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

FORM 10-Q
(Mark one)

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

For the quarterly period ended March 31, 2025

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, MA 02453
(Address of principal executive offices and zip code)

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

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 share	CKPT	NASDAQ Capital Market

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, a smaller reporting company, or an emerging growth company. See definition 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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

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 May 9, 2025**
Class A Common Stock, $0.0001 par value	700,000
Common Stock, $0.0001 par value	86,320,002

CHECKPOINT THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended March 31, 2025

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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.
- Tariffs and other trade measures could adversely affect our business, results of operations, financial position and cash flows.

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.

Item 1. Financial Statements.

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

	March 31, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 33,042	$ 6,604
Prepaid expenses and other current assets	1,122	867
Total current assets	34,164	7,471
Total Assets	**$ 34,164**	**$ 7,471**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 14,741	$ 17,465
Accounts payable and accrued expenses - related party	2,868	2,433
Common stock warrant liabilities	260	198
Total current liabilities	17,869	20,096
Total Liabilities	**17,869**	**20,096**
Commitments and Contingencies (Note 5)		
Stockholders' Equity (Deficit)		
Common Stock ($0.0001 par value), 175,000,000 shares authorized as of March 31, 2025 and December 31, 2024		
Class A common shares, 700,000 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common shares, 83,063,733 and 53,640,422 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	8	5
Common stock issuable, 0 and 2,386,808 shares as of March 31, 2025 and December 31, 2024, respectively	—	7,638
Additional paid-in capital	398,072	350,305
Accumulated deficit	(381,785)	(370,573)
Total Stockholders' Equity (Deficit)	16,295	(12,625)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 34,164**	**$ 7,471**

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

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

	For the three months ended March 31,	
	2025	2024
Revenue - related party	$ —	$ —
Operating expenses:		
Research and development	3,788	8,497
General and administrative	7,361	2,451
Total operating expenses	11,149	10,948
Loss from operations	(11,149)	(10,948)
Other income (loss):		
Interest income	1	4
Loss on common stock warrant liabilities	(62)	—
Foreign currency exchange loss	(2)	(1)
Total other income (loss)	(63)	3
Net Loss	**$ (11,212)**	**$ (10,945)**
Loss per Share:		
Basic and diluted net loss per Class A common shares and common shares outstanding	$ (0.19)	$ (0.33)
Basic and diluted weighted average number of Class A common shares and common shares outstanding	59,823,565	32,930,977

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

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

For the Three Months Ended March 31, 2025

	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, 2024	**700,000**	**$ —**	**53,640,422**	**$ 5**	**$ 7,638**	**$ 350,305**	**$ (370,573)**	**$ (12,625)**
Issuance of common shares - Founders Agreement	—	—	2,405,308	—	(7,638)	7,690	—	52
Stock-based compensation expense	—	—	3,150,000	—	—	1,956	—	1,956
Exercise of common stock warrants	—	—	23,868,003	3	—	38,121	—	38,124
Net loss	—	—	—	—	—	—	(11,212)	(11,212)
Balances at March 31, 2025	**700,000**	**$ —**	**83,063,733**	**$ 8**	**$ —**	**$ 398,072**	**$ (381,785)**	**$ 16,295**

For the Three Months Ended March 31, 2024

	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, 2023	**700,000**	**$ —**	**27,042,035**	**$ 3**	**$ 3,419**	**$ 297,864**	**$ (314,333)**	**$ (13,047)**
Issuance of common shares, net of offering costs - Registered direct offering	—	—	1,275,000	1	—	12,636	—	12,637
Issuance of common shares - Founders Agreement	—	—	193,905	—	—	396	—	396
Stock-based compensation expense	—	—	2,680,106	—	—	709	—	709
Exercise of pre-funded and common stock warrants	—	—	3,795,233	—	—	—	—	—
Net loss	—	—	—	—	—	—	(10,945)	(10,945)
Balances at March 31, 2024	**700,000**	**$ —**	**34,986,279**	**$ 4**	**$ 3,419**	**$ 311,605**	**$ (325,278)**	**$ (10,250)**

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

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

	For the three months ended March 31,	
	2025	2024
Cash Flows from Operating Activities:		
Net loss	$ (11,212)	$ (10,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,956	709
Issuance of common shares - Founders Agreement	52	396
Loss on common stock warrant liabilities	62	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(255)	(284)
Accounts payable and accrued expenses	(2,724)	3,524
Accounts payable and accrued expenses - related party	435	126
Net cash used in operating activities	(11,686)	(6,474)
Cash Flows from Financing Activities:		
Proceeds from issuance of common shares - Registered direct offering	—	14,000
Payment of offering costs for the issuance of common shares - Registered direct offering	—	(1,213)
Cash received for exercise of warrants	38,124	—
Net cash provided by financing activities	38,124	12,787
Net increase in cash and cash equivalents	26,438	6,313
Cash and cash equivalents at beginning of period	6,604	4,928
Cash and cash equivalents at end of period	**$ 33,042**	**$ 11,241**
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 7,638	$ —
Issuance of common shares - Registered direct offering (offering costs incurred but not paid)	$ —	$ 150

The accompanying notes are an integral part of these condensed 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."

Recent Developments

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.

On April 14, 2025, the Company, Parent and Merger Sub entered into an Amendment to the Merger Agreement (the "Merger Agreement Amendment"). Pursuant to the Merger Agreement Amendment, the shareholder voting standard to approve the Merger was amended in response to recently enacted amendments to the Delaware General Corporation Law, as amended. Other than as expressly set forth in the Merger Agreement Amendment, the Merger Agreement remains unmodified and in full force and effect in accordance with its terms.

On April 14, 2025, the Company filed the definitive proxy statement relating to the Merger. The special meeting of Company stockholders to vote on the Merger and related matters will be held on May 28, 2025, at 10:00 a.m., Eastern Time, solely in virtual format.

For a more detailed description of the Merger Agreement, see Note 10.

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 March 31, 2025, the Company had an accumulated deficit of $381.8 million.

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 includes 6,481,233 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 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 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 includes 4,623,659 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 will 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 exercise of warrants for the issuance of 3,256,269 shares of common stock 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. These shares were fully issued to the holder in February 2025.

In January 2025, the Company received approximately $2.1 million from the exercise of warrants for the issuance of 740,000 shares of common stock with an exercise price of $2.84 per share.

In March 2025, the Company 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.

In April 2025, the Company received approximately $9.2 million from the exercise of warrants for the issuance of 3,256,269 shares of common stock with an exercise price of $2.821 per share.

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 of Directors 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 first quarter of 2026, assuming no exercises of outstanding common stock warrants. The Company has suffered recurring losses from operations and has a net capital deficiency that raises 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 that 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 accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. They may not include all of the information and notes required by GAAP for complete financial statements. Therefore, these condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2024, which were included in the Company's Form 10-K and filed with the SEC on March 28, 2025. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

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 9).

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.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2024 Annual Report on Form 10-K.

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.

Inventory

Prior to regulatory approval, the Company expensed 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 materials, costs associated with regulatory filings, laboratory costs and other supplies.

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

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 2,386,808 shares of common stock to Fortress on January 1, 2025 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 Condensed 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 (expense), in the Condensed 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 the standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

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

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

- the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct); and
- 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% likelihood 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 March 31, 2025, and December 31, 2024, 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. 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 March 31, 2025 and 2024 that were excluded from the computation of diluted net loss per share, as they would be anti-dilutive:

	March 31,	
	2025	2024
Warrants (Note 6)	14,640,637	42,139,278
Stock options (Note 6)	127,000	127,000
Unvested restricted stock awards (Note 6)	6,618,198	3,742,676
Unvested restricted stock units (Note 6)	—	598,246
Total	21,385,835	46,607,200

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 Pronouncements

In January 2025, the Financial Accounting Standards Board issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40) - Clarifying the Effective Date*, to clarify the effective date of ASU 2024-03, 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.

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 programmed death-ligand 1 ("PD-L1"), Glucocorticoid-induced TNFR-related protein ("GITR") and Carbonic anhydrase IX ("CAIX"). 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, of which $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.

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.

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. 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. 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.

Note 4 - Related Party Agreements

Agreements 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.

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 of the Merger (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 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.

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.

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 each of the three months ended March 31, 2025 and 2024, the Company recognized $125,000 in expense in the Condensed Statements of Operations related to the MSA.

Caribe BioAdvisors, LLC

In December 2016, the Company entered into an advisory agreement effective January 1, 2017 with Caribe BioAdvisors, LLC ("Caribe"), owned by Michael Weiss, to provide the advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the agreement, Caribe will be paid an annual cash fee of $60,000, in addition to any and all annual equity incentive grants paid to members of the board. In June 2023, Mr. Weiss assigned the agreement to Hawkins BioVentures, LLC. For the three months ended March 31, 2025 and 2024, the Company recognized approximately $32,000 and $27,000, respectively, in expense in its Condensed Statements of Operations related to the advisory agreement, including approximately $17,000 and $12,000 in expense related to annual 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 and its board of directors have been named as defendants in lawsuits filed in New York state court regarding the proposed Merger. The actions are styled Collins v. Checkpoint Therapeutics, Inc., et al., No. 652730/2025 (the "Collins Action") and Malone v. Checkpoint Therapeutics, Inc., et al., No. 652740/2025 (the "Malone Action"). The Complaints in the Collins and Malone Actions, which were filed on May 1 and May 2, 2025, respectively, assert claims against all defendants under New York law for negligent misrepresentation and concealment as well as negligence.

Finally, Checkpoint has received demand letters from purported Checkpoint stockholders generally alleging disclosure deficiencies in connection with the disclosures associated with the proposed Merger (the "Demand Letters").

The Company believes that the allegations in the Securities Class Action, the Derivative Action, the Collins Action, the Malone Action, and the Demand Letters 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 March 31, 2025 and December 31, 2024, there were 700,000 shares of Class A common stock issued and outstanding to Fortress. 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 March 2023, the Company filed a shelf registration statement on Form S-3 (the "March 2023 Form S-3"), which was declared effective May 5, 2023 (File No. 333-270843). Under the March 2023 Form S-3, the Company may sell up to a total of $150 million of its securities.

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.

As of March 31, 2025, approximately $65.7 million of securities remain available for sale under the March 2023 Form S-3.

The Company may offer the securities under the Form S-3's 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.

Warrant Exercises

In November 2024, the Company received approximately $9.2 million from the exercise of warrants for the issuance of 3,256,269 shares of common stock 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. The final remaining 1,437,000 shares held in abeyance were issued to the holder in February 2025.

In January 2025, the Company received approximately $2.1 million from the exercise of warrants for the issuance of 740,000 shares of common stock with an exercise price of $2.84 per share.

In March 2025, the Company 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.

Shares Issued Under the Founders Agreement

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 to Fortress 2.5% of the aggregate number of shares of common stock issued in the January 2024 Registered Direct Offering. Accordingly, the Company issued 193,905 shares of common stock to Fortress and recorded expense of approximately $396,000 related to these issuances, which is included in general and administrative expenses in the Company's Condensed Statements of Operations for the three months ended March 31, 2024.

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 (see Notes 2 and 4). 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 issued to Fortress 2.5% of the aggregate number of shares of common stock issued in the January 2025 warrant exercises noted above. Accordingly, the Company issued 18,500 shares of common stock to Fortress and recorded expense of approximately $52,000, which is included in general and administrative expenses in the Company's Condensed Statements of Operations for the three months ended March 31, 2025.Pursuant to the terms of the Support Agreement entered into concurrently with the Merger Agreement, there were no shares issued to Fortress in relation to the warrant exercises in March 2025 noted above.

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 March 31, 2025, 4,860,406 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 three months ended March 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2024	4,887,499	$ 2.48
Granted	3,150,000	2.84
Vested	(1,419,301)	2.59
Non-vested at March 31, 2025	6,618,198	$ 2.63

As of March 31, 2025, there was $11.8 million of total unrecognized compensation cost related to non-vested restricted stock, which is expected to be recognized over a weighted-average period of 1.8 years.

Restricted Stock Units

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. All outstanding restricted stock units vested upon this achievement and as of March 31, 2025, there were no restricted stock units outstanding.

Stock Options

The following table summarizes stock option award activity for the three months ended March 31, 2025:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2024	127,000	$ 8.88	7.60
Outstanding as of March 31, 2025	127,000	$ 8.88	7.35
Vested and exercisable as of March 31, 2025	121,000	$ 6.63	7.62

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.

Warrants

A summary of warrant activities for the three months ended March 31, 2025 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2024	39,567,888	$ 2.10	3.09
Exercised	(22,431,003)	1.70	
Expired	(2,496,248)	2.84	
Outstanding as of March 31, 2025	14,640,637	$ 2.60	3.67

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

Stock-Based Compensation

The following table summarizes stock-based compensation expense for the three months ended March 31, 2025 and 2024 ($ in thousands):

	For the three months ended March 31,	
	2025	2024
Research and development	$ 689	$ 490
General and administrative	1,267	220
Total stock-based compensation expense	$ 1,956	$ 709

Note 7 - Common Stock Warrant Liabilities

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 a registered direct offering. The common stock and the pre-funded warrants were sold together with Series A and Series B common stock warrants. The Company also issued the placement agent warrants to purchase shares of common stock as part of the offering. After the Company entered into an inducement agreement with a certain holder to exercise the Series A and Series B common stock warrants in October 2023, only the placement agent warrants remained outstanding from this offering.

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.

The Company deemed the placement agent warrants issued in December 2022 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 warrants were recorded at the time of closing at a fair value, determined by using the Black-Scholes Model, and will be revalued at each reporting period thereafter for as long as they remain outstanding. The Company revalued the warrants at March 31, 2025 and December 31, 2024, resulting in a fair value of approximately $260,000 and $198,000, respectively.

	Common Stock Warrant Liabilities
Common Stock Warrant liabilities at December 31, 2024	$ 198
Change in fair value of Common Stock Warrant liabilities	62
Common Stock Warrant liabilities at March 31, 2025	$ 260

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:

	March 31, 2025	December 31, 2024
Exercise price	$ 5.41	$ 5.41
Volatility	114.9 %	111.1 %
Expected life	2.7	3.0
Risk-free rate	3.9 %	4.3 %
Dividend yield	—	—

Note 8 - Accounts Payable and Accrued Expenses

At March 31, 2025 and December 31, 2024, accounts payable and accrued expenses consisted of the following ($ in thousands):

	March 31, 2025	December 31, 2024
Accounts payable	$ 5,113	$ 6,091
Accrued compensation	554	1,877
Accrued legal	2,987	1,243
Accrued Research and development	5,838	8,036
Other	249	218
Total accounts payable and accrued expenses	$ 14,741	$ 17,465

Note 9 - 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 three months ended March 31, 2025 and 2024, the significant expense categories regularly provided to the CODM consisted of the following (in thousands):

	For the three months ended March 31,	
	2025	2024
Revenue - related party	$ —	$ —
Operating expenses:		
Employee Expenses	2,463	2,109
Stock-based Compensation	1,956	709
Fortress Founder's Agreement and MSA Expenses	177	521
Manufacturing and Development Expenses	352	4,442
Clinical Expenses	605	1,300
Regulatory Expenses	20	303
License Fees	93	50
Legal & Accounting Expense	3,137	643
R&D Other Expense [1]	134	275
G&A Other Expense [2]	2,212	596
Total Operating Expenses	11,149	10,948
Other Segment Items [3]	(63)	3
Net Loss	**$ (11,212)**	**$ (10,945)**

(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. For 2025, it also includes other Merger related costs, including fees paid to financial advisors.
(3) Other Segment Items include interest income, foreign currency exchange loss, and loss on common stock warrant liabilities.

Note 10 - Merger Agreement

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

Pursuant to the Merger Agreement, at the Effective Time of the Merger, 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 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 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 Founders Agreement, dated as of July 11, 2016, as amended 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 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, 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.

The Company is currently evaluating the tax implications of the Merger.

Note 11 - Subsequent Events

On April 14, 2025, the Company, Parent and Merger Sub entered into the Merger Agreement Amendment. Pursuant to the Merger Agreement Amendment, the shareholder voting standard to approve the Merger was amended in response to recently enacted amendments to the Delaware General Corporation Law, as amended. Other than as expressly set forth in the Merger Agreement Amendment, the Merger Agreement remains unmodified and in full force and effect in accordance with its terms.

On April 14, 2025, the Company filed the definitive proxy statement relating to the Merger. The special meeting of Company stockholders to vote on the Merger and related matters will be held on May 28, 2025, at 10:00 a.m., Eastern Time, solely in virtual format.

In April 2025, the Company received approximately $9.2 million from the exercise of warrants for the issuance of 3,256,269 shares of common stock with an exercise price of $2.821 per share.

Item 2. Financial Information.

Management's Discussion and Analysis of Financial Condition and 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 not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to significant risks and uncertainties and we can give no assurances that our expectations will prove to be correct. Actual results could differ materially 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.

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 10 to our financial statements.

On April 14, 2025, the Company, Parent and Merger Sub entered into an Amendment to the Merger Agreement (the "Merger Agreement Amendment"). Pursuant to the Merger Agreement Amendment, the shareholder voting standard to approve the Merger was amended in response to recently enacted amendments to the Delaware General Corporation Law, as amended. Other than as expressly set forth in the Merger Agreement Amendment, the Merger Agreement remains unmodified and in full force and effect in accordance with its terms.

On April 14, 2025, the Company filed the definitive proxy statement relating to the Merger. The special meeting of Company stockholders to vote on the Merger and related matters will be held on May 28, 2025, at 10:00 a.m., Eastern Time, solely in virtual format.

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 March 31, 2025, we have an accumulated deficit of $381.8 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 generally accepted accounting principles in the United States of America ("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. We evaluate our estimates and judgments on an ongoing basis, including, but not limited to, those related to research and development expenses, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the MD&A in the 2024 Form 10-K. There were no material changes in our critical accounting estimates or accounting policies from December 31, 2024.

Accounting Pronouncements

In January 2025, the Financial Accounting Standards Board issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40) - Clarifying the Effective Date*, to clarify the effective date of ASU 2024-03, 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. We are currently evaluating the impact of the new standard on our disclosures.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

Revenue

For the three months ended March 31, 2025 and 2024, we recognized no revenue.

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 three months ended March 31, 2025, research and development expenses were approximately $3.8 million, compared to $8.5 million for the three months ended March 31, 2024, a decrease of $4.7 million. The current period research and development expenses primarily consisted of $0.4 million related to manufacturing related costs, $0.6 million related to clinical costs, primarily for the CK-301-101 study, $1.6 million related to salary expenses, and $0.7 million related to non-cash stock compensation expense. The prior period research and development expenses primarily consisted of $4.4 million related to manufacturing related costs and inventory build, which is expensed prior to approval, to support a potential launch of UNLOXCYT, $1.3 million related to clinical costs, primarily for the CK-301-101 study, $1.5 million related to salary expenses, and $0.5 million related to non-cash stock compensation expense.

We anticipate our research and development expenses will remain relatively consistent for the remainder of 2025.

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, marketing and facilities-related expenses.

For the three months ended March 31, 2025, general and administrative expenses were approximately $7.4 million, compared to $2.5 million for the three months ended March 31, 2024, an increase of $4.9 million. The current period general and administrative expenses primarily consisted of non-cash stock compensation expense of $1.3 million, $0.5 million related to salary expenses, $3.1 million related to legal and accounting fees, with legal fees increasing due to costs related to the Merger, $1.5 million in other Merger related costs, including fees paid to financial advisors, $0.1 million related to our issuance of shares to Fortress pursuant to the Founders Agreement in connection with the exercise of warrants, and $0.1 million related to investor relation fees. The prior period general and administrative expenses primarily consisted of non-cash stock compensation expense of $0.2 million, $0.4 million related to salary expenses, $0.6 million related to legal and accounting fees, $0.1 million related to investor relation fees, $0.1 million related to marketing costs, and $0.4 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.

We anticipate our general and administrative expenses will increase for the remainder of 2025, pending the outcome of the Merger.

Other Income (Expense)

For the three months ended March 31, 2025, interest income was approximately $1,000 compared to approximately $4,000 for the three months ended March 31, 2024, a decrease of approximately $3,000. The decrease was primarily due to a decrease in interest earned from money in interest bearing accounts between the periods.

For the three months ended March 31, 2025, the loss on common stock warrant liabilities was approximately $62,000. For the three months ended March 31, 2024, there was no change in the value of common stock warrant liabilities compared to December 31, 2023. The loss on common stock warrant liabilities is comprised of the fair value remeasurement of the common stock warrant liabilities on March 31, 2025 associated with the registered direct offering we completed in December 2022. 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 three months ended March 31, 2025 and 2024, foreign currency exchange loss was approximately $2,000 and $1,000, respectively, 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 March 31, 2025, we had an accumulated deficit of $381.8 million.

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 exercise of warrants for the issuance of 3,256,269 shares of common stock 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. These shares were fully issued to the holder in February 2025.

In January 2025, we received approximately $2.1 million from the exercise of warrants for the issuance of 740,000 shares of common stock with an exercise price of $2.84 per share.

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.

In April 2025, we received approximately $9.2 million from the exercise of warrants for the issuance of 3,256,269 shares of common stock with an exercise price of $2.821 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 first quarter of 2026, assuming no exercises of outstanding common stock warrants. 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.

Cash Flows for the Three Months Ended March 31, 2025 and 2024

Operating Activities

Net cash used in operating activities was approximately $11.7 million for the three months ended March 31, 2025, compared to approximately $6.5 million for the three months ended March 31, 2024. The increase in net cash used in operating activities was primarily related to paying down accounts payables in the current period, as well as costs related to the Merger.

Investing Activities

There were no investing activities for the three months ended March 31, 2025 and 2024.

Financing Activities

Net cash provided by financing activities was $38.1 million for the three months ended March 31, 2025, compared to $12.8 million for the three months ended March 31, 2024. Cash provided by financing activities in the current period was from proceeds upon the exercise of warrants issued in previous registered direct offerings. The prior period amount was related to the net proceeds from the issuance of common shares as part of our January 2024 registered direct offering.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended March 31, 2025, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective. Management does not expect that our internal control over financial reporting will prevent or detect 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 systems 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 a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2025 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. 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 and our board of directors have been named as defendants in lawsuits filed in New York state court regarding the proposed Merger. The actions are styled Collins v. Checkpoint Therapeutics, Inc., et al., No. 652730/2025 (the "Collins Action") and Malone v. Checkpoint Therapeutics, Inc., et al., No. 652740/2025 (the "Malone Action"). The Complaints in the Collins and Malone Actions, which were filed on May 1 and May 2, 2025, respectively, assert claims against all defendants under New York law for negligent misrepresentation and concealment as well as negligence.

Finally, we have received demand letters from purported stockholders generally alleging disclosure deficiencies in connection with the disclosures associated with the proposed Merger (the "Demand Letters").

We believe that the allegations in the Securities Class Action, the Derivative Action, the Collins Action, the Malone Action, and the Demand Letters are without merit and intend to defend ourselves and our directors and executive officers vigorously. There is no assurance, however, that we or the other defendants will be successful in our or their defense of either of these allegations or that our insurance policy coverage will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time.

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 UNLOXCYT or 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 $381.8 million as of March 31, 2025. 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 first quarter of 2026.

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 unaudited condensed financial statements as of March 31, 2025 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 shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities or even terminate our operations.

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.

Tariffs and other trade measures could adversely affect our business, results of operations, financial position and cash flows.

Our business and results of operations may be adversely affected by uncertainty and changes in U.S. trade policies, including tariffs, trade agreements or other trade restrictions imposed by the U.S. or other governments. Our input costs for raw materials and other goods, chemical reagents and laboratory equipment, could be adversely affected by tariffs imposed by the U.S. government on products imported into the United States. Any imposition of or increase in tariffs on the goods we purchase could increase our inventory and research and development costs.

Additional tariffs, further trade restrictions and retaliatory trade measures could disrupt our supply chain and logistics, restrict or limit the availability of goods or supplies, cause adverse financial impacts due to volatility in foreign exchange rates and interest rates, and place inflationary pressures on raw materials. It may be time-consuming and expensive for us to alter our business operations to adapt to or comply with any changes in international trade policies and agreements and any failure to do so could have a material adverse effect on our business. Any potential impact will depend on future developments with respect to trade policy and the results of trade negotiations, all of which are beyond our control. These potential impacts, while uncertain, could adversely affect our business, results of operations and financial condition.

Tariffs or other trade restrictions may lead to continuing uncertainty and volatility in U.S. and global financial and economic conditions and commodity markets, declining consumer confidence, significant inflation and diminished expectations for the economy, and ultimately reduced demand for our products. Such conditions could have a material adverse impact on our business, results of operations and cash flows.

Any rising trade and political tensions or unfavorable government policies on international trade may affect the demand for our drug products, the competitive position of our drug products, the hiring of research and development personnel, the import or export of raw materials in relation to drug development or prevent us from selling our drug products in certain countries.

Inadequate funding for the FDA, the SEC and other government agencies, including from government-shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels and statutory, regulatory and policy changes. As a result of such factors, average review times at the FDA have fluctuated in recent years. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed

and/or approved by necessary government agencies, which would adversely affect business operations of regulated entities. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have furloughed critical FDA, SEC and other government employees and have also stopped critical activities. Further, future government shutdowns could impact the ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 have received demands and could be subject to 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 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 II, Item 1, Legal Proceedings.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

We have not furnished information under this item to the extent that such information previously has been included in our Annual Report on Form 10-K or in a Current Report on Form 8-K.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. 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.##
2.2	Amendment to the Agreement and Plan of Merger, dated as of April 14, 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 April 15, 2025 (File No. 001-38128) and incorporated herein by reference.
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	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.
10.1	Executive Employment Agreement, dated January 7, 2025, by and between William Garrett Gray and Checkpoint Therapeutics, Inc., filed as Exhibit 10.1 to Form 8-K filed on January 10, 2025 (File No. 001-38128) and incorporated herein by reference.#
10.2	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.##
31.1	Certification of Principal Executive Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 13, 2025.*
31.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 13, 2025.*
32.1	Certification of Principal Executive Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 13, 2025.**
32.2	Certification of Principal Financial Officer of Checkpoint Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 13, 2025.**
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

SIGNATURES

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

Checkpoint Therapeutics, Inc.
(Registrant)

Date : May 13, 2025

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James F. Oliviero, certify that:

1. I have reviewed this report on Form 10-Q of Checkpoint Therapeutics, Inc;

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 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 this 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 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.

/s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)
May 13, 2025

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garrett Gray, certify that:

1. I have reviewed this report on Form 10-Q of Checkpoint Therapeutics, Inc;

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 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 this 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 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.

/s/ Garrett Gray
Garrett Gray
Chief Financial Officer
(Principal Financial Officer)
May 13, 2025

Exhibit 32.1

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

I, James F. Oliviero, Chief Executive Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James F. Oliviero
James F. Oliviero
President and Chief Executive Officer
(Principal Executive Officer)
May 13, 2025

Exhibit 32.2

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

I, Garrett Gray, Chief Financial Officer of Checkpoint Therapeutics, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2025 (the "Report") filed with the Securities and Exchange Commission:

· Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

· The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Garrett Gray
Garrett Gray
Chief Financial Officer
(Principal Financial Officer)
May 13, 2025