupon automatically terminate and have no force or effect.

3. **Administration**. Subject to Section 12.2 hereof, the Plan shall be interpreted, administered and operated by the Committee, which shall have complete authority, subject to the express provisions of the Plan, to interpret the Plan, to prescribe, amend and rescind rules and regulations relating to the Plan, and to make all other determinations necessary or advisable for the administration of the Plan. The Committee may delegate any of its duties hereunder to a subcommittee, or to such person or persons from time to time as it may designate. All decisions, interpretations and other actions of the Committee shall be final, conclusive and binding on all parties who have an interest in the Plan.

4. **Severance Benefits**. Upon a Participant's Qualifying Termination: (i) the Participant shall receive a cash payment equal to the sum of (A) the Participant's Annual Base Salary, and (B) the annual bonus earned by the Participant for the fiscal year immediately prior to the year in which the Date of Termination occurs, if any, payable in a lump sum within sixty (60) days following the Date of Termination (the " Severance Payment"); and (ii) the Participant shall receive a cash payment equal to the total monthly premium payment (both the Company's portion and the Participant's portion of such premium) under the Company's group healthcare plan multiplied by twelve (12), payable in a lump sum within sixty (60) days following the Date of Termination (the "COBRA Payment"). Notwithstanding anything herein to the contrary, the Participant shall not be eligible to receive the Severance Payment or the COBRA Payment unless he or she first executes a general release of claims and covenant not to sue in a form satisfactory to the Company and does not revoke such release of claims and covenant not to sue.

5. **Non-Qualifying Termination**. If a Participant's status as an employee is terminated for any reason other than due to a Qualifying Termination, the Participant shall not be entitled to receive the Severance Payment or the COBRA Payment, and the neither the Company nor any Successor Entity shall have any obligation to such Participant under this Plan.

6. **Section 409A**

6.1 General. It is intended that the payments and benefits provided under the Plan shall either be exempt from the application of, or comply with, the requirements of Section 409A of the Code. The Plan shall be construed in a manner that effects such intent. Nevertheless, the tax treatment of the benefits provided under the Plan is not warranted or guaranteed. Neither the Company, the Successor Entity, nor their respective directors, officers, employees or advisers (other than in his or her capacity as a Participant) shall be held liable for any taxes, interest, penalties or other monetary amounts owed by any Participant or other taxpayer as a result of the Plan.

6.2 Definitional Restrictions. Notwithstanding anything in the Plan to the contrary, to the extent that any amount or benefit that would constitute non-exempt "deferred compensation" for purposes of Section 409A of the Code ("Non-Exempt Deferred Compensation") would otherwise be payable or distributable under the Plan by reason of the occurrence of the Participant's separation from service, such Non-Exempt Deferred Compensation will not be payable or distributable to the Participant by reason of such circumstance unless the circumstances giving rise to such separation from service meet any description or definition of "separation from service" in Section 409A of the Code and applicable regulations (without giving effect to any elective provisions that may be available under such definition). This provision does not prohibit the vesting of any amount upon a separation from service, however defined. If this provision prevents the payment or distribution of any Non-Exempt Deferred Compensation, such payment or distribution shall be made on the date, if any, on which an event occurs that constitutes a Section 409A-compliant "separation from service," or such later date as may be required by subsection 6.3 below.

6.3 Six-Month Delay in Certain Circumstances. Notwithstanding anything in the Plan to the contrary, if any amount or benefit that would constitute Non-Exempt Deferred Compensation would otherwise be payable or distributable under this Plan by reason of a Participant's separation from service during a period in which the Participant is a Specified Employee (as defined below), then, subject to any permissible acceleration of payment by the Committee under Treas. Reg. Section 1.409A-3(j)(4)(ii) (domestic relations order), (j)(4)(iii) (conflicts of interest), or (j)(4)(vi) (payment of employment taxes): (i) the amount of such Non-Exempt Deferred Compensation that would otherwise be payable during the six-month period immediately following the Participant's separation from service will be accumulated through and paid or provided on the first day of the seventh month following the Participant's separation from service (or, if the Participant dies during such period, within thirty (30) days after the Participant's death) (in either case, the "Required Delay Period"); and (ii) the normal payment or distribution schedule for any remaining payments or distributions will resume at the end of the Required Delay Period. For purposes of this Plan, the term "Specified Employee" has the meaning given such term in Code Section 409A and the final regulations thereunder.

6.4 Timing of Release. Whenever in this Agreement a payment or benefit is conditioned on the Participant's execution of a release of claims and covenant not to sue, the Company shall provide such release to the Participant promptly following the Date of Termination, and such release and covenant not to sue must be executed and all revocation periods shall have expired in accordance with terms set forth in the release, but in no case later than sixty (60) days

after the Date of Termination; failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes Non-Exempt Deferred Compensation, then, subject to subsection 6.3 above, such payment or benefit (including any installment payments) that would have otherwise been payable during such 60-day period shall be accumulated and paid on the 60th day after the Date of Termination provided such release shall have been executed and such revocation periods shall have expired. If such payment or benefit is exempt from Section 409A of the Code, the Company may elect to make or commence payment at any time during such 60-day period.

7. **Termination Procedures**. Any purported termination of a Participant's employment shall be communicated by written Notice of Termination from the terminating party to the other party in accordance with Section 10 hereof. For purposes of this Section 7, a "Notice of Termination" shall mean (a) in the case of termination by the Company with Cause or by the Participant with Good Reason, a notice indicating (i) in reasonable detail the facts and circumstances giving rise to the determination that Cause or Good Reason exists, as applicable, and (ii) the effective date of the termination of employment (absent cure, as provided below and, in the case of termination by the Participant with Good Reason, in compliance with the time period set forth in Section 1.12 herein), and (b) in the case of all other terminations of employment, a notice indicating the effective date of the termination of employment, in each case, subject to any other contractual obligations that may exist between the Company and the Participant (the date specified in any such Notice of Termination, the "Date of Termination"). Notwithstanding the foregoing, in the case of a termination by the Participant with Good Reason, the Company shall have an opportunity to cure the circumstances giving rise to Good Reason within thirty (30) days after receipt of such Notice of Termination. If the Company fails to cure such circumstances, the Date of Termination shall be as specified in the Notice of Termination, notwithstanding such thirty (30) day cure period.

8. **No Mitigation**. No Participant shall be required to seek other employment or to attempt in any way to reduce or mitigate any benefits payable under this Plan and the amount of any such benefits shall not be reduced by any other compensation paid or provided to any Participant following such Participant's termination of service.

9. **Successors.**

9.1 Company Successors. This Plan shall inure to the benefit of and shall be binding upon the Company, the Successor Entity, and their successors and assigns. Any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume and agree to perform the obligations of the Company under this Plan.

9.2 Participant Successors. This Plan shall inure to the benefit of and be enforceable by each Participant's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees, legatees or other beneficiaries. If a Participant shall die while any amount remains payable to such Participant hereunder, all such amounts shall be paid in accordance with the terms of this Plan to the executors, personal representatives or administrators of such Participant's estate.

10. **Notices**. All communications relating to matters arising under this Plan shall be in writing and shall be deemed to have been duly given when hand delivered, faxed, emailed or mailed by reputable overnight carrier or United States certified mail, return receipt requested, addressed, if to a Participant, to the address on file with the Company and, if to the Company, to the address set forth below, or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notice of change of address shall be effective only upon actual receipt:

Checkpoint Therapeutics, Inc.
95 Sawyer Road, Suite 110
Waltham, Massachusetts 02453
Attention: Board of Directors

11. **Code Section 280G.**

11.1 Notwithstanding anything in this Agreement to the contrary, in the event it shall be determined that any benefit, payment or distribution by the Company to or for the benefit of the Participant (whether payable or distributable pursuant to the terms of this Plan or otherwise) (such benefits, payments or distributions are hereinafter referred to as "Payments") would, if paid, be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then the aggregate present value of the Payments shall be reduced (but not below zero) to an amount expressed in present value that maximizes the aggregate present value of the Payments without causing the Payments or any part thereof to be subject to the Excise Tax and therefore nondeductible by the Company because of Section 280G of the Code (the "Reduced Amount"). The reduction of the Payments due hereunder, if applicable, shall be made by first reducing cash Payments and then, to the extent necessary, reducing those Payments having the next highest ratio of Parachute Value to actual present value of such Payments as of the date of the change of control, as determined by the Determination Firm (as defined in subsection (b) below). For purposes of this Section 11, present value shall be determined in accordance with Section 280G(d)(4) of the Code. For purposes of this Section 11, the "Parachute Value" of a Payment means the present value as of the date of the change of control of the portion of such Payment that constitutes a "parachute payment" under Section 280G(b)(2) of the Code, as determined by the Determination Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

11.2 All determinations required to be made under this Section 11, including whether an Excise Tax would otherwise be imposed, whether the Payments shall be reduced, the amount of the Reduced Amount, and the assumptions to be utilized in arriving at such determinations, shall be made by an independent, nationally recognized accounting firm or compensation consulting firm mutually acceptable to the Company and the Participant (the "Determination Firm") which shall provide detailed supporting calculations both to the Company and the Participant within fifteen (15) business days of the receipt of notice from the Participant that a Payment is due to be made, or such earlier time as is requested by the Company. All fees and expenses of the Determination Firm shall be borne solely by the Company. Any determination by the Determination Firm shall be binding upon the Company and the Participant. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Determination Firm hereunder, it is possible that Payments hereunder will have been

unnecessarily limited by this Section 11 ("Underpayment"), consistent with the calculations required to be made hereunder. The Determination Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Participant together with interest at the applicable Federal rate provided for in Section 7872(f)(2) of the Code, but no later than March 15 of the year after the year in which the Underpayment is determined to exist, which is when the legally binding right to such Underpayment arises.

11.3 In the event that the provisions of Code Section 280G and 4999 or any successor provisions are repealed without succession, this Section 11 shall be of no further force or effect.

12. **Miscellaneous.**

12.1 No Right to Continued Service. Nothing contained in this Plan shall (i) confer upon any Participant any right to continue as an employee of the Company or any Successor Entity, (ii) constitute any contract of employment or agreement to continue employment for any particular period, or (iii) interfere in any way with the right of the Company or any Successor Entity to terminate a service relationship with any Participant, with or without Cause.

12.2 Termination and Amendment of Plan. Except as provided below, during the eighteen (18) month period following a Change in Control, neither the Company nor any Successor Entity may terminate this Plan, nor may the Company or any Successor Entity amend this Plan if any such amendment would have an adverse impact on the interests of any Participant under this Plan, in either case, without the express written consent of each Participant so affected. At any time prior to a Change in Control, the Board may, in its sole discretion, terminate or amend this Plan by resolution. Following a Participant's Qualifying Termination, no Plan termination or amendment shall adversely affect the rights of such Participant under the Plan without such Participant's written consent.

12.3 Withholding. The Company shall have the authority and the right to deduct and withhold an amount sufficient to satisfy federal, state, local and foreign taxes required by law to be withheld with respect to any benefits payable under this Plan.

12.4 Benefits not Assignable. Except as otherwise provided herein or by law, no right or interest of any Participant under the Plan shall be assignable or transferable, in whole or in part, either directly or by operation of law or otherwise, including without limitation by execution, levy, garnishment, attachment, pledge or in any manner; no attempted assignment or transfer thereof shall be effective; and no right or interest of any Participant under the Plan shall be liable for, or subject to, any obligation or liability of such Participant. When a payment is due under this Plan to a Participant who is unable to care for his or her affairs, payment may be made directly to his or her legal guardian or personal representative.

12.5 Applicable Law. This Plan shall be construed and interpreted in accordance with the laws of the State of Delaware without reference to the conflict of laws provisions thereof, to the extent not preempted by federal law, which shall otherwise control.

12.6 Validity. The invalidity or unenforceability of any provision of this Plan shall not affect the validity or enforceability of any other provision of this Plan, which shall remain in full force and effect.

12.7 Captions. The captions contained in this Plan are for convenience only and shall have no bearing on the meaning, construction or interpretation of the Plan's provisions.

12.8 Expenses. The expenses of administering the Plan shall be borne by the Company or any Successor Entity.

12.9 Unfunded Plan. The Plan is intended to be an "unfunded" plan for severance benefits. Nothing contained in the Plan shall give the Participant any rights that are greater than those of a general unsecured creditor of the Company or any Successor Entity.

The foregoing is hereby acknowledged as being the Change in Control Severance Plan as adopted by the Board on April 26, 2022.

CHECKPOINT THERAPEUTICS, INC.

By: /s/ James Oliviero
Its: Chief Executive Officer

Exhibit 19.1

FORTRESS BIOTECH, INC. AND SUBSIDIARIES

INSIDER TRADING POLICY

January 22, 2024

PERSONS COVERED

This Insider Trading Policy applies to Fortress Biotech, Inc. ("***Fortress***") and each of its publicly traded and private subsidiaries in which Fortress has a 50% or greater ownership interest or otherwise has a minority economic interest but majority voting interest. Fortress and each such subsidiary are referenced herein individually as a "***Company***" and collectively the "***Companies***."

The term "***Insiders***" includes: (a) all directors, officers, and employees of the Companies, together with their Family Members (as defined below); and (b) any person who receives Inside Information (as defined below) regarding the Companies, for so long as such Inside Information is material and not publicly known. The term "***Family Members***" includes (1) any family member who resides with an Insider, (2) any other person who lives in the Insider's household, and (3) any other person who does not live in an Insider's household but whose transactions in a Company's securities are directed by, or subject to the influence or control of, such Insider, or who is otherwise financially dependent on the Insider. Directors, officers, and employees are responsible for informing their Family Members about this Insider Trading Policy.

A director, officer, or employee of a Company must pre-clear trading in, or transfer of, any securities of the Companies for himself or herself and any Family Member in accordance with the procedures in Exhibit A. The pre-clearance requirement applies to all accounts of such persons, including any legal entity that he or she controls (e.g., as general partner of a partnership account, trustee of a trust account, and executor or administrator of an estate account).

Certain consultants to a Company may receive Inside Information and may be subject to trading pre-clearance requirements on a case-by-case basis.

PURPOSE

The purpose of this Insider Trading Policy is to describe the Companies' pre-trading clearance procedures and the circumstances under which trading in, and causing the trading of, the stock of a Company or another publicly-traded company with which a Company has business dealings (each, a "***Third Party***") by an Insider will result in civil liability and criminal penalties, as well as disciplinary action by the Company.

During the course of your employment or service with a Company, you may receive material information about one or more of the Companies or a Third Party that is not publicly available, *i.e.*, not disclosed to the public in a press release or filing with the United States Securities and Exchange Commission ("***Inside Information***"). The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Because of your access to this type of information, you may be in a position to profit financially by buying or

selling or in some other way dealing in one or more of a Company's or a Third Party's stock while in possession of Inside Information, or to disclose (or "tip") such information to a third party who does so (known as a "***Tippee***").

This policy and applicable law prohibit any Insider from trading on or otherwise using Inside Information to gain a personal benefit or to disclose such information to someone else who might do so. There is no *de minimis* exception to this rule. Using Inside Information to gain a personal benefit and tipping are as illegal with respect to a few shares of stock as they are with respect to a large number of shares. You can be held liable both for your own transactions and for transactions by a Tippee, or even a third party who receives Inside Information from a Tippee. Furthermore, it is important that the *appearance* as well as the act of insider trading in stock be avoided.

From time to time, securities regulators have requested that the Companies disclose the names of Insiders of the Companies who may possess Inside Information. The purpose of these requests is to determine whether any insider trading has occurred among our Insiders or their "tippees." The Companies have complied with all such requests in the past and will continue to do so in the future. It is our intention to cooperate with securities regulators in uncovering any insider trading.

GENERAL POLICY

No Trading or Causing Trading While in Possession of Inside Information

a) No Insider may purchase or sell any Company security while in possession of Inside Information about the Company.

b) No Insider who knows of any Inside Information about a Company may communicate that information to any other person, including family and friends.

c) In addition, no Insider may purchase or sell any security of any other company while in possession of Inside Information about that company that was obtained in the course of his or her involvement with the Companies. Furthermore, no Insider who knows of any such Inside Information may communicate that information to any other person, including family and friends.

d) For compliance purposes, you should never trade, tip, or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that could be viewed as Inside Information, unless you first comply with the pre-trade clearance procedures in Exhibit A.

e) All transactions in a Company's stock, including purchases, sales, transfers, and the like, by an Insider, must be pre-cleared in accordance with the procedures in Exhibit A.

EXCEPTIONS

Please note that, generally, transactions directly with a Company, *i.e.*, option exercises, the exercise of a tax withholding right pursuant to which a person elects to have a Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock or restricted stock unit or purchases under a Company's employee stock purchase plan, will not have insider trading implications. However, the subsequent sale or other disposition of such stock *is* fully subject to these restrictions. In addition, purchases or sales pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (a "***10b5-1 Plan***"), may be made without restriction provided that it complies with the provisions regarding 10b5-1 Plans set forth below. Finally, automatic sales of shares of the Company's common stock through a Company-contracted service provider or broker to cover any taxes due as a result of the vesting of restricted stock or restricted stock units, where the amount of shares sold is based on the Insider's taxable income, the market price of the common stock on the date that the restricted stock or restricted stock or restricted stock units vest (the "***Vesting Date***") and the market price on the date of the sale, which date will be as soon as possible after the Vesting Date.

INSIDE INFORMATION

As a practical matter, it is sometimes difficult to determine whether you possess Inside Information. The key to determining whether nonpublic information you possess about a public company is Inside Information is whether dissemination of the information would be likely to affect the market price of the company's stock or would be information that a reasonable investor would want to know before making an investment decision. Certainly, if the information makes *you* want to trade, it would probably have the same effect on others. Both positive and negative information can be material. If you possess Inside Information about a Company, you must refrain from trading in that Company's stock, advising anyone else to do so or communicating the information to anyone else until you know that the information has been disseminated to the public. These restrictions also apply with respect to Fortress stock if the Company is a Fortress subsidiary. "Trading" includes engaging in short sales, transactions in put or call options, hedging transactions, and other inherently speculative transactions.

Additionally, you may not discuss material, nonpublic information about a Company with anyone outside the Company. This prohibition covers spouses, family members, friends, business associates, or persons with whom we are doing business (except to the extent that such persons are covered by a non-disclosure agreement and the discussion is necessary to accomplish a business purpose of a Company). You may not participate in "chat room" or other electronic discussion groups on the Internet concerning activities of a Company or other companies with which the Companies do business, even if you do so anonymously. You may never recommend to another person that he or she buy or sell a Company stock.

Although this is by no means an exhaustive list, information about the following items may be considered to be Inside Information until it is publicly disseminated:

a) regulatory developments, including developments with the United States Food and Drug Administration and Drug Enforcement Administration;

b) clinical developments;

c) financial results or forecasts;

d) major new products or processes;

e) establishment of, or developments in, strategic partnerships, joint ventures, or similar collaborations;

f) communications with government agencies;

g) strategic plans;

h) potential mergers, acquisitions, tender offers, or the sale of assets of a Company or a subsidiary thereof;

i) significant write-offs;

j) potential acquisitions of additional product candidates or technology;

k) notice of issuance of patents or the acquisition of other material intellectual property rights;

l) significant changes or developments in the biopharmaceutical industry or technological innovations;

m) new major contracts, orders, suppliers, customers, or finance sources, or the loss thereof;

n) significant changes or developments in supplies;

o) significant pricing changes;

p) events regarding a Company's securities (e.g., defaults on senior securities, call of securities for redemption, repurchase plans, stock splits, public or private equity/debt offerings, or changes in a Company's dividend policies or amounts);

q) significant changes in control or senior management;

r) significant changes in compensation policies;

s) bankruptcies or receiverships;

t) actual or threatened major litigation, or a major development in or the resolution of such litigation; and

u) change in auditors or a notification that a Company can no longer rely on an auditor's report.

PROHIBITION OF SPECULATIVE TRADING

No Insider may engage in short sales, transactions in put or call options, hedging transactions, or other inherently speculative transactions with respect to a Company's stock at any time.

Directors and officers of a Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Securities Exchange Act of 1934, as amended. Directors and officers may not purchase and sell a Company's securities within a six-month period whether or not they had knowledge of any Inside Information during those times. Neither the receipt of an option under a Company's equity plans, nor the exercise of that option, will be deemed a purchase under Section 16; however, the sale of any such shares is a sale under Section 16. Moreover, no officer or director may ever make a short sale of a Company's stock.

PRE-CLEARANCE PROCEDURES

A director, officer, or employee of a Company must pre-clear trading in, or transfer of, any securities of the Companies for himself or herself and any Family Member in accordance with the procedures in Exhibit A. The pre-clearance requirement applies to all accounts of such persons, including any legal entity that he or she controls (e.g., as general partner of a partnership account, trustee of a trust account, and executor or administrator of an estate account).

BLACKOUT PERIODS

a) ***Quarterly Blackout Periods***. Pre-clearance requests will not be approved during the period beginning at the close of the market on the third trading day prior to the date a Company's financial results are publicly disclosed and ending at the close of market on the second trading day following the date such Company's financial results are publicly disclosed. During these periods, Insiders generally possess or are presumed to possess Inside Information about the Company's financial results.

b) ***Exception***. These trading restrictions do not apply to transactions under a 10b5-1 Plan, provided that such 10b5-1 Plan:

i. Is submitted to and approved by the Insider Trading Compliance Officer after you execute the certification attached to this Insider Trading Policy;

ii. Is entered into in good faith by the Insider at a time when the Insider is not in possession of material non-public information about the Company (or Fortress if it is a subsidiary); and

iii. Gives a third party discretionary authority to execute such purchases and sales, outside the control of the Insider, so long as such third party does not possess any material non-public information about the Company (or Fortress if it is a subsidiary); or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

After a 10b5-1 Plan is approved by the Insider Trading Compliance Officer, any revision to it must be reviewed and approved by the Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) at least one month in advance of any trade under the revised 10b5-1 Plan.

TRADING WINDOW

From time to time, one or more of the Companies may announce via email that Insiders are permitted to trade in one or more Company's securities during a particular period of time (the "***Trading Window***"). The Company is not obligated to open a Trading Window and may do so infrequently or not at all. If a Trading Window is announced, the Company may in some instances close the Trading Window early if there is new Inside Information. Insiders are still required to submit pre-clearance requests during a Trading Window.

MARGIN ACCOUNTS AND COLLATERAL

Holding stock of a Company in margin accounts is strongly discouraged. These accounts authorize brokers to sell stock to cover amounts owed to them. A forced sale could occur at a time when the individual has knowledge of Inside Information about a Company. A similar result can occur when Company stock is pledged as collateral for a loan.

APPLICATION

a) ***Legal Penalties***. Anyone who effects transactions in a Company's or a Third Party's stock (or provides information to enable others to do so) while in possession of Inside Information in violation of this policy can be subject to civil and criminal sanctions, including imprisonment, fines, and civil penalties, and be subject to discipline or adverse employment action.

In addition, a person who tips others may also be liable for transactions by the Tippees to whom he or she has disclosed material non-public information. Tippers can be subject to the same penalties and sanctions as Tippees, and the United States Securities and Exchange Commission (the "***SEC***") has imposed large penalties even when the tipper did not profit financially from the transaction.

The SEC can also seek substantial penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Companies and/or management and supervisory personnel. These control persons may be held liable for up to the greater of $1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek a minimum of $1 million from a company and/or management and supervisory personnel as control persons.

b) Company-imposed Penalties. Directors, officers, and employees who violate this Insider Trading Policy (or whose Family Members violate this Insider Trading Policy) may be subject to disciplinary action by a Company, including dismissal for cause. Any exceptions to the Insider Trading Policy, if permitted, may only be granted in writing by the Insider Trading Compliance Officer of the relevant Company (or, in his or her absence, the Chief Executive Officer of the Company) and must be provided before any activity contrary to the above requirements

takes place. This Insider Trading Policy will continue to apply to your transactions in a Company's or a Third Party's stock even after your employment or service with the Company has terminated. If you are in possession of material nonpublic information when your employment or service terminates, you may not trade in the Company's stock (or Fortress's stock if the Company is a subsidiary) until the information has become public or is no longer material.

An Insider who has questions about these matters should speak with his or her own attorney or to the Company's Insider Trading Compliance Officer.

Any Insider who knows of or suspects a violation of this Insider Trading Policy should report the violation immediately to the Company's Insider Trading Compliance Officer, Chief Executive Officer, or Compensation Committee of the Board of Directors. Each Company will comply with all requests from the SEC, any securities exchange on which the Company's securities are listed, and other agencies for information related to insider trading investigations.

EXHIBIT A

FORTRESS BIOTECH, INC. AND SUBSIDIARIES

PRE-CLEARANCE AND COMPLIANCE PROCEDURES

To ensure compliance with the Companies' Insider Trading Policy and to help prevent in advance any inadvertent violations of the federal securities laws, and to avoid even the appearance of trading on inside information, we are implementing the following pre-clearance and compliance procedures. Terms not otherwise defined herein have the meanings ascribed to them in the Companies' Insider Trading Policy.

1. Our Mandatory Pre-Clearance Procedure. Insiders and any other persons designated under our Insider Trading Policy or otherwise designated by a Company Board of Directors may not engage in any transaction involving any of the Companies' securities (including market or private purchases or sales, option exercises, pledges, gifts, contributions to a trust, or any other transfers) without first obtaining pre-clearance of the transaction from the Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company). A request for pre-clearance must be submitted via email as set forth below to the Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) at least two days in advance of the proposed transaction. You must state in the email that you do not possess, material non-public information. The Company's Insider Trading Compliance Officer (or in his or her absence, the Chief Executive Officer of the Company) will then determine whether the transaction may proceed and, if so, provide a response via email and assist in complying with the new reporting requirements.

Fortress Employees, Officers & Directors

- Requests by Fortress employees, officers and directors to trade in the securities of Fortress or any of the Companies: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

Avenue Employees, Officers & Directors

- Requests by employees, officers or directors of Avenue Therapeutics, Inc. ("***Avenue***") to trade in the securities of Avenue: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

- Requests by employees, officers or directors of Avenue to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

Checkpoint Employees, Officers & Directors

- Requests by employees, officers or directors of Checkpoint Therapeutics, Inc.

("***Checkpoint***") to trade in the securities of Checkpoint: Checkpoint's principal financial officer (as of the date first above written Garrett Gray at ggray@checkpointtx.com)

- Requests by employees, officers or directors of Checkpoint to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

Journey Employees, Officers & Directors

- Requests by employees, officers or directors of Journey Medical Corporation ("***Journey***") to trade in the securities of Journey: Journey's chief legal officer and principal financial officer (as of the date first above written, Ramsey Alloush at ralloush@jmcderm.com and Joseph Benesch at jbenesch@jmcderm.com)

- Requests by employees, officers or directors of Journey to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

Mustang Employees, Officers & Directors

- Requests by employees, officers or directors of Mustang Bio, Inc. ("***Mustang***") to trade in the securities of Mustang: Mustang's chief legal officer and principal financial officer (as of the date first above written, for purposes of this Insider Trading Policy, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

- Requests by employees, officers or directors of Mustang to trade in the securities of Fortress or any other affiliate: Fortress' chief legal officer and principal financial officer (as of the date first above written, Samuel Berry at sberry@fortressbiotech.com and David Jin at djin@fortressbiotech.com)

Any Insider who wishes to implement a new trading plan under SEC Rule 10b5-1 must first pre-clear the plan with the Insider Trading Compliance Officer for each Company whose securities are included in the plan. Transactions effected pursuant to a pre-cleared trading plan will not require further pre-clearance at the time of the transaction if the plan specifies the dates, prices, and amounts of the contemplated trades, or establishes a formula for determining the dates, prices, and amounts. Those transactions, however, must be reported immediately to the Insider Trading Compliance Officer.

2. Broker-Assisted Cashless Exercises of Options. The Sarbanes-Oxley Act makes it illegal for issuers to extend or maintain credit or arrange for the extension of credit in the form of a personal loan to any officer or director. In most broker-assisted cashless exercises, there is typically a delay of a few days from the time of exercise to the date the issuer receives the exercise price. Some attorneys have speculated that these arrangements could be deemed an impermissible

extension of credit arranged by issuers for their insiders. Consequently, unless and until this issue gets resolved to our satisfaction, we require receipt of cash simultaneous with any issuance of shares pursuant to the exercise of an option by an insider. We believe that most brokers can do cashless exercises for you this way.

Any person who has a question about these procedures or their application to any proposed transaction may obtain additional guidance from the Insider Trading Compliance Officer.

Certifications and Attestations

All directors, officers, and employees subject to the procedures set forth in this Insider Trading Policy must certify their understanding of and intent to comply with it, as it may be amended and updated from time to time. Please return the enclosed certification immediately (unless you have previously submitted an executed certification).

You also may be required to periodically attest in writing to your compliance with this Insider Trading Policy and its pre-clearance procedures.

FORTRESS BIOTECH, INC.

INSIDER TRADING POLICY

CERTIFICATION

To Fortress Biotech, Inc. and its Subsidiaries

I,_____, have received and read a copy of the Fortress Biotech, Inc. and Subsidiaries Insider Trading Policy. I hereby agree to comply with the specific requirements of the policy in all respects during my employment or other service relationship with Fortress Biotech, Inc. and/or its subsidiaries. I understand that this policy constitutes a material term of my employment or other service relationship with Fortress Biotech, Inc. and/or its subsidiaries and that my failure to comply in all respects with the policy is a basis for termination for cause.

_____
(Signature)

_____
(Name)

_____
(Date)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-270474, 333-270843, 333-271171, 333-275644, 333-278397, 333-281650) on Form S-3 and (Nos. 333-216856, 333-221488, 333-251000, 333-268740, 333-275643, 333-279716) on Form S-8 of our report dated March 28, 2025, with respect to the financial statements of Checkpoint Therapeutics, Inc.

/s/ KPMG LLP

Boston, Massachusetts
March 28, 2025

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James F. Oliviero certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2024 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 28, 2025

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garrett Gray, certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2024 of Checkpoint Therapeutics, Inc. (the registrant);

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

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

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

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

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

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

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

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

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

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

Dated: March 28, 2025

By: /s/ Garrett Gray
Garrett Gray
Chief Financial Officer
Principal Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James F. Oliviero, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 28, 2025

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Checkpoint Therapeutics, Inc. (the "Company") for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrett Gray, Principal Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Dated: March 28, 2025

By: /s/ Garrett Gray
Garrett Gray
Chief Financial Officer
Principal Financial Officer