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

FORM 10-K

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

For the fiscal year ended December 31, 2025

OR

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

Commission file number 001-40654

CONTEXT THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-3738787**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2001 Market Street, Suite 3915, Unit #15
Philadelphia, Pennsylvania 19103
(Address of principal executive offices, including zip)

(267) 225-7416
(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 $0.001 per share	CNTX	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $57.9 million based on the last reported sale price of the registrant's common stock on The Nasdaq Stock Market on June 30, 2025.

As of March 19, 2026, the registrant had 91,879,177 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement for its 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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Unless the context otherwise requires, all references in this Form 10-K to "Context," the "Company," "we," "us," and "our" refer to Context Therapeutics Inc. and its subsidiaries.

Trademark Notice

This Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Context Therapeutics® is a registered trademark of Context in the United States. All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners. We do not intend our use or

display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

RISK FACTOR SUMMARY

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. For more information, see "Item 1A. Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2025. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

Risks Related to Our Business and Industry

- We have never been profitable and may never achieve or maintain profitability.
- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.
- We may not be able to successfully integrate recent and future acquisitions.
- We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.
- We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.
- Fluctuating foreign exchange rates could increase our operating expenses and adversely affect our results of operations.
- Inflation, geopolitical developments, global supply chain disruptions and public health concerns could adversely affect our business and results of operations.
- Changes in U.S. trade policy, including the imposition of tariffs and the resulting consequences, may have a material adverse impact on our business, financial condition, and results of operations.

Risks Related to Our Product Candidates

- Our business is dependent on the successful development, regulatory approval and commercialization of our therapeutic product candidates, CTIM-76, CT-95 and CT-202, which are in the early stages of development.
- Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.
- Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- Any product candidate may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales.
- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.

Risks Related to Our Organization, Structure and Operations

- Our reliance on a central team consisting of a limited number of employees and consultants who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.
- Our future success depends on our ability to retain our executive officers and other key executives and to attract, retain and motivate qualified personnel.

Risks Related to Our Reliance on Third Parties

- We expect to, and do, depend on collaborations with third parties for certain research, development and commercialization activities, and to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, as well as for the manufacturing process of product candidates. If any such collaborations or services by such third parties are not successful or not performed in a satisfactory manner, it may harm our business and prospects, and we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business.
- We may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of our current or past product candidates, which may be time consuming, costly and could harm our efforts to develop our current or future product candidates.

Risks Related to Government Regulation

- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our current and any future product candidates.
- We expect that CTIM-76, CT-95 and CT-202 will be regulated as biological products, or biologics, and therefore they may be subject to competition from biosimilar applicants.
- The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of any product candidate.
- Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of such product candidate in other jurisdictions.
- Even if we obtain regulatory approval of a product candidate, the product may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.
- Coverage and reimbursement may be limited or unavailable in certain market segments for a product candidate, which could make it difficult for us to sell such product candidate, if approved, profitably.

Risks Related to Intellectual Property

- Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position.
- Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our current and any future product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.
- Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may not be able to protect our intellectual property rights throughout the world.

Risks Related to the Market for Our Common Stock

- Our common stock may be volatile or may decline regardless of our operating performance.
- We may not be able to maintain compliance with the continued listing requirements of The Nasdaq Stock Market.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management's beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts are forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the ability of our preclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for CTIM-76, CT-95, CT-202 and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of U.S. and foreign regulatory filings and approvals, including timing of Investigational New Drug ("IND") applications and final U.S. Food and Drug Administration ("FDA") approval, as well as similar applications and approvals in foreign jurisdictions, of CTIM-76, CT-95, CT-202 and any other future product candidates;
- our ability to develop and advance CTIM-76, CT-95, CT-202 and any other future product candidates, and successfully complete clinical studies;
- our manufacturing, commercialization, and marketing capabilities, implementations thereof, and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus, sales strategy, and our ability to grow a sales team;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering CTIM-76, CT-95, CT-202, and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- any disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of our current or past product candidates, which may be time consuming, costly and could harm our efforts to develop our current or future product candidates;
- the impact of economic uncertainties on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations and employees;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our competitive position and the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;

- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe, Australia, and other jurisdictions;
- our continued reliance on third parties to conduct and support clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of CTIM-76, CT-95, CT-202 and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of CTIM-76, CT-95, CT-202 and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our current plans to seek additional capital in the future through equity and/or debt financings, partnerships, collaborations, licensing agreements or other strategic arrangements, or other sources and the availability of such future sources of capital;
- our financial performance;
- our ability to maintain compliance with the continued listing requirements of The Nasdaq Stock Market;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- our anticipated use of our existing cash and cash equivalents; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” and elsewhere in this Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. As a result, you should not place undue reliance on forward-looking statements.

This Form 10-K also contains certain data and information which we obtained from various government and private publications or third parties. Although we believe that the publications, information, data and reports are reliable, we have not independently verified the data. Statistical data in these publications includes projections that are based on a number of assumptions. If any one or more of the assumptions underlying the market data is later found to be incorrect, actual results may differ from the projections based on these assumptions. Scientific and clinical data presented herein are – by definition prior to completion of the clinical trial and a clinical study report – preliminary in nature and subject to further quality checks including customary source data verification.

The forward-looking statements made in this Form 10-K relate only to events or information as of the date of the Form 10-K (or any earlier date indicated in such statement). Although we are a public company and have ongoing disclosure obligations under United States federal securities laws, we do not intend to update or otherwise revise the forward-looking statements in this Form 10-K, whether as a result of new information, future events or otherwise.

MARKET, INDUSTRY AND OTHER DATA

This Annual Report on Form 10-K contains estimates, projections, market research and other information concerning our industry, our business, markets for our product candidates, the size of those markets, and the prevalence of certain medical conditions. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information.

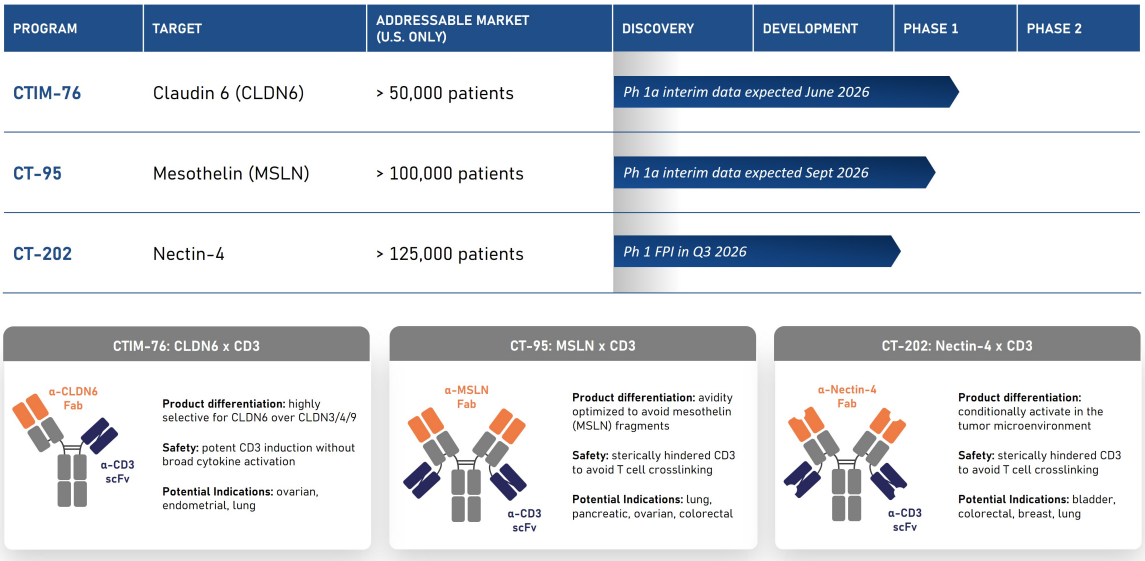
PART I.

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies ("bsAb") for solid tumors. Our goal is to build an innovative portfolio of TCE bispecific therapeutics, including CTIM-76, a Claudin 6 ("CLDN6") x CD3 TCE, CT-95, a Mesothelin ("MSLN") x CD3 TCE, and CT-202, a Nectin cell adhesion protein 4 ("Nectin-4") x CD3 TCE.

Our pipeline is shown below:



CTIM-76 is a CLDN6 x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target expressed in multiple solid tumors and absent from or expressed at low levels in healthy adult tissues. IND-enabling studies on CTIM-76 have been completed. On May 2, 2024, we announced the U.S. Food and Drug Administration (the "FDA") cleared our IND application to support the initiation of a Phase 1 dose escalation and expansion trial of CTIM-76 in patients with CLDN6-positive gynecologic and testicular cancers. We dosed the first patient in our CTIM-76 Phase 1 trial in January 2025. We expect to share Phase 1a interim data for the CTIM-76 trial in June 2026.

CT-95 is an MSLN x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing MSLN. MSLN is a membrane protein overexpressed in approximately 30% of cancers. We dosed the first patient in our CT-95 Phase 1 trial in April 2025. We expect to share Phase 1a interim data for the CT-95 trial in September 2026.

CT-202 is a Nectin-4 x CD3 TCE that targets Nectin-4, a cell surface protein that is highly and frequently overexpressed in a variety of solid tumors, including bladder, colorectal, lung and breast. Nectin-4 is a clinically validated target for cancer therapy using a traditional antibody-drug conjugate ("ADC"), but it is also associated with certain adverse events, including neuropathy and rash. CT-202 is a pH-dependent TCE that is designed to be preferentially active within the tumor microenvironment. We submitted our application to the Australian Bellberry Human Research Ethics Committee ("HREC") in March 2026 to support the initiation of a first-in-human trial for CT-202. We expect to dose the first patient in our CT-202 Phase 1 trial in the third quarter of 2026.

Beyond these product candidates, we continue to evaluate opportunities to expand our pipeline. We believe our team and capabilities position us to be a leader in developing novel therapies targeting solid tumors. We retain full worldwide development and commercialization rights to certain CTIM-76 patents in the field of bispecific

antibodies, full worldwide development and commercialization rights to CT-95 patents, and full worldwide development and commercialization rights to certain CT-202 patents.

Our Strategy

Our goal is to deliver safe and effective selective cancer therapies for patient populations with significant unmet medical needs. Key elements of our strategy include:

- ***Rapidly advance our CTIM-76 and CT-95 clinical programs through Phase 1 proof of concept.*** We are currently evaluating CTIM-76 in a Phase 1 clinical trial and plan to provide Phase 1a interim data for the CTIM-76 trial in June 2026. Additionally, we plan to provide Phase 1a interim data for the CT-95 trial in September 2026.

- ***Rapidly advance our third program, CT-202, into clinical development.*** We submitted our application to the HREC in March 2026 to support the initiation of a first-in-human trial for CT-202. We expect to dose the first patient in our CT-202 Phase 1 trial in the third quarter of 2026.

- ***Seek opportunities to expand our pipeline of selective cancer drug candidates and targets.*** We intend to continue to seek opportunities to expand our TCE pipeline for solid tumors. If we identify targets that we deem to have high potential to address unmet medical needs, we may develop, in-license or acquire assets with therapeutic potential against those identified selective cancer targets.

- ***Evaluate strategic opportunities to potentially accelerate development timelines and enhance the commercial potential of our product candidates globally.*** We intend to leverage our TCE expertise to advance a novel pipeline. We plan to commercialize our product candidates in key markets, either alone or with strategic partners, and seek to maximize the worldwide commercial potential of our programs, including the potential to out-license certain assets during development to a third party that may accelerate development and commercialization of one or all of our assets.

Our Product Pipeline and Development

CLDN6xCD3 TCE program: CTIM-76

Our clinical product candidate, CTIM-76, is a CLDN6 x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target that has high prevalence across many solid tumors and is absent from or expressed at low levels in healthy adult tissues.

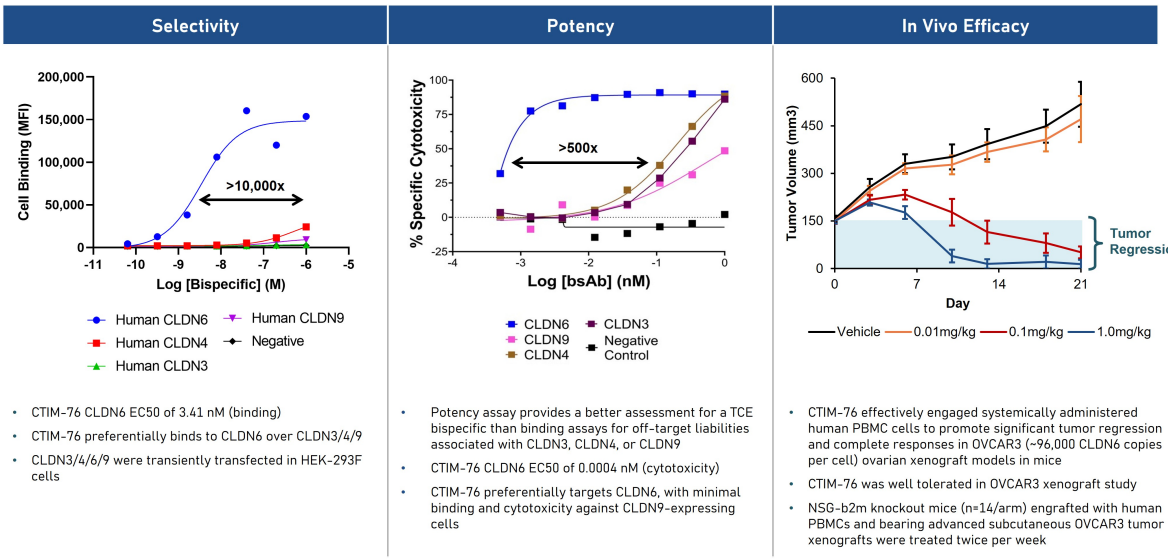
We believe CTIM-76 has the potential to be a differentiated CLDN6 product candidate, due in part to: (i) its high selectivity for CLDN6 over Claudin 3 (“CLDN3”), Claudin 4 (“CLDN4”), and Claudin 9 (“CLDN9”); and (ii) its potential ability to target tumors with low, medium or high levels of CLDN6 expression, which could potentially result in a broader target population and greater commercial opportunity compared with other approaches.

Structure and Mechanism of Action

CLDN6 is an oncofetal protein that is normally present at higher levels during embryonic development. In normal, adult tissue, CLDN6 is turned off or has very low levels of expression due to epigenetic silencing. CLDN6 is thought to be reactivated by some cancers to adopt a more embryonic phenotype through the process of dedifferentiation.

The structural complexity of CLDN6 and its similarity to other Claudin proteins expressed on healthy tissue, particularly CLDN3, CLDN4, and CLDN9, make selectivity a key development challenge that must be addressed by CLDN6-targeting assets in development.

The preclinical data below illustrate that CTIM-76 is a highly selective and potent CLDN6 x CD3 TCE.



- CTIM-76 CLDN6 EC50 of 3.41 nM (binding)
- CTIM-76 preferentially binds to CLDN6 over CLDN3/4/9
- CLDN3/4/6/9 were transiently transfected in HEK-293F cells

- Potency assay provides a better assessment for a TCE bispecific than binding assays for off-target liabilities associated with CLDN3, CLDN4, or CLDN9
- CTIM-76 CLDN6 EC50 of 0.0004 nM (cytotoxicity)
- CTIM-76 preferentially targets CLDN6, with minimal binding and cytotoxicity against CLDN9-expressing cells

- CTIM-76 effectively engaged systemically administered human PBMC cells to promote significant tumor regression and complete responses in OVCAR3 (~96,000 CLDN6 copies per cell) ovarian xenograft models in mice
- CTIM-76 was well tolerated in OVCAR3 xenograft study
- NSG-b2m knockout mice (n=14/arm) engrafted with human PBMCs and bearing advanced subcutaneous OVCAR3 tumor xenografts were treated twice per week

Market Opportunity

There is a significant global opportunity for the treatment of patients with tumors expressing CLDN6. CLDN6 is overexpressed in several cancers with significant unmet needs, including ovarian, non-small cell lung, colon, endometrial, breast and testicular, with expression being highest in ovarian, endometrial, and testicular adenocarcinomas.

Estimated incidence information for annual new cancer cases in the United States and CLDN6 expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 50,000 patients per year in the United States have CLDN6- positive relapse/refractory ("R/R") disease.

Initial indications of interest are based on: (i) CLDN6 prevalence; (ii) patient population size; (iii) observed clinical responses; and (iv) potential for accelerated development.

Selected Cancer indications	**Incidence (US Only)**	**R/R Incidence**	**CLDN6 Positive**	**CLDN6 Med/High**	**Patient Population** Based on R/R Incidence
Ovarian	19,900	12,800	75%[1]	35%[1]	9,600
Endometrial	65,900	14,000	50%[1]	22%[1]	7,000
Testicular	9,910	400	100%[3]	>95%[3]	400
Non-Small Cell Lung	201,229	110,653	26%[2]	6%[2]	28,769
Colon	152,810	53,010	43%[3]	0%[3]	22,794
Breast	290,600	43,800	40%[3]	0%[3]	17,520

1 Context internal Phase 1 data; **2** Context internal biopsy prevalence screen data; **3** Mackensen, Nature Medicine, 2023. Incidences based on public estimates; R/R or last-line patient population approximated by annual mortality; CLDN6 target prevalence is based on IHC or RNAseq from published reports. Patient population derived from midpoint of CLDN6 positive population multiplied by R/R incident population.

Clinical Validation of the Target and Potential for Broader Patient Population

Based on clinical data reported for other therapeutic agents targeting CLDN6, including BioNTech (BNT211), TORL (TORL-1-23), and Daiichi Sankyo (DS9606a), in various phases of clinical development, including ADC and CAR T-cell approaches, we believe this target has been clinically validated. Whereas both ADC and CAR T-cell anti-CLDN6 approaches have required a substantial portion of tumor cells with high expression of CLDN6 for anti-

tumor activity, we believe a T cell engager approach could potentially target tumors with varying levels of CLDN6 expression, including tumors with low levels of expression. Therefore, CTIM-76 could potentially capture a broader patient population and greater commercial opportunity.

Clinical Development Plan

We have an active IND for CTIM-76 with the FDA. In January 2025, we announced that the first patient had been dosed in the CTIM-76 Phase 1 clinical trial, which is a dose escalation and expansion trial in patients with solid tumors likely to express CLDN6. In the dose escalation part of our Phase 1 trial, we are enrolling patients with advanced unresectable or metastatic ovarian, endometrial or testicular cancer in increasing dose levels. The primary objective in dose escalation is to evaluate the safety and tolerability of CTIM-76. In the expansion part of our Phase 1 trial, we plan to evaluate two doses and at least two dose schedules in a single cancer type based upon dose escalation data. The primary objective in expansion will be to evaluate preliminary anti-tumor activity of CTIM-76 and to select a dose and dose schedule for future trials. CLDN6 expression is required for enrollment in our Phase 1 trial for patients with ovarian and endometrial cancer. Due to high CLDN6 expression, prospective screening for testicular cancer is not required.

Mesothelin x CD3 TCE program: CT-95

Our clinical product candidate, CT-95, is an MSLN x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing MSLN. MSLN is a membrane protein overexpressed in approximately 30% of cancers. One challenge in developing MSLN-targeted therapies has been the presence of MSLN fragments, also referred to as shed MSLN ("sMSLN"), found in both blood and the tumor microenvironment that can serve as a decoy or sink for MSLN-targeting antibodies. CT-95 is a fully humanized bispecific T cell engager that has a moderate affinity but high avidity for membrane-bound MSLN, minimizing the impact of the sMSLN.

We believe CT-95 has the potential to be a differentiated MSLN product candidate, due in part to: (i) its ability to bind to the membrane-proximal side of MSLN, which has been shown to increase potency compared to a historic program from Harpoon Therapeutics (HPN536), potentially driving improved outcomes for patients; (ii) avidity enhancement that aims to minimize the risk of adverse events, including cytokine release syndrome and hypoxia; and (iii) its potential ability to target tumors with low, medium or high levels of MSLN expression, which could potentially result in a broader target population and greater commercial opportunity compared with non-TCE approaches.

On July 9, 2024, we entered into an asset purchase agreement (the "Asset Purchase Agreement") pursuant to which we acquired CT-95 (formerly known as LNK-101), from Link (assignment for the benefit of creditors), LLC ("Link"), which succeeded to the assets of Link Immunotherapeutics Inc. The FDA previously cleared the IND application for CT-95.

Pursuant to the Asset Purchase Agreement, we purchased the assets of Link associated with CT-95, including patent rights, know-how, regulatory filings, and inventory of drug substance and drug product (the "Transferred Assets"), on an "as is" and "where is" basis. CT-95 patents are currently being prosecuted and/or maintained in the United States, Europe, Canada, Australia, Japan and Taiwan. We also assumed certain liabilities relating to the Transferred Assets. In consideration of the Transferred Assets, we made a one-time payment to Link of $3.75 million.

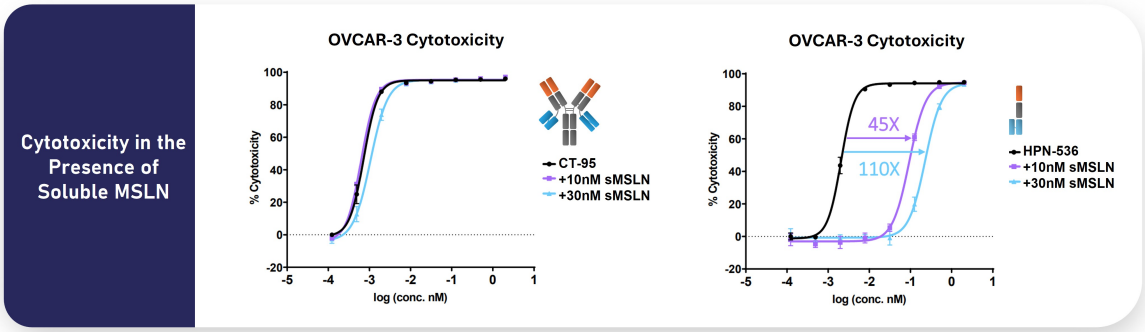
Structure and Mechanism of Action

MSLN is bound to tumor cells via a glycosylphosphatidylinositol ("GPI") linker. Like many GPI-anchored proteins, MSLN can be cut into smaller fragments. The MSLN gene encodes a precursor that is cleaved into two products: a soluble N-terminal protein called megakaryocyte potentiating factor (MPF), and a membrane-bound fragment called full length mesothelin ("FL-MSLN"). FL-MSLN can then be further cleaved into even smaller sMSLN fragments. sMSLN serves as a competitive sink, preventing antibodies from binding to the tumor, which can lead to suboptimal drug exposure and efficacy.

CT-95 was designed to overcome the sMSLN sink through binding to membrane-proximal MSLN epitope and avidity enhancement. CT-95 exhibits moderate affinity for membrane-proximal MSLN but cooperative binding through bivalent binding of CT-95 to two MSLN epitopes results in high avidity binding of CT-95 to the tumor. This

results in a potentially wide therapeutic window due to: (i) limited crosslinking by sMSLN, mitigating off-tumor T cell activation; and (ii) cooperative binding of MSLN on tumor surface to crosslink CD3, thereby activating T cells.

The figure below indicates that HPN-536 (Harpoon Therapeutics) binds to MSLN fragments in a dose proportional manner, limiting therapeutic exposure, whereas CT-95 does not lose potency in the same OVCAR-3 cell line model.



Market Opportunity

There is a significant global opportunity for the treatment of patients with tumors expressing MSLN. MSLN is overexpressed in several cancers with significant unmet needs, high grade serous ovarian, non-small cell lung, colon, esophageal, pancreatic carcinoma, endometrial, gastric, and mesothelioma, with expression being highest in high-grade serous ovarian cancer, pancreatic carcinoma, and mesothelioma.

Estimated incidence information for annual new cancer cases in the United States and MSLN expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 100,000 patients per year in the United States have mesothelin-positive R/R disease.

Initial indications of interest are based on: (i) MSLN prevalence; (ii) patient population size; (iii) observed clinical responses; and (iv) potential for accelerated development.

Selected Cancer indications	**Incidence (US Only)**	**R/R Incidence**	**MSLN Positive**	**MSLN Med/High**	**Patient Population** Based on R/R Incidence
Non-Small Cell Lung	201,229	110,653	55%	36%	60,859
Pancreatic	66,440	51,750	80%	61%	41,400
Colon	152,810	53,010	41%	17%	21,734
Ovarian	19,900	12,800	90%	80%	11,520
Mesothelioma	3,000	2,500	70%	60%	1,750
Esophageal	22,370	16,130	41%	26%	6,613
Endometrial	65,900	14,000	45%	23%	6,300
Gastric	26,380	11,090	49%	23%	5,434

Incidences based on public estimates; R/R or last-line patient population approximated by annual mortality; MSLN target prevalence is based on Simon et al, Biomedicines, 2021. Patient population derived from MSLN positive population multiplied by R/R incident population.

Clinical Validation of the Target and Potential for Broader Patient Population

Based on clinical data reported for other therapeutic agents targeting MSLN, including RemeGen Biosciences (RC88) and TCR2 Therapeutics (gavocabtagene autoleucel), in various phases of clinical development, including

ADC and CAR T-cell approaches, we believe this target has been clinically validated. Whereas both ADC and CAR T-cell anti-MSLN approaches have required a substantial portion of tumor cells with high expression of MSLN for anti-tumor activity, we believe a T cell engager approach could potentially target tumors with varying levels of MSLN expression, including tumors with low levels of expression. Therefore, MSLN could potentially capture a broader patient population and greater commercial opportunity.

Clinical Development Plan

We have an active IND for CT-95 with the FDA. In April 2025, we announced that the first patient had been dosed in the CT-95 Phase 1 trial, which is a dose escalation trial in patients with solid tumors likely to express MSLN. We are enrolling patients with advanced unresectable or metastatic high grade serous ovarian cancer, pancreatic carcinoma, and mesothelioma. The primary objective in dose escalation is to evaluate the safety and tolerability of CT-95. Expression of MSLN is not required for enrollment in our Phase 1 trial; tumor tissue samples are being collected for retrospective biomarker assessment of MSLN expression by immunohistochemistry ("IHC").

Nectin-4 x CD3 TCE program: CT-202

Our preclinical product candidate, CT-202, targets Nectin-4, which is highly and frequently overexpressed in a variety of cancers. Nectin-4 is a clinically-validated target for cancer therapy using a traditional antibody-drug conjugate, but it is also associated with certain adverse events, including neuropathy and rash. CT-202 is a pH-dependent TCE that is designed to be preferentially active within the acidic tumor microenvironment.

On September 23, 2024, we entered into a license agreement (the "BioAtla License Agreement") with BioAtla, Inc. ("BioAtla"), pursuant to which we obtained an exclusive, worldwide license to develop, manufacture and commercialize two licensed antibodies (the "BioAtla Assets"), including BA3362 (renamed by the Company as CT-202), BioAtla's Nectin-4 x CD3 TCE.

As partial consideration for the exclusive license under the BioAtla License Agreement, we made an upfront payment of $11.0 million, and BioAtla is eligible to receive up to $122.5 million in additional milestone payments based upon the achievement of specified pre-clinical, clinical, development and commercial milestones, as well as tiered mid-single-digit to low double-digit royalties on future net sales for products containing the BioAtla Assets, subject to standard reductions.

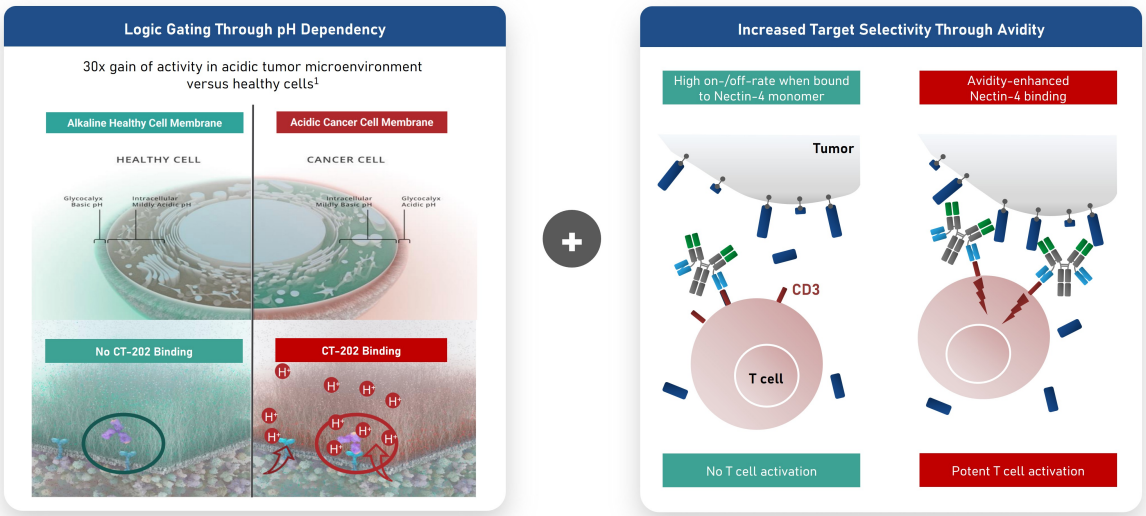
We believe CT-202 has the potential to be a differentiated Nectin-4 product candidate, due in part to: (i) its ability to preferentially bind to Nectin-4 and CD3 in the low pH environment of tumor relative to pH neutral normal tissue, which has the potential to reduce the risk of dermatologic side effects associated with Nectin-4 expression in the skin; (ii) avidity enhancement to improve CT-202 residence in the tumor microenvironment and minimize the risk of cytokine release syndrome; and (iii) its potential ability to target tumors with low, medium or high levels of Nectin-4 expression, which could potentially result in a broader target population and greater commercial opportunity compared with non-TCE approaches.

Structure and Mechanism of Action

CT-202 incorporates logic gating through pH dependence and avidity enhancement which is intended to spare Nectin-4 in normal tissue. Because of its expression in healthy epidermal keratinocytes, sweat glands, and hair follicles, Nectin-4 targeted treatments are often associated with dermatological side effects. CT-202 incorporates pH dependent binding to both Nectin-4 and CD3 to minimize binding to healthy tissues and maximize binding and T cell activation within the tumor microenvironment.

CT-202 is avidity optimized to mitigate cytokine release syndrome risk. Cooperative Nectin-4 binding through bivalent binding to the tumor cell surface is intended to reduce T cell crosslinking in the absence of target. Steric hindrance of CD3 binding by Fc domain prevents T cell crosslinking by single CT-202 molecules.

The figure below indicates our two-pronged approach for CT-202 to overcome Nectin-4 expression in the skin and to generate robust antitumor responses while minimizing the risk of cytokine release syndrome.



1 Chang, PNAS, 2021

Market Opportunity

There is a significant global opportunity for the treatment of patients with tumors expressing Nectin-4. Nectin-4 is overexpressed in several cancers with significant unmet needs, including bladder (urothelial), non-small cell lung, pancreatic, head and neck, esophageal, colorectal, gastric, and triple negative breast cancer ("TNBC"), with expression being highest in bladder, colorectal, and TNBC.

Estimated incidence information for annual new cancer cases in the United States and Nectin-4 expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 125,000 patients per year in the United States have Nectin-4- positive R/R disease. Initial indications of interest are based on: (i) Nectin-4 prevalence; (ii) patient population size; and (iii) observed clinical responses.

Selected Cancer indications	Incidence (US Only)	R/R Incidence	Nectin-4 Positive	Nectin-4 Med/High	Patient Population Based on R/R Incidence
Colon	152,810	53,010	87%[1]	78%[2]	46,119
Bladder (urothelial)	83,190	20,000	83%[3]	60%[3]	16,600
Breast (TNBC)	62,054	15,500	78%[3]	58%[5]	12,090
Non-Small Cell Lung	201,229	110,653	64%[3]	58%[6]	70,818
Pancreatic	66,440	51,750	71%[3]	37%[3]	36,743
Head and Neck	54,000	12,000	59%[3]	18%[3]	7,080
Esophageal	22,370	16,130	55%[3]	24%[3]	8,872
Gastric	26,890	12,000	94%[7]	60%[4]	11,280

Incidences based on public estimates; Relapsed/refractory (R/R) or last-line patient population approximated by annual mortality; Patient population derived from Nectin-4 positive population multiplied by R/R incident population. **1** Kobecki, Int J Mol Sci, 2023; **2** Nikanjan, Can Let, 2025; **3** Challita, Can Res, 2016; **4** Zhang, Oncol Lett, 2018; **5** Zeindler, Front Med, 2019; **6** Takano, Mol Bio, 2009; **7** Muro, ESMO Open, 2025

Clinical Validation of the Target and Potential for Broader Patient Population

Based on clinical data reported for other therapeutic agents targeting Nectin-4, including Pfizer (Padcev®) and Bicycle Therapeutics (BT8009), including ADC approaches, we believe this target has been clinically validated. Padcev is currently approved for locally advanced or metastatic urothelial carcinoma, which is associated with high

levels of Nectin-4 expression. Whereas ADC Nectin-4 approaches require a substantial portion of tumor cells with high expression of Nectin-4 for anti-tumor activity, we believe a TCE approach could potentially target tumors with varying levels of Nectin-4 expression, including tumors with low levels of expression. Therefore, Nectin-4 could potentially capture a broader patient population and greater commercial opportunity.

Clinical Development Plan

We submitted our application to the HREC in March 2026 to support the initiation of a first-in-human trial for CT-202. We expect to dose the first patient in our CT-202 Phase 1 trial in the third quarter of 2026. The primary objective in dose escalation will be to evaluate the safety and tolerability of CT-202.

Our collaboration and license agreements

Collaboration and Licensing Agreement with Integral Molecular

In April 2021, we entered into a collaboration and licensing agreement with Integral Molecular, Inc. ("Integral") (the "Integral License Agreement") for the development of a CLDN6 bsAb for cancer therapy. Under the terms of the Integral License Agreement, we and Integral developed a CLDN6 bsAb that is intended to trigger the activation of T cells and eliminates cancer cells displaying CLDN6. We will conduct preclinical and all clinical development, as well as regulatory and commercial activities through exclusive worldwide rights to develop and commercialize the novel CLDN6 candidates. As a part of the Integral License Agreement, Integral was eligible to receive remaining development and regulatory milestone payments totaling approximately $55 million, sales milestone payments totaling up to $130 million, and tiered royalties of up to 12% of net sales of certain products developed under the Integral License Agreement.

On March 20, 2023, we amended the Integral License Agreement (the "First Amendment") to remove the previously agreed to second milestone payment and to change the amount of the third milestone payment to increase such payment by the amount of the prior second milestone payment and to add payment for third-party research funding obtained and used by Integral in connection with the development of CTIM-76.

On February 29, 2024, we further amended the Integral License Agreement to reflect updated financial terms. In the course of our further due diligence review of CTIM-76, we determined that certain of the licensed rights under the Integral License Agreement may incorporate intellectual property rights currently held by a third party. Specifically, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034, and then in 2025 became aware of a patent that issued in the United States expiring in March 2042, in each instance that potentially cover certain of the intellectual property included in CTIM-76. While we believe we will have reasonable defenses against any potential claim of infringement, we may not be successful in such efforts, and we also may not be able to obtain a license to such patent on commercially reasonable terms, or at all.

As part of Amendment 2 to the Integral License Agreement (the "Second Amendment"), Integral's right to receive certain future payments was reduced as follows: aggregate development and regulatory milestone payments were reduced from $55 million to $15 million, aggregate sales milestone payments were reduced from $130 million to $12.5 million, and a tiered royalty of 8-12% that commenced at first commercial sale was reduced to a flat royalty rate of 6% on net sales beginning no sooner than February 1, 2034. The Second Amendment also narrowed the license grant from Integral to us to only cover CTIM-76, removed any further obligation of us to reimburse Integral for any independently obtained research funding Integral applied against CTIM-76 research, and included mutual releases by the parties.

The reduced development and regulatory milestones now reflect a payment due at each of: first patient's first screening visit in a Phase 1b/2 or Phase 2 clinical trial for CTIM-76, first patient's first screening visit in a Phase 3 clinical trial for CTIM-76, United States marketing approval for CTIM-76, European Union marketing approval for CTIM-76, United Kingdom marketing approval for CTIM-76, and Japan marketing approval for CTIM-76. The amended commercial milestones now also reflect a payment due upon the achievement of annual net sales of $500 million and annual net sales of $1 billion.

Asset Purchase Agreement with Link

On July 9, 2024, we entered into the Asset Purchase Agreement pursuant to which we acquired CT-95 (formerly known as LNK-101), from Link, which succeeded to the assets of Link Immunotherapeutics Inc. The FDA previously cleared the IND application for CT-95.

Pursuant to the Asset Purchase Agreement, we purchased all of the Transferred Assets on an "as is" and "where is" basis. CT-95 patents are currently being prosecuted and/or maintained in the United States, Europe, Canada, Australia, Japan and Taiwan. We also assumed certain liabilities relating to the Transferred Assets. In consideration of the purchase of the Transferred Assets, we made a one-time payment to Link of $3.75 million.

Collaboration and Licensing Agreement with BioAtla

On September 23, 2024, we entered into the BioAtla License Agreement with BioAtla, pursuant to which we obtained an exclusive, worldwide license to develop, manufacture and commercialize the BioAtla Assets, including BA3362 (renamed by the Company as CT-202), BioAtla's Nectin-4 x CD3 TCE.

As partial consideration for the exclusive license under the BioAtla License Agreement, we made an upfront payment of $11.0 million, and BioAtla is eligible to receive up to $122.5 million in additional milestone payments based upon the achievement of specified pre-clinical, clinical, development and commercial milestones, as well as tiered mid-single digit to low double-digit royalties on future net sales for products containing the BioAtla Assets, subject to standard reductions.

Commercialization

We retain full worldwide development and commercialization rights to certain CLDN6 patents in the field of bispecific antibodies, full worldwide development and commercialization rights to CT-95 patents, and full worldwide development and commercialization rights to certain CT-202 patents. We periodically evaluate out-license opportunities for our product candidates and seek to identify drug candidates for novel indications and/or patient subpopulations with an oncology focus that we might in-license. Our commercial plans and strategy for any of our programs may change as programs advance, markets change, and we receive more clinical data, and will depend on availability of current and future capital.

Sales and marketing

We currently have no sales, marketing, or commercial product distribution capabilities, and we may explore partnerships with larger pharmaceutical organizations that already have these capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of a product candidate.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our current and any future product candidates for preclinical and clinical testing, as well as for commercial manufacture if any product candidate obtains marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our current and any future investigational product candidates, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our current and any future product candidates.

To date, we have obtained active pharmaceutical ingredients ("API") and drug product for our product candidates from several third-party contract manufacturers, including Lonza Sales AG ("Lonza Sales") and Lonza AG ("Lonza AG", and collectively with Lonza Sales, "Lonza") and Just-Evotec Biologics, Inc. We continue to develop our supply chain for CTIM-76, CT-95 and CT-202, and intend to put in place additional framework agreements under which third-party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs.

On November 7, 2022, we entered into a license agreement (the "Lonza CTIM-76 License Agreement") with Lonza Sales. Under the terms of the Lonza CTIM-76 License Agreement, to the extent Lonza's technology is incorporated into CTIM-76, Lonza granted us a non-exclusive license to use certain proprietary Lonza intellectual property and systems for us to develop, manufacture and commercially exploit CTIM-76.

On November 3, 2025, we entered into a license agreement (the "Lonza CT-202 License Agreement") with Lonza Sales. Under the terms of the Lonza CT-202 License Agreement, to the extent Lonza's technology is incorporated into CT-202, Lonza granted us a non-exclusive license to use certain proprietary Lonza intellectual property and systems for us to develop, manufacture and commercially exploit CT-202.

We shall pay certain royalties and annual payments to Lonza under the applicable license agreement with respect to the manufacturing and sale of CTIM-76 or CT-202, as applicable, which amounts shall be determined by the party manufacturing CTIM-76 or CT-202, as applicable, and ranges from a potential annual payment of up to less than $500,000 per asset and a royalty per asset on net sales from 0% up to a low single digit percentage. Under each respective license agreement, the royalty payments and annual payments would be reduced per asset in certain circumstances, including should the valid claims for any such patent rights not exist in the country in which CTIM-76 or CT-202, as applicable, is being sold, and the royalty payments per asset would expire upon the later of the expiration of the licensed patents in the country in which CTIM-76 or CT-202, as applicable, is being sold, the expiration of the licensed patents in the country in which CTIM-76 or CT-202, as applicable, is being manufactured, and 10 years from the first commercial sales of CTIM-76 or CT-202, as applicable, in such country of sale.

The Lonza CTIM-76 License Agreement and the Lonza CT-202 License Agreement each continue until respectively terminated. We or Lonza may terminate either the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement, as applicable, for uncured material breaches or insolvency of the other party. We can unilaterally terminate the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement upon certain actions by us.

The Lonza CTIM-76 License Agreement and Lonza CT-202 License Agreement also each contain customary representations, warranties, indemnification and other obligations of us and Lonza.

As we advance our current and any future product candidates through development, we will consider our lack of redundant supply for the API and drug product for each product candidate to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, the experience of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

For CTIM-76, our CLDN6 x CD3 TCE, we are aware of several companies developing T cell engagers against CLDN6. Several TCE candidates are currently in clinical development, including those of Beigene (BGB-B455), Third Arc Bio (ARC101), and Xencor (XmAb541). We may face further competition from companies pursuing the development of product candidates that target CLDN6 through other modalities, including Daiichi Sankyo (DS9606), BioNTech (BNT211), and TORL (TORL-1-23).

For CT-95, our MSLN x CD3 TCE, we are aware that Amgen (AMG-305) has a TCE candidate currently in clinical development. We may face further competition from companies pursuing the development of product candidates that target MSLN through other modalities, including RemeGen Biosciences (RC88), Outpace Bio (OPB-101), and Navrogen (NAV001, NAV008).

For CT-202, our Nectin-4 x CD3 TCE, we are aware of several companies developing T cell engagers against Nectin-4. Several TCE candidates are currently in clinical development, including those of Bicycle Therapeutics (BT7480). We may face further competition from companies pursuing the development of product candidates that target Nectin-4 through other modalities, including Pfizer (Padcev®), Bicycle Therapeutics (BT8009), Eli Lilly (LY4052031, LY4101174), Corbus Pharmaceuticals (CRB-701), Bio-Thera (BAT8007), Mabwell (PMW2821), Adcentrx (ADRX-0706), Aktis Oncology (AKY-1189), and Shanghai Henlius Biotech (HLX-309).

Intellectual property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending our patent rights. We retain full worldwide development and commercialization rights to certain CLDN6 antibody patents in the field of bispecific antibodies, full worldwide development and commercialization rights to CT-95 patents, and full worldwide development and commercialization rights to certain CT-202 patents. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology to protect our product candidates and continuing to innovate to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our product candidates, technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of March 1, 2026, the Integral Molecular, Inc. patent portfolio covering CTIM-76 and methods of use that we exclusively licensed pursuant to the Integral License Agreement includes three granted U.S. patents, two pending U.S. non-provisional applications, granted patents in China, Eurasia, Japan, Saudi Arabia, Vietnam, Ukraine, and South Africa, and pending foreign applications in United Arab Emirates, Australia, Brazil, Canada, Chile, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, South Korea, Mexico, New Zealand, the Philippines, Saudi Arabia, Singapore, South Africa, Thailand, Taiwan and Vietnam, of which the Philippines and Vietnam are allowed. The U.S. patents are expected to expire in 2040 and 2043, subject to any extensions or disclaimers. We also own two pending U.S. provisional applications, two pending International Patent Cooperation Treaty applications, and a pending application in Taiwan covering CTIM-76 and methods of using it, which, if converted and issued, will expire in 2045, subject to any extensions or disclaimers.

As of March 1, 2026, we own the patent portfolio covering CT-95 and methods of use, which includes one U.S. patent, one pending U.S. non-provisional application, two pending U.S. provisional applications, and pending

foreign applications in Australia, Canada, Europe, Japan, and Taiwan. The U.S. patent and any patents that grant from the pending applications are expected to expire in 2042, subject to any extensions or disclaimers.

As of March 1, 2026, the BioAtla patent portfolio covering CT-202 and methods of use that we exclusively licensed pursuant to the BioAtla License Agreement includes one U.S. patent, two pending U.S. non-provisional applications, a granted patent in Japan, Mexico and Taiwan, and pending foreign applications in Australia, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Macau, Mexico, Singapore, Thailand, and Taiwan, of which Israel is allowed. The issued patent and any patents that grant from the pending applications are expected to expire from 2039 to 2041, subject to any extensions or disclaimers.

We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

With respect to our current and any future product candidates and processes, we intend to develop and commercialize in the normal course of business, and we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our product candidates, technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents may not guarantee us the right to commercialize our product candidates, if approved. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. Third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary product candidates, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. Moreover, such third parties may obtain damages against us, which could require us to make commercially reasonable royalty payments, payments for lost profits, or other damages, costs and expenses. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar products. Furthermore, our competitors may independently develop similar products that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be

commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Government Regulation

U.S. Regulatory Pathway

We expect that CTIM-76, CT-95 and CT-202 will each be classified and regulated by the FDA as a biologic. We expect that any small molecule product that we may develop will be classified and regulated by the FDA as a drug. A new drug application ("NDA") is required to introduce a drug into interstate commerce. A biologics license application ("BLA") is required to introduce a biologic product into interstate commerce. The specific requirements of NDAs and BLAs include applicant information, product information, manufacturing information, pre-clinical data, clinical data, and labelling. The most important, time-consuming, and expensive aspect of preparing for a BLA or NDA is conducting clinical trials to demonstrate safety and effectiveness. The requirements of such clinical trials heavily influence the eventual allowable product label claims. The FDA has a performance goal as defined in the Prescription Drug User Fee Act of 10 months for a standard submission and six months for priority review. It is not uncommon for NDAs and BLAs to require medical advisory board review prior to the FDA granting marketing approval. A facility inspection verifying the manufacturing systems is also usually performed prior to FDA approval.

The FDA offers a number of expedited development and review programs for qualifying product candidates, including the fast track program. New drug and biological product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation considers the combination of the product candidate's therapeutic potential and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate product candidate as fast track at any time during clinical development. The sponsor of a fast track designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product candidate development. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA/BLA on a rolling basis before the complete application is submitted upon agreement with the FDA. Fast track designation does not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for this program, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs and biologics intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA/BLA. If the FDA grants orphan drug designation, the FDA then discloses publicly the identity of the therapeutic agent and its potential orphan use. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA market approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, could also block the approval of one of our products for seven years if a competitor obtains approval of the same drug for the same indication or disease as defined by the FDA.

We have in the past used and intend to continue to utilize the services of third-party experts to supplement internal regulatory planning and implementation.

Ongoing FDA Regulation

After the FDA permits a product to enter commercial distribution, numerous and pervasive regulatory requirements continue to apply to our business operations, products and technologies. These include:

- current good manufacturing practice ("cGMP") requirements applicable to drugs and biologics, which require manufacturers, including third-party manufacturers, to follow stringent production, control, quality assurance, supplier qualification, documentation and other procedures throughout all aspects of the manufacturing process;
- labeling and marketing regulations which require that promotion is truthful, not misleading, fairly balanced and consistent with FDA-approved labeling for prescription drug and biologic products;
- advertising and promotion requirements, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses and FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- restrictions on sale, distribution or use;
- product establishment, registration and listing requirements and reporting requirements;
- recall requirements, including a mandatory recall if there is a reasonable probability that a product would cause serious adverse health consequences or death;
- an order of repair, replacement or refund; and
- post-market surveillance activities and regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data.

The FDA has broad post-market and regulatory enforcement powers. Manufacturers of biologic products and drug products are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with cGMP and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, untitled letters, Form 483s, fines, injunctions, consent decrees and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- the FDA's refusal of requests for approval of new products or indications for existing products;
- the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

Regulatory Pathway in the EU

Like the United States, the most important and time-consuming part of seeking marketing authorization in the European Union ("EU") is the clinical trial process. In the EU, the various stages of non-clinical and clinical testing are subject to a significant volume of regulatory requirements and controls.

The EU Clinical Trials Regulations ("EU CTR"), adopted in April 2014, became applicable on January 31, 2022 and repealed and replaced the EU Clinical Trials Directive. The EU CTR applies to all EU member states, unlike the precedent directive, which required each member state to enact the directive into national law. The EU CTR aims to harmonize the assessment and supervision process for clinical trials throughout the EU through the Clinical Trials Information System ("CTIS"). The CTR creates a centralized process, permitting clinical trial sponsors to submit a single clinical trial application, applicable to all multi-center trial sites within the EEA.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

To be placed on the market in the European Economic Area ("EEA") following the clinical trial process, new medical products, including biologics, require a marketing authorization ("MA"). An MA application may be made through either the centralized or decentralized process, dependent, among other things, on the type of medical product seeking authorization. A centralized MA is issued by the European Commission based on the opinion of the European Medicines Agency ("EMA"). Centralized MAs are valid throughout the EU and required for certain types of medicinal products like those derived from biotechnological processes, orphan medical products, advanced therapy medicinal products, and medicinal products with a new active substance for the treatment of certain diseases. Where the centralized procedure is not mandatory or chosen, applicants may seek authorization through national procedures, the decentralized procedure, or the mutual recognition procedure, which result in national marketing authorizations granted by individual EU Member States.

Regulatory Pathway in the United Kingdom

As of January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws related to medical products. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK; however, new EU legislation such as the EU CTR is not applicable in the UK.

As of January 1, 2025, all of the UK (including England, Wales, Scotland, and Northern Ireland) are regulated under the Medicines and Healthcare products Regulatory Agency ("MHRA"), the standalone UK medicines and medical device regulator. The UK regulatory framework for clinical trials is the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU Clinical Trials Directive. In 2024, the UK introduced amendments to the law that seek to streamline the process and accelerate approvals, while maintaining appropriate safety standards. The amendment is set to take full effect starting in April 2026.

In order to obtain a UK marketing authorization to place medical products on the market in the UK, an applicant must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. The MHRA may rely on the International Recognition Procedure ("IRP") when reviewing certain types of MA applications. Pursuant to the IRP, the MHRA will consider the expertise and decisions of trusted regulatory partners (*e.g.*, the medicines regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the U.S. and the EMA). The MHRA will conduct a targeted assessment of IRP applications but retains the authority to reject applications if the evidence provided is considered insufficiently robust.

Regulatory Pathway in Australia

The Australian Therapeutic Goods Administration ("TGA") and the National Health and Medical Research Council ("NHMRC") set the legislative, regulatory and good clinical practice ("GCPs") requirements for clinical trials in Australia. Australia has also adopted the ICH guidelines on GCP. Like other jurisdictions discussed above, pre-clinical trials are required to support a first-in-human trial in Australia.

The Therapeutic Goods Act 1989 and related regulations establish and maintain the national system of controls relating to the efficacy, quality, safety and timely availability of drugs and medical devices in Australia. The TGA administers two pathways for clinical trials, the Clinical Trials Notification ("CTN") and Clinical Trials Approval

("CTA") schemes. These pathways govern the process through which "unapproved" (*i.e.*, not yet authorized for the Australian market) therapeutic goods may be supplied solely for experimental use in humans. The choice of which pathway to use (CTN or CTA) is made by the clinical trial sponsor, which must be an Australian legal entity or have an Australian sponsor responsible to the TGA. That decision is reviewed and confirmed by the HREC that approves the protocol. The CTA pathway, which requires prior regulatory approval, is designed primarily for high-risk or novel treatments where there is limited or no knowledge of the therapeutic good's safety for use in humans.

All therapeutic goods must be approved for inclusion in the Australian Register of Therapeutic Goods (the "ARTG") before it may be marketed (or imported, exported, manufactured or supplied) in Australia. In order to obtain registration of the product on the ARTG, the medical product's sponsor must provide evidence supporting quality, safety, and efficacy, which may include clinical trials, and evidence demonstrating that the manufacture of the therapeutic product complies with all applicable principles of current good manufacturing practices ("cGMPs").

Privacy and Security Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including health information. Among others, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, (collectively referred to as "HIPAA"), establish privacy and security standards that limit the use and disclosure of protected health information ("PHI") and require covered entities and business associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form, among other requirements.

Violations of HIPAA may result in civil and criminal penalties. Companies subject to HIPAA must also comply with HIPAA's breach notification rule which requires notification of affected patients and the U.S. Department of Health and Human Services ("HHS"), and in certain cases of media outlets, in the case of a breach of unsecured PHI. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate. State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states, and HIPAA standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance.

Many states have laws that protect the privacy and security of sensitive and personal information, including health information, to which we are subject. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, California enacted the California Consumer Privacy Act (the "CCPA"), which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations as of July 1, 2020. On January 1, 2023, California adopted the California Privacy Rights Act ("CPRA"), which amended the CCPA to enhance certain of the privacy protections for California consumers that were created by the CCPA. The enhancements include imposing additional compliance obligations for covered entities and removing certain exemptions previously available under the CCPA. While the California Attorney General retains civil enforcement authority, the CPRA also created the California Privacy Protection Agency to implement and enforce the law. Since the CCPA, many other states have passed or are considering passing similar state privacy laws.

We may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on certain types of activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. The EU-wide General Data Protection Regulation ("GDPR") became applicable on May 25, 2018, replacing the previous data protection laws issued by each EU Member State based on the Directive 95/46/EC. Unlike the Directive (which needed to be

transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations, requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant—the greater of EUR 20 million or 4% of global turnover. The GDPR provides that EU Member States may introduce further conditions, including limitations, to the processing of genetic, biometric or health data. In the UK, the UK General Data Protection Regulation (the "UK GDPR") came into effect on January 1, 2021. Similar to the GDPR, the UK GDPR sets out the key principles, rights, and obligations for most processing of personal data in the UK. The Data Protection Act of 2018, which came into effect on May 25, 2018 and was amended on January 1, 2021, works alongside and supplements the UK GDPR.

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, the Patient Protection and Affordable Care Act ("PPACA") substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical, medical device and biologics industries, among others.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA, and there may be additional amendments to PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA"), was passed, which among other things, allows for the Centers for Medicare & Medicaid Services ("CMS") to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with 10 high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of the IRA on our business is not yet known.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and/or patients' willingness to pay for our products. While in general it is too early to predict what effect, if any, any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and prospects.

Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and efforts are underway to reduce the cost of medical products and services overall. We may need to conduct expensive studies in order to demonstrate the cost-effectiveness of our products. Our current and any future product candidates may not be considered cost-effective.

Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate revenue level. Future legislation could limit payments for our current and any future product candidates.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of less costly products. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on medical product and service pricing.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of pharmaceutical products and devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of HHS (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/ educational grant programs must comply with the Federal Food, Drug, and Cosmetic Act, the Anti-Kickback Statute, as amended, the False Claims Act, as amended, the privacy regulations promulgated under HIPAA, and similar state laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our sales and marketing practices and/or our relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we plan to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are subject.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including pharmaceutical products, that are false or fraudulent. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate

false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a provision of PPACA, referred to as the Sunshine Act, requires pharmaceutical product manufacturers to track and report to the federal government certain payments or other transfers of value made to physicians, registered nurses and teaching hospitals, among others, in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Other Federal Healthcare Fraud and Abuse Laws

We may also be subject to other federal healthcare fraud and abuse laws, including provisions of HIPAA, which prohibit knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payors, as well as knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. Similar to the federal Anti-Kickback Statute, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (the "FCPA"), prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

Human Capital

As of March 1, 2026, we had fifteen full-time employees and no part-time employees. None of these employees are represented by labor unions or covered by collective bargaining agreements. We believe that our employee relations are good.

Culture is a critical element in the management of our organization. Our talented employees are focused on driving our business with the foundation for all our efforts being to advance medicines for solid tumors. Our goal is that each colleague feels a deep connection to what they do, loves coming to work, and is aligned to our mission.

Culture begins with our hiring process and continues throughout an employee's time with Context. We support our colleagues with a comprehensive offering of competitive pay and benefits.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 2021. Our corporate office is located at 2001 Market Street, Suite 3915, Unit #15, Philadelphia, PA 19103. Our telephone number is (267) 225-7416. We maintain an Internet website at www.contexttherapeutics.com. The information contained on our website is not incorporated by reference into this Form 10-K.

We make available free of charge under the "Investors & News" — "Financials" — "SEC Filings" section of our website all of our filings with the SEC, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before making a decision to invest in our common stock. Our business, results of operations, financial condition or prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the risks actually occur, our business, results of operations, financial condition and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below. See "Note Regarding Forward-Looking Statements."

Risks Related to Our Business and Industry

We have never been profitable and may never achieve or maintain profitability.

We have not commercialized any products and have yet to generate any revenue from product sales. The amount of our future net losses will depend, in part, on our expenses and our ability to generate revenues. Our current and any future product candidates will require substantial additional development time and resources before we may realize revenue from product sales, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our current research and development programs, including conducting laboratory, preclinical and clinical studies for product candidates;
- continue and initiate clinical trials for product candidates;
- seek to identify, assess, acquire or develop additional research programs or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for any product candidates that may successfully complete development;
- establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval;
- further develop and refine the manufacturing process for our current and any future product candidates;
- change or add additional manufacturers or suppliers of pharmaceutical or biological materials or product candidates;
- acquire or in-license other technologies;
- seek to attract and retain new and existing personnel; and
- expand our facilities.

We recently began our clinical trial for CTIM-76 and CT-95 and no clinical studies have begun on CT-202. It will be several years, if ever, before we obtain regulatory approval for a therapeutic product candidate, at which time any revenues for such product candidate will depend upon many factors, including market conditions, costs and effectiveness of manufacturing, sales, marketing and distribution operations related to such product candidate, the scope of intellectual property protection for such product candidate, and the terms of any collaboration or other strategic arrangement we may have with respect to such product candidate and levels of reimbursement from third-party payors.

If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, including through the potential out-licensing of our product candidates, or if revenues from any product candidate that receives marketing approval or is commercialized are insufficient, we may not achieve profitability or sustain profitability, which would have an adverse effect on the value of our common stock.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

The continuation of our business is dependent upon raising additional capital. We will need additional funding to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic transactions and/or marketing, distribution or licensing arrangements. There can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or, if available, to obtain funds through financing transactions with unfavorable terms.

If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.

The process of identifying product candidates and conducting preclinical and clinical trials is time consuming, expensive, uncertain and takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical trials of, and seek marketing approval for, product candidates. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for CTIM-76, CT-95, CT-202 or any other future product candidates;
- clinical development plans we have established and may establish for CTIM-76, CT-95, CT-202 and any other future product candidates;
- obligation to make milestone, royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of product candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and/or commercialization efforts or we might have to obtain funds through arrangements, such as selling or out-licensing our product candidates, with collaborative partners or others that may require us to relinquish rights to our technologies or product candidates that we otherwise would not relinquish. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects.

If we are not able to successfully integrate recent and future acquisitions, our management's attention could be diverted, and efforts to integrate future acquisitions could consume significant resources.

Our obtainment of the rights to CT-202 and the acquisition of CT-95, and any other future acquisition that we may undertake, involve risks related to the integration of the acquired assets into the Company after the acquisition is completed. These risks include delays in development timelines, increased expenses, and assumption of undisclosed liabilities.

We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.

We are a biopharmaceutical company with a limited operating history. We were founded in 2015 and spent the first three years of our company's history developing and refining our therapeutic approach, and only since then have we focused our efforts on advancing the development of product candidates.

Investment in biopharmaceutical product development is a highly speculative endeavor and entails substantial upfront capital expenditures. There is significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain any required regulatory approvals or become commercially viable. Our product candidates and the therapeutic approach we are using are new and unproven. We have not demonstrated an ability to successfully complete any clinical trials, obtain any required marketing approvals, manufacture products, conduct sales, marketing and distribution activities, or arrange for a third party to do any of the foregoing on our behalf.

Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products. Our limited operating history, particularly in light of the rapidly evolving nature of the biopharmaceutical industries and the cancer therapeutics field, may make it difficult to evaluate our technology and business prospects or to predict our future performance.

We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.

Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. The successful completion of a clinical trial with regard to any of our product candidates is not assured despite the expenditure of significant resources in pursuit of their development, and our spending on current and future research and development programs and product candidates may not yield any commercially viable products.

Additionally, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Fluctuating foreign exchange rates could increase our operating expenses and adversely affect our results of operations.

We have vendors located outside of the United States that provide services relating to the development and manufacture of our product candidates, and as a result, we have had and expect to continue to have more significant foreign currency risks related to our operating expenses denominated in currencies other than the U.S. dollar. A weakening U.S. dollar could increase our operating expenses, which would adversely impact our results of operations and financial position.

Inflation, geopolitical developments, global supply chain disruptions and public health concerns could adversely affect our business and results of operations.

While inflation in the United States has been relatively low in recent years, the economy in the United States has encountered a higher level of inflation since 2021. Inflation has raised our costs for commodities, labor, materials, and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with geopolitical developments, global supply chain disruptions and public health concerns, have caused, and may in the future cause, global economic uncertainty and instability, which may make it more difficult or costly for us to secure additional financing or acquire the supplies necessary to run our clinical trials. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations, or cash flows.

Changes in U.S. trade policy, including the imposition of tariffs and the resulting consequences, may have a material adverse impact on our business, financial condition, and results of operations.

The U.S. government has adopted new approaches to trade policy, and in some cases may renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. The U.S. government has also imposed tariffs on most foreign goods and has threatened to impose significant tariff increases or expand the tariffs to capture other countries and types of goods, including pharmaceutical products. Tariffs on imports from nations from whom we procure raw materials used in the manufacturing process, clinical supplies or other required products are likely to increase the difficulty and cost of our research and development, and/or could require us to incur significant costs to transition to alternative suppliers. Future tariff increases, expanding the tariffs to cover other countries or other changes in U.S. trade policy could exacerbate these challenges.

Further increasing uncertainty related to trade policies, on February 20, 2026, the U.S. Supreme Court ruled against the U.S. presidential administration's use of tariffs under the International Emergency Economic Powers Act ("IEEPA"). However, the decision creates uncertainty related to various aspects of the tariffs previously collected under the IEEPA, and not all tariffs announced throughout 2025 were impacted by this U.S. Supreme Court decision. Additionally, in response to the U.S. Supreme Court ruling, the U.S. presidential administration imposed a new worldwide tariff effective for 150 days from February 24, 2026. The imposition of these new, worldwide tariffs, as well as the potential for further tariff actions by the U.S. presidential administration or others, represents a significant source of uncertainty.

In addition, in response to these tariffs, other countries have threatened, announced or implemented retaliatory tariffs on U.S. goods. Political tensions and uncertainty as a result of rapidly changing trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets, which could in turn have a material adverse impact on our business, financial condition and results of operations.

Our governing documents designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of state law actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does

not have jurisdiction, the United States District Court for the District of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). Notwithstanding the foregoing, the exclusive forum provision shall not apply to claims seeking to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the "Exchange Act").

This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to our Product Candidates

Our business is dependent on the successful development, regulatory approval and commercialization of our therapeutic product candidates, CTIM-76, CT-95 and CT-202, which are in the early stages of development.

We have no products approved for sale. The success of our business, including our ability to finance our Company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of CTIM-76, CT-95 and CT-202, which may never occur.

In the future, we may also become dependent on other product candidates that we may develop or acquire; however, not all of our product candidates have been tested in humans and given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a cancer treatment sufficient to warrant approval for commercialization.

We have not previously submitted an NDA or BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Further, any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our current and any future product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of

our current and any future product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise additional required capital on acceptable terms, or at all;
- our ability to complete IND and BLA-enabling studies and successfully submit an IND and BLA;
- timely completion of our preclinical studies and clinical trials, which may be slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- the results of our clinical trials;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to consistently provide for manufacturing of our product candidates or future approved products, if any, on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMPs;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of our product candidates;
- the prevalence, duration and severity of any side effects or other safety issues experienced with our product candidates or future approved products, including when tested or used in combination with other approved products or product candidates;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or future approved products, if any;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our product candidates or any future product candidates;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others, including through the potential out-licensing of our product candidates;
- competition from other applicants' products authorized for marketing before or after we receive regulatory authorization, if any, for our product candidates;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;
- the convenience of our treatment or dosing regimen;

- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our current or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our current or future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of a product candidate may not be predictive of the results of later-stage clinical trials. A product candidate in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from our clinical studies. Interim or preliminary 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. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Any product candidate, whether used alone or in combination with other approved products or product candidates, may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales.

Serious adverse events or undesirable side effects caused by a product candidate, whether used alone or in combination with other approved products or product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, certain patients treated with CTIM-76 or CT-95 experienced adverse events that included, but were not limited to, cytokine release syndrome, fatigue, liver enzyme elevations and nausea.

If unacceptable side effects arise in the development of any product candidate, we, the FDA or comparable foreign regulatory authorities, the institutional review boards ("IRBs") at the institutions in which our studies are conducted, or the data safety monitoring board, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease

further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using a product candidate, whether used alone or in combination with other approved products or product candidates, to understand the side effect profiles for our clinical trials and upon any commercialization of any product candidate. Inadequate training in recognizing or managing the potential side effects of any product candidate, whether used alone or in combination with other approved products or product candidates, could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if any product candidate receives marketing approval, and we or others later identify undesirable side effects caused by such product, whether used alone or in combination with other approved products or product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy ("REMS"), or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue clinical trials for our current or any future product candidates if we are unable to identify 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. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the ability to obtain and maintain informed consents, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases that we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The process of finding and recruiting patients may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The

eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved or authorized therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a specified number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or similar regulatory authorities outside the United States to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.

We have initiated Phase 1 clinical trials for CTIM-76 and CT-95 in 2025 and are planning for the initiation of a first-in-human trial for CT-202. We may be unsuccessful in advancing any product candidate during clinical development or otherwise into clinical development or in identifying and developing additional product candidates.

Our ability to identify and develop product candidates is subject to the numerous risks associated with preclinical, clinical and early stage biopharmaceutical development activities, including that:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates, including through the potential out-licensing of our product candidates;
- we may not be able to enter into collaborative arrangements to facilitate development of product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- our product candidates may be covered by third parties' patents or other exclusive rights;
- the regulatory pathway for a product candidate may be too complex, expensive or otherwise difficult to navigate successfully; or
- our product candidates may be shown to not be effective, have harmful side effects or otherwise pose risks not outweighed by such product candidate's benefits or have other characteristics that may make the products impractical to manufacture, unlikely to receive any required marketing approval, unlikely to generate sufficient market demand or otherwise not achieve profitable commercialization.

Even if we do commence additional clinical trials of product candidates and continue to identify new product candidates, such product candidates may never be approved. Failure to successfully identify and develop new product candidates and obtain regulatory approvals for our product candidates would have a material adverse effect on our business and financial condition and could cause us to cease operations.

Our innovative therapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

Our foundational science and product development approach are based on the selective targeting of solid-tumor cancers to elicit meaningful anticancer activity. We believe that this approach may offer an improved therapeutic effect by redirecting T-cell-mediated lysis toward malignant cells expressing the tumor antigens that are targeted (CLDN6, MSLN or Nectin-4). However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to develop therapeutics that effectively inhibit membrane protein targets is both preliminary and limited.

As such, we cannot assure you that even if we are able to develop cancer therapeutic candidates capable of redirecting T-cell-mediated lysis toward malignant cells, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic.

Furthermore, no regulatory authority has granted approval for a T cell redirecting cancer therapy based on a selective targeting of CLDN6, MSLN or Nectin-4 positive cancers. As such, we believe the FDA has limited experience with evaluating our approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

If a product candidate does not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidate may be delayed, and our business will be harmed.

We sometimes estimate, and may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives.

The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. For example, in 2025 we adjusted our guidance regarding the anticipated dosing of the first patient in the CT-95 Phase 1 trial.

If we or our collaborators fail to achieve announced milestones in the expected timeframes, the commercialization of the affected product candidate may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the price of our common stock may decline.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.

We face an inherent risk of product liability and professional indemnity exposure related to the testing in clinical trials of our product candidates. We will face an even greater liability risk if we commercially sell any products that we or our collaborators may develop for human use.

Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control. For example, our liability could be sought by patients participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient's condition, patient injury or even death.

Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing any product candidates or products that we develop alone or with collaborators. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that product candidates or products we develop alone or with collaborators caused harm, we could incur substantial liabilities.

Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory approval, may exhibit unforeseen side effects. If any

product candidate were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities.

Product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we expand our clinical trials and if we or our collaborators successfully commercialize any products.

We may be required by the FDA to obtain approval of a companion diagnostic in connection with approval of our current product candidates, and if we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. We have collaborated, and expect to continue to collaborate, with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such diagnostic, which would be subject to regulatory approval requirements. The process of obtaining or creating a diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product candidate and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

We and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product candidate. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Fast track designation from the FDA may not actually lead to a faster development or regulatory review or approval process.

Investigational biological product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product candidate development.

Even if the FDA grants fast track designation to one of our product candidates, such designation may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures, and the designation does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation in the U.S. and in the European Union for our product candidates. Upon receipt of FDA approval, orphan drug status would provide us with seven years of market exclusivity in the U.S. under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our product candidates for any indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan

drug designation for the same indication, or which may receive orphan drug designation in the future, will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $0.4 million per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications if we elect to seek such designation. Even if orphan designation is granted, it may be withdrawn by the FDA for non-compliance with regulations.

Risks Related to Our Organization, Structure and Operations

Our reliance on a central team consisting of a limited number of employees and consultants who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

As of March 1, 2026, we had fifteen full-time employees. We also have various consultants who we rely on for research and development, business development and other services. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our centralized team may limit our ability to devote adequate personnel, time and resources to support the operations of our business, including our research and development activities, and the management of financial, accounting and reporting matters. If our centralized team fails to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition and results of operations could be harmed.

Our future success depends on our ability to retain our Chief Executive Officer, Chief Medical Officer, Chief Financial Officer, Chief Legal Officer, and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development experience, technical skills, leadership and continued service of certain members of our management and scientific teams, including Martin Lehr, our Chief Executive Officer, Dr. Karen Chagin, our Chief Medical Officer, Jennifer Minai-Azary, our Chief Financial Officer, and Alex Levit, our Chief Legal Officer.

Although we have formal employment agreements with all of our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms or at all given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

The inability to recruit, integrate, motivate and retain additional skilled and qualified personnel, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We will need to significantly expand our organization, and our future financial performance, ability to develop and commercialize product candidates alone or with collaborators and ability to compete effectively will depend in part on our ability to effectively manage any future growth. We may have difficulty identifying, hiring and integrating new personnel.

Many of the biopharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can identify and develop product candidates, enter into collaborative arrangements and otherwise operate our business will be limited.

Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel.

Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources from other projects, such as the development of product candidates. If we are not able to effectively manage the expansion of our operations, it may result in weaknesses in our infrastructure, increase our expenses more than expected, give rise to operational mistakes, loss of business opportunities, loss of employees, consultants and contractors and reduced productivity.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and clinical trials or regulatory approvals for any product candidate could be suspended. As a public company it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, our board committees or as our executive officers.

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. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful liability claim or series of claims brought against us could require us to pay substantial amounts and cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of product candidates.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions, could adversely affect our current and projected business operations, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems, which could adversely affect us and our suppliers and collaboration partners. Any supplier or collaboration partner bankruptcy or insolvency, or the failure of any collaboration partner to make payments when due, or any breach or default by a supplier or collaboration partner, or the loss of any significant supplier or collaboration partner relationships, could result in material losses to us and may have a material adverse impact on our business.

Risks Related to Our Reliance on Third Parties

We expect to, and do, depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.

Working with collaborators poses several significant risks, including the following:

- limited availability of resource allocation and other developmental decisions made by our collaborators about the product candidates that we seek to develop with them may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval;

- collaborators could independently develop, or develop with third parties, product candidates that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and

- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations, including those in which we may out-license our product candidates, do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive the expected deliverables or services from our collaborators, nor receive any future funding or milestone or royalty payments under the collaboration.

If we do not receive the funding or deliverables or services from our collaborators that we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop such product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and may need to raise additional capital to pursue further development or commercialization of the applicable product candidates.

These events could delay development programs and negatively impact the perception of our company in business and financial communities. Failure to develop or maintain relationships with any current collaborators

could result in the loss of opportunity to work with that collaborator or reputational damage that could impact our relationships with other collaborators in the relatively small industry communities in which we operate.

Moreover, all of the risks relating to product development, regulatory approval and commercialization described in this Form 10-K apply to the activities of our collaborators. If our existing collaboration agreements or any collaborative or strategic relationships we may establish in the future are not effective and successful, it may damage our reputation and business prospects, delay or prevent the development and commercialization of product candidates and inhibit or preclude our ability to realize any revenues.

We may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and/or commercialization of our current or past product candidates, which may be time consuming, costly and could harm our efforts to develop our current or future product candidates.

We have entered into various agreements and licenses with licensees, licensors and other counterparties related to the development and/or commercialization of our current and past product candidates. These agreements and licenses impose a variety of obligations on us and the counterparties to such agreements and licenses. Disagreements and disputes between us and certain counterparties may arise, such as regarding each parties' obligations under the respective agreement or license.

Any such disagreement or dispute could become time consuming, costly and could harm our efforts to develop current or future product candidates. Any disagreements or disputes with such parties that lead to litigation, arbitration or similar proceedings will result in us incurring significant legal expenses and potential significant legal liability and could jeopardize our ability to continue development of the related product candidate.

Further, any disagreements or disputes over our obligations or intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms. If we fail to meet our obligations under these agreements or licenses, the respective counterparty may have the right to terminate the respective agreement or license and to re-obtain the related technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement or license was in force that relates to the applicable technology. While we would expect to exercise our rights and remedies available to us in the event we fail to meet our obligations under such agreement or license in any material respect and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured breach under any agreement or license relating to a product candidate could result in our loss of rights and may lead to a complete termination of the respective agreement or license. Termination of one of these agreements or licenses for any reason could prevent us from completing a transaction to sell or out-license a product candidate.

Additionally, any disagreements or disputes over our counterparties' obligations or intellectual property rights that we have licensed or acquired may prevent or impair our ability to develop any of our product candidates. If any counterparty fails to meet their obligations under these agreements or licenses or does not have the right to intellectual property rights that they may contractually claim to have, it could materially impact our development of such product candidate. While we may have the right to terminate the respective agreement or license and to maintain some or all of the related technology as well as some or all aspects of any intellectual property controlled by such counterparty, we may not be able to do so in a timely manner, at an acceptable cost or at all, and it may lead to litigation, arbitration or similar proceedings that may result in us incurring significant legal expenses and jeopardize our ability to continue development of the related product candidate. A dispute regarding, or termination of, one of these agreements or licenses for any reason also could prevent us from completing a transaction to sell or out-license a product candidate for which we have decided to discontinue development.

We have relied on and we expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We have relied on and we expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations ("CROs"), to conduct preclinical studies and clinical trials for product candidates. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on such third parties will not relieve us of our regulatory responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as GCPs, for conducting, monitoring, 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.

Although we have designed and intend to design future trials for product candidates either alone or with collaborators, third parties may conduct some parts of or all of the trials. As a result, many important aspects of our research and development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current and future studies and trials will also result in less direct control over the management of data developed through studies and trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Such third parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors.

We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs or other third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If we, our collaborators, our CROs or other third parties 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 also are required to register certain ongoing clinical trials and post the results of such completed clinical trials on a government-sponsored database, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If our CROs or other third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, trials for a product candidate may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for, or successfully commercialize, any product candidates. If we are required to repeat, extend the duration of or increase the size of any trials we conduct, it could significantly delay commercialization and require significantly greater expenditures.

Further, conducting clinical trials in foreign countries, which we are pursuing for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, failure to comply with privacy and related legal requirements, managing additional administrative burdens and costs associated with foreign regulatory schemes, managing cross-border operational activities, and political and economic risks relevant to such foreign countries.

As a result of any of these factors, our financial results and the commercial prospects for the affected product candidate would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business.

We are dependent on third parties for the supply of various pharmaceutical and biological materials and the manufacture of product supplies that are necessary to produce our current and any future product candidates. The supply of these materials could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all.

Changing suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we or our collaborators may not be able to develop, manufacture and market the affected product candidate in a timely and competitive manner, or at all. If any product candidate receives approval, we will likely need to seek alternative sources of supply of raw materials or manufactured product supplies and there can be no assurance that we will be able to establish such relationships to provide such supplies on commercially reasonable terms or at acceptable quality levels, if at all. If we are unable to identify and procure additional sources of supply that fit our required needs, we could face substantial delays or incur additional costs in procuring such materials.

We do, and may further, rely on third parties for the manufacturing process of our current and any future product candidates, and failure by those parties to adequately perform their obligations could harm our business.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and do rely, and expect that we will continue to rely, on outside vendors, including vendors outside the United States, for at least a portion, if not all, of the manufacturing process of our current and any future product candidates that we or our collaborators develop.

The facilities used by our contract manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections conducted after we submit an application to the FDA or other foreign regulatory agencies. When we or our collaborators engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing providers for compliance with cGMP requirements for manufacture of the product candidates.

We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are safe and effective. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any of our or our collaborators' potential products.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of our current and any future product candidates will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements, including the potential out-licensing of some or all of our product candidates, for the development and potential commercialization of some or all of our current and any future product candidates or the development of ancillary technologies.

We face significant competition in establishing relationships with appropriate collaborators. In addition, there continues to be consolidation among large pharmaceutical companies, which has resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product, an assessment of the opportunities and risks of our product candidates, the design or results of studies or trials, the likelihood of approval, if necessary, by the U.S. Department of Agriculture, the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and industry and market conditions generally.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidate or others. Such collaborations may also impact our ability to control the nature, timing and cadence of developing and commercializing the product candidates subject to such collaborations. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our current and any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics and pharmaceuticals, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of CLDN6, MSLN and Nectin-4 therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The novel mechanism of action and immunotherapy characteristics of our TCE bsAb product candidates may present unique clinical safety risks, which could delay or prevent regulatory approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of product candidates based on the completed clinical trials, as the FDA often makes decisions consistent with the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective 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 approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;

- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- the possibility that immune-mediated toxicities associated with our TCE bsAb produce candidates may require trial protocol modifications, dose interruptions or reductions, or could delay or prevent the completion of clinical trials;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of a product candidate in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities 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 product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. The FDA's review of our data of our clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of a product candidate, the commercial prospects for such product candidate will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. In addition, because the product candidates utilize a TCE bsAb mechanism of action, clinical development may be particularly susceptible to immune-mediated adverse events, which may required protocol modifications, dose interruptions or reductions, enhanced patient monitoring, or hospitalization requirements, and could delay, suspend or prevent the completion of clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our current and any future product candidates.

We expect that CTIM-76, CT-95 and CT-202 will be regulated as biological products, or biologics, and therefore they may be subject to competition from biosimilar applicants.

The Biologics Price Competition and Innovation Act was enacted as part of PPACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the Biologics Price Competition and Innovation Act, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. Regulatory decisions implementing the Biologics Price Competition and Innovation Act may have a material adverse effect on the future commercial prospects for our biological products.

We believe that CTIM-76, CT-95 and CT-202, if approved in the United States as biological products under BLAs, should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of any product candidate.

If and when our clinical trials for our current and any future product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The current general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from at least one well-controlled, Phase 3 clinical study of the relevant biologic or drug in the relevant patient population, although the FDA has historically required, and many foreign regulatory authorities still require, dispositive data from two such studies. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results from our clinical trials are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for the relevant product candidate. For example, the FDA may require that we conduct a comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources. As well, in 2022 the Oncology Center of Excellence (OCE) of the FDA implemented Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development, which has impacted and could continue to impact our current and future clinical trials and significantly delay our development timelines and require substantially more resources. In addition, because our product candidates utilize a TCE bsAb mechanism of action, clinical development may be subject to risks associated with immune-mediated toxicities, which may require protocol modifications, dose interruptions or reductions, enhanced patient monitoring, or hospitalization and could delay or prevent regulatory approval.

The FDA may grant accelerated approval for a product candidate and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe an accelerated approval strategy may be warranted given the limited alternatives for patients that our product candidates target, but the FDA may ultimately require a Phase 3 clinical trial prior to approval. In addition, the standard of care may change with the use of currently approved products or the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product candidates are superior to the new products.

Our clinical trial results may also not support approval. In addition, our current and any future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our current or any future product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our current and any future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our current and any future product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a

BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of such product candidate in other jurisdictions.

Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our current and any future product candidates will be harmed.

Even if we obtain regulatory approval of a product candidate, the product may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of T cell engaging bispecific antibodies as potential cancer treatments is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community and we may not be able to convince them to use a product candidate for many reasons. Additional factors will influence whether a product candidate is accepted in the market, including:

- the clinical indications for which a product candidate is approved;
- physicians, hospitals, cancer treatment centers and patients considering a product candidate as safe and effective treatments;
- the potential and perceived advantages of a product candidate over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of a product candidate as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If a product candidate is approved but fails to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for a product candidate, which could make it difficult for us to sell such product candidate, if approved, profitably.

Successful sales of a product candidate, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of 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. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use a product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of that product candidate. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers, and reduce the willingness of physicians to use a product candidate.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our current and any future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for a product candidate, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with a product candidate.

Any regulatory approvals that we receive for a product candidate will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for that product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of

distribution restrictions or other restrictions under a risk evaluation and mitigation strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product candidate, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of a product candidate; and
- injunctions or the imposition of civil or criminal penalties.

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

The advancement of healthcare reform may negatively impact our ability to sell our current and any future product candidates, if approved, profitably.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, PPACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of PPACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following:

- manufacturers and importers of certain biologics with annual sales of more than $5 million made to or covered by specified federal healthcare programs are required to pay an annual, nondeductible fee according to their market share of all such sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% of the average manufacturer price for most branded drugs, biologics, and biosimilars and to 13.0% for generic drugs, and a cap of the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health program, commonly referred to as the "340B Program;"

- a requirement to annually report drug samples that manufacturers and distributors provide to physicians, also known as the "Physician Payments Sunshine Act;"
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA, and there may be additional challenges and amendments to PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which repealed the tax-based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate."

In addition, other legislative changes have been proposed and adopted in the United States since PPACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers.

For example, on August 16, 2022, the IRA, was passed, which among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with 10 high-cost drugs paid for by Medicare Part D in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of the IRA on our business and the healthcare industry in general is not yet known.

These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers.

To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of a product candidate to other therapies that are considered the local standard of care. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, a product candidate may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Changes to United States federal regulatory agencies may cause disruptions and delays in government approval processes and regulations relating to our product candidates.

On January 20, 2025, President Trump signed an executive order creating an advisory commission, the Department of Government Efficiency, tasked with eliminating regulations, cutting expenditures, and restructuring federal agencies. Any future government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related U.S. government agencies. These budgetary pressures may result in a reduced ability by the FDA and others to perform their respective roles.

Robert F. Kennedy Jr., the Secretary of the U.S. Department of Health and Human Services ("HHS"), which oversees the FDA, has previously stated his intent to reform, downsize or restructure these agencies. For example, HHS terminated 10,000 employees in 2025, and the FDA has released a plan to phase out animal testing requirements in preclinical safety studies. 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, our current or any future product candidates may not achieve regulatory approval. Even if we are successful in achieving regulatory approval for one of more of our product candidates, such approval could be significantly delayed by changes at the FDA.

Risks Related to Intellectual Property

Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position.

The patent positions of biopharmaceutical companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office (the "USPTO") and its foreign counterparts are sometimes uncertain and could change in the future.

Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or designed around. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination, post-grant review and/or inter partes review proceedings in the USPTO.

International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not adequately protect our technology and product candidates or products that we develop alone or with collaborators or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications that we hold with respect to our product candidates or potential products is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, such product candidates or potential products.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and product candidates or products without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our, and our licensors rely on their, outside counsel and employ an outside firm to pay these fees due to USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If the patent applications we hold or have in-licensed with respect to our current and future research and development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our technology or any products and product candidates that we or our collaborators develop, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our or our collaborators' ability to commercialize our current and any future product candidates. Any such outcome could have a material adverse effect on our business.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our current and any future product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

Our commercial success depends in part upon our ability to develop, manufacture, market and sell product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology field is common, including patent infringement lawsuits, and such interference, derivation, reexamination, post-grant review, inter partes review and opposition proceedings before the USPTO and corresponding international patent offices.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors.

Numerous United States, EU and other internationally issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. For example, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 and March 2042 that potentially cover certain parts of the intellectual property included in CTIM-76. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and any future product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from a third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights.

These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more product candidates, forced to modify such product candidates, forced to cease some aspect of our business operations, or be required to pay substantial damages to a third party, which could harm our business significantly.

We or our collaborators might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us, our collaborators or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims may cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third-party's patent rights. We may not have sufficient resources to bring these actions to a successful conclusion.

These damages potentially include treble damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our or our collaborators' ability to further develop or commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technologies, compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those technologies, compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our or our collaborators' ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we or our collaborators obtain a license.

Competitors may infringe our patents. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and/or being interpreted narrowly and could put our patent applications at risk of not issuing and/or could impact the validity or enforceability positions of our other patents. Furthermore, 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.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology.

Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages.

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect CTIM-76, CT-95, CT-202 and any future product candidates. Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to CTIM-76, CT-95, CT-202 and any future product candidates, as well as successfully defending these rights against third-party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect CTIM-76, CT-95, CT-202 and any future product candidates from unauthorized use by third parties to the extent that valid and enforceable patents or effectively protected trade secrets cover them.

Our ability to obtain and maintain patent protection for CTIM-76, CT-95, CT-202 and any future product candidates is uncertain due to a number of factors, including the following factors:

- we may not have been the first to invent the technology covered by our pending patent applications or issued patents;

- we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- others may identify prior art or other bases upon which to challenge and ultimately invalidate our patents or otherwise render them unenforceable;
- our compositions and methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions, or methods of use thereof;
- others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- we may not seek or obtain patent protection in countries and jurisdictions that may eventually provide us a significant business opportunity;
- we may decide not to maintain or pursue patents and patent applications that, at some point in time, may cover our products, potential products, or product candidates;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- our representatives or their agents may fail to apply for or maintain patents in a timely fashion; and
- despite our efforts to enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in patents and patent applications, an inventorship or ownership dispute could arise that may permit one or more third parties to practice our technologies or enforce our patent rights, including possible efforts to enforce patent rights against us.

Even if we have or obtain patents covering CTIM-76, CT-95, CT-202 and any future product candidates or compositions, others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop a product candidate or to successfully commercialize any approved products alone or with collaborators. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that may cover CTIM-76, CT-95, CT-202 or any future product candidates or compositions. These patent applications may have priority over patent applications filed by us. For example, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 and March 2042 that potentially cover certain parts of the intellectual property included in CTIM-76. While we believe we will have reasonable defenses against any potential claim of infringement, including challenging the validity of any such patents, we may not be successful in such efforts, and we also may not be able to obtain a license to such patents on commercially reasonable terms, or at all. If such patent is valid and not yet expired when, and if, we receive marketing approval for CTIM-76 we may need to seek a license to such patent, which may not be available on commercially reasonable terms or at all. Failure to receive a license to such patent, or other potentially relevant patents currently unknown to us, could delay the manufacture or commercialization of CTIM-76 or require us to incur additional payments and expenses, including legal fees, court issued damages or settlement costs.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and 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 freedom to operate 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.

In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

Without patent protection for current or any future product candidates, we may be open to competition from generic or biosimilar versions of such potential products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such 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 those we or our collaborators may develop.

In addition, we also try to protect our trade secrets, know-how and other proprietary information through non-disclosure and confidentiality provisions in our agreements with parties who have access to them, such as our employees, consultants and research partners. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets, know-how and/or other proprietary information in the event of unauthorized uses or disclosure or other breaches of the provisions, and we may not be able to prevent such unauthorized uses or disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized and inadvertent disclosure and uses is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. In addition, monitoring unauthorized disclosure and uses of our trade secrets is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the United States may be less willing to protect trade secrets.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, are used inappropriately to create new inventions or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. Additionally, we may need to outsource and rely on third parties for many aspects of the development, sales and marketing of any products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our licensors. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Additionally, if such licensor fails to have patent rights that they otherwise may claim to have for the proprietary intellectual property we license from such licensor or they infringe the intellectual property rights of a third party, it could delay or materially impact our ability to commercialize our product candidates that rely on such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology, to address any infringement claims that may be made by such third party, and to compensate a third party for any infringement.

If we are unable to develop or license replacement technology, we or our collaborators may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. In other cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor or a third party that is not subject to the licensing agreement;
- the extent to which the licensed intellectual property may infringe the intellectual property of a third party that is not subject to the licensing agreement, as well as the licensor's potential breach of its related warranties or obligations in a licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our current and any future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our current and any future product candidates, thereby potentially extending the term of marketing exclusivity for such product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our current and any future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process.

In the European Union, our current and any future product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements.

Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Changes in U.S. patent law, and the laws of other countries, could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted, and continues to consider, wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of

patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO, and the courts and regulatory agencies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to the Market for Our Common Stock

Our common stock may be volatile or may decline regardless of our operating performance.

The market price of our common stock has been, and may continue to be, volatile and fluctuate significantly in response to several factors, most of which we cannot control, including:

- quarterly variations in our operating results compared to market expectations;
- adverse publicity about us, the industries we participate in or individual scandals;
- announcements of new offerings or significant price reductions by us or our competitors;
- stock price performance of our competitors;
- fluctuations in stock market prices and volumes;
- large purchases or sales causing stock price fluctuations due to low trading volumes;
- changes in senior management or key personnel;
- changes in financial estimates by securities analysts;
- the market's reaction to our reduced disclosure as a result of being an "emerging growth company" under the JOBS Act;
- negative earnings or other announcements by us or our competitors;
- defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock;
- global economic, legal and regulatory factors unrelated to our performance; and
- the other factors listed in this "Risk Factors" section.

Volatility in the market price of our common stock may prevent investors from being able to sell their shares at or above their purchase price. As a result, you may suffer a loss on your investment.

We may not be able to maintain compliance with the continued listing requirements of The Nasdaq Stock Market.

Our common stock is listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $1.00 per share. On February 27, 2025, we received a letter from Nasdaq stating that the we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule") because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. While we have since regained compliance with the Minimum Bid Price Rule, if we fail to maintain compliance with the Minimum Bid Price Rule or we fail to continue to meet any other applicable continued listing requirement for The Nasdaq Stock Market, our common stock may be delisted, which would adversely affect the market liquidity of our common stock and our ability to obtain financing to fund our operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and/or debt financings, partnerships and collaborations, licensing agreements or

other strategic arrangements. To the extent that we raise additional capital or pay expenses through the sale or issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

To the extent that we raise additional capital through debt financing, it would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends.

To the extent we raise additional capital through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, research programs, product development activities, product candidates and/or future revenue streams, license our technologies and/or product candidates on unfavorable terms or otherwise agree to terms unfavorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or current or future product candidates.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.

The Financial Industry Regulatory Authority ("FINRA") has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

We are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies and our stockholders could receive less information than they might expect to receive from more mature public companies.

We are required to publicly report on an ongoing basis as an "emerging growth company" (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company, which we currently expect to occur as of December 31, 2026. Because we are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot determinate if investors find our common stock less attractive because we elect to rely on these exemptions, or if taking advantage of these exemptions has or will result in less active trading or more volatility in the price of our common stock.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are subject to the reporting requirements of the Exchange Act, as well as the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time.

If we or our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness or significant deficiency in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

General Risk Factors

We incur increased costs as a result of being a public company and in the administration of our organizational structure.

As a public company, we have incurred significant legal, accounting, insurance, and other expenses, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and ongoing periodic expenses in connection with the administration of our organizational structure. These laws and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.

We are subject to income and non-income taxes in the United States and Ireland, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. We could become subject to income and non-income taxes in non-U.S. jurisdictions other than Ireland as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm's length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear and we may be subject to tax audits relating to such rules or taxes. We are also currently not subject to any tax audits.

However, various items cannot be accurately forecasted and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. Furthermore, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect). If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, or existing tax laws, statutes, rules, regulations or ordinances are so interpreted, changed or modified, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

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

Our computer systems, as well as those of third parties with which we have relationships, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures. If we or a third party with which we have relationships were to experience a system failure, accident or security breach, such an event could cause interruptions in our or their operations, or it could result in delays and/or material disruptions of our research and development programs. For example, the loss of trial data from completed, ongoing or planned trials 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 were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the development of our current and any future product candidates could be delayed.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals, and U.S. federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use and dissemination of data. In the ordinary course of our business, we and third parties with which we have relationships collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, consultants and contractors, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance or other disruptions, and any such breach could compromise our or their networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant costs, including regulatory penalties, fines and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our collaborators' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

We or third parties with whom we have relationships may be adversely affected by natural or manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural or manmade disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged our infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time, and our research and development activities could be setback or delayed.

The disaster recovery and business continuity plan(s) we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of

confidence in us and our or third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may now and in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and consultants.

We could be subject to securities class action litigation or litigation challenging the validity of provisions in our amended and restated certificate of incorporation or amended and restated bylaws.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. In addition, litigation challenging the validity of provisions in a public company's certificate of incorporation or bylaws has been increasing in recent years, and we have in the past, and may again in the future, be the subject of such litigation. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

We have strategically integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity risk management. This integration is intended to ensure that cybersecurity considerations are an integral part of our decision-making processes at every level. Our management team works closely with our Information Technology provider to continuously evaluate and address cybersecurity risks in alignment with our business objectives and operational needs.

Engage Third Parties on Risk Management

Recognizing the complexity and evolving nature of cybersecurity threats, we engage with external experts, including cybersecurity assessors, consultants, and auditors in evaluating and testing our risk management systems. These partnerships enable us to leverage specialized knowledge and insights as part of our cybersecurity strategies and processes. Our collaboration with these third parties includes regular audits, threat assessments, and consultation on security enhancements.

Risks from Cybersecurity Threats

We have not encountered cybersecurity threats that have materially affected, or are reasonably likely to materially affect, our company, including our business strategy, results of operations or financial condition. For a discussion of whether and how any risks from cybersecurity threats may materially affect us, see Part I, Item 1A. Risk Factors.

Governance

Our Board of Directors is acutely aware of the critical nature of managing risks associated with cybersecurity threats and has tasked the Audit Committee with overseeing our cybersecurity program. As described above, we obtain periodic assessments of our cybersecurity program from independent third-party experts. Additionally, cybersecurity threats and incidents determined through our cybersecurity program to present potential material impacts to our financial results, operations, or reputation are required to be immediately reported to our Audit Committee in accordance with our escalation framework.

Management's Role Managing Risk

Our Senior Vice President ("SVP") of Operations plays a pivotal role in informing our Board of Directors on cybersecurity risks. Our SVP of Operations also had responsibility for managing cybersecurity matters at a prior employer. Our SVP of Operations provides comprehensive briefings to the Board of Directors on a regular basis, with a minimum frequency of once per year. These briefings encompass a broad range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Learnings from any cybersecurity events; and
- Compliance with regulatory requirements and industry standards.

In addition to our scheduled meetings, the SVP of Operations and Chief Executive Officer maintain an ongoing dialogue regarding emerging or potential cybersecurity risks.

Monitor Cybersecurity Incidents

The SVP of Operations is continually informed about the latest developments in cybersecurity, including potential threats and innovative risk management techniques. This ongoing knowledge acquisition is crucial for the effective prevention, detection, mitigation, and remediation of cybersecurity incidents. The SVP of Operations implements and oversees processes for the regular monitoring of our information systems. This includes the deployment of advanced security measures and regular system audits to identify potential vulnerabilities.

Reporting to Senior Leadership

The SVP of Operations, in his capacity, regularly informs the Chief Financial Officer and Chief Executive Officer of all aspects related to material cybersecurity risks and incidents. This is intended to ensure that the highest levels of management are kept abreast of the cybersecurity posture and potential risks facing us.

Item 2. Properties

Our corporate headquarters are located at 2001 Market Street, Suite 3915, Unit #15, Philadelphia, PA 19103, where we occupy approximately 6,200 square feet of office space pursuant to a lease most recently amended in January 2026 that expires on November 30, 2027. This amended lease included additional office space and allows us to renew the lease at our option for one additional successive one-year period. We believe our facility is adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. If needed, we believe appropriate alternative space will be readily available on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Except as disclosed below, we are not presently a party to any material legal proceedings.

On February 4, 2026, the Vladimir Gusinsky Revocable Trust filed a stockholder class action complaint (the "Action") against us and our directors in the Court of Chancery of the State of Delaware (the "Court") asserting that (i) Article V, Section 2 of our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), provides for a full term of three years for directors in violation of Section 211(b) of the General Corporation Law of the State of Delaware (the "DGCL") and (ii) Article VI, Section 1 of the Certificate of Incorporation limits removal of directors only for cause in violation of Section 141(k) of the DGCL.

On February 24, 2026, a stipulation and proposed consent judgment (the "Stipulated Judgment") was filed with the Court regarding the Action, and on March 11, 2026, the Court approved the Stipulated Judgment, pursuant to which Article V, Section 2 and Article VI, Section 1 of the Certificate of Incorporation were determined to be invalid and unenforceable. On March 11, 2026, we filed a Certificate of Correction with the Delaware Secretary of State reflecting such provisions as invalid, unenforceable and no longer part of the Certificate of Incorporation. Accordingly, the term of office of our current members of the Board of Directors will expire at our 2026 annual meeting of stockholders, with each serving until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. In addition, directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors.

On March 11, 2026, pursuant to the Stipulated Judgment, the Action was dismissed with prejudice with respect to the plaintiff; however, the Court retains jurisdiction to address any mootness fee application.

Item 4. Mine Safety Disclosures

None.

PART II.

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

Market Information

Our common stock has been traded on The Nasdaq Stock Market under the symbol "CNTX" since October 20, 2021 following our initial public offering.

Stockholders

As of March 19, 2026, we had 91,879,177 shares of common stock outstanding held by 45 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid cash dividends on any class of our stock to date, and we do not anticipate paying any cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

During the fourth quarter of 2025, we granted inducement stock options outside of the 2021 Long-Term Performance Incentive Plan covering 30,000 shares of the Company's common stock to a new employee (the "Inducement Grant") with an exercise price of $0.97 per share. The Inducement Grant will vest as to 25% of the shares on the first anniversary of the date of grant and in successive equal monthly installments over the subsequent three years, subject to continued employment with the Company and the terms and conditions in the stock option agreement. The options were granted pursuant to the exemption contained in Section 4(a)(2) of the Securities Act of 1933.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Form 10-K. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below. Please also see the section entitled "Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company advancing TCE bispecific antibodies for solid tumors. Our goal is to build an innovative portfolio of TCE bispecific therapeutics, including CTIM-76, a CLDN6 x CD3 TCE, CT-95, an MSLN x CD3 TCE, and CT-202, a Nectin-4 x CD3 TCE.

CTIM-76 is a CLDN6 x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target expressed in multiple solid tumors and absent from or expressed at low levels in healthy adult tissues. We have an active IND for CTIM-76 with the FDA. We dosed the first patient in our CTIM-76 Phase 1 clinical trial in January 2025. We expect to share Phase 1a interim data for the CTIM-76 trial in June 2026.

CT-95 is an MSLN x CD3 TCE that is intended to redirect T-cell-mediated lysis toward malignant cells expressing MSLN. MSLN is a membrane protein overexpressed in approximately 30% of cancers. We dosed the first patient in our CT-95 Phase 1 trial in April 2025. We expect to share Phase 1a interim data for the CT-95 trial in September 2026.

CT-202 is a Nectin-4 x CD3 TCE that targets Nectin-4, a cell surface protein that is highly and frequently overexpressed in a variety of solid tumors, including bladder, colorectal, lung and breast. Nectin-4 is a clinically validated target for cancer therapy using a traditional antibody-drug conjugate, but it is also associated with certain adverse events, including neuropathy and rash. CT-202 is a pH-dependent TCE that is designed to be preferentially active within the tumor microenvironment. We submitted our application to the HREC in March 2026 to support the initiation of a first-in-human trial for CT-202. We expect to dose the first patient in our CT-202 Phase 1 trial in the third quarter of 2026.

We were incorporated in April 2015 under the laws of the State of Delaware. Since inception, we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We operate as one business segment and have incurred recurring losses, the majority of which are attributable to research and development activities, and negative cash flows from operations. We have funded our operations primarily through the sale of common stock, warrants, convertible debt and convertible preferred stock. Our net loss was $36.1 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $130.9 million.

Asset Acquisition Agreements

CTIM-76: Integral Molecular License Agreement

In April 2021, we entered into a collaboration and licensing agreement with Integral Molecular, Inc. ("Integral") (the "Integral License Agreement") for the development of a CLDN6 bsAb for cancer therapy. On February 29, 2024, we further amended (the "Second Amendment") the Research Collaboration and License Agreement (the "Integral License Agreement", as amended) with Integral to reflect updated financial terms. In the course of our further due diligence review of CTIM-76, we determined that certain of the licensed rights under the Integral License Agreement may incorporate intellectual property rights currently held by a third party. Specifically, at the time of the Second Amendment, we were aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034, and then in 2025 became aware of a patent that issued in the United States expiring in March 2042, in each instance that potentially covers certain parts of the intellectual property included in CTIM-76. While we believe we will have reasonable defenses against any potential claim of infringement, we may

not be successful in such efforts, and we also may not be able to obtain a license to such patent on commercially reasonable terms, or at all.

As part of the Second Amendment, Integral's right to receive certain future payments was reduced as follows: aggregate development and regulatory milestone payments were reduced from $55 million to $15 million, aggregate sales milestone payments were reduced from $130 million to $12.5 million, and a tiered royalty of 8-12% that commenced at first commercial sale was reduced to a flat royalty rate of 6% on net sales beginning no sooner than February 1, 2034. The Second Amendment also narrowed the license grant from Integral to us to only cover CTIM-76, removed any further obligation of us to reimburse Integral for any independently obtained research funding Integral applied against CTIM-76 research, and included mutual releases by the parties.

The reduced development and regulatory milestones now reflect a payment due at each of: first patient's first screening visit in a Phase 1b/2 or Phase 2 clinical trial for CTIM-76, first patient's first screening visit in a Phase 3 clinical trial for CTIM-76, United States marketing approval for CTIM-76, European Union marketing approval for CTIM-76, United Kingdom marketing approval for CTIM-76, and Japan marketing approval for CTIM-76. The amended commercial milestones now also reflect a payment due upon the achievement of annual net sales of $500 million and annual net sales of $1 billion.

CT-95: Link Purchase Agreement

On July 9, 2024, we entered into an asset purchase agreement (the "Asset Purchase Agreement") pursuant to which we acquired CT-95 (formerly known as LNK-101), from Link (assignment for the benefit of creditors), LLC ("Link"), which succeeded to the assets of Link Immunotherapeutics Inc. The FDA previously cleared the IND application for CT-95.

Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Link associated with CT-95, including patent rights, know-how, regulatory filings, and inventory of drug substance and drug product (the "Transferred Assets"), on an "as is" and "where is" basis. CT-95 patents are currently being prosecuted and/or maintained in the United States, Europe, Canada, Australia, Japan and Taiwan. We also assumed certain liabilities relating to the Transferred Assets. In consideration of the Transferred Assets, we made a one-time payment to Link of $3.75 million.

CT-202: BioAtla License Agreement

On September 23, 2024, we entered into a license agreement (the "BioAtla License Agreement") with BioAtla, Inc. ("Bioatla"), pursuant to which we obtained an exclusive, worldwide license to develop, manufacture and commercialize two licensed antibodies (the "BioAtla Assets"), including BA3362 (renamed by the Company as CT-202), BioAtla's Nectin-4 x CD3 TCE bispecific antibody.

As partial consideration for the exclusive license under the BioAtla License Agreement, we made an upfront payment of $11.0 million, and BioAtla is eligible to receive up to $122.5 million in additional milestone payments based upon the achievement of specified pre-clinical, clinical, development and commercial milestones, as well as tiered mid-single-digit to low double-digit royalties on future net sales for products containing the BioAtla Assets, subject to standard reductions. In October 2025, we achieved a $2.0 million development milestone under the BioAtla License Agreement, which we paid to BioAtla in the fourth quarter of 2025.

Financial Overview

Currently, our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, as well as general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or any future product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our current and any future product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain regulatory approval for any product candidate, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we have incurred and continue to incur significant costs associated with operating as a public company, including legal,

accounting, investor relations and other expenses. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenses on other research and development activities.

As of December 31, 2025, we had cash and cash equivalents of $66.0 million, which we expect will be sufficient to fund the estimated duration of the Phase 1a dose escalation portions of our CTIM-76 and CT-95 trials, the estimated expenses to initiate patient enrollment in a first-in-human trial for CT-202, as well as our operations into mid-2027. If the Company is unable to obtain additional financing, the lack of liquidity could have a material adverse effect on the Company's future prospects.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic transactions and/or marketing, distribution or licensing arrangements. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.

At-the-Market Offering

On December 2, 2024, we entered into a Sales Agreement (the "ATM Sales Agreement") with Leerink Partners LLC (the "Agent"). Pursuant to the terms of the ATM Sales Agreement, we may offer and sell shares of common stock having an aggregate offering amount of up to $75.0 million from time to time through the Agent (the "ATM Shares"). Sales of the ATM Shares may be made in sales deemed to be an "at-the-market offering" as defined in Rule 415 under the Securities Act. On December 23, 2024, we sold 14,705,882 shares of our common stock under the ATM Sales Agreement for net proceeds of approximately $14.5 million. On October 24, 2025, we entered into Amendment No. 1 to Sales Agreement (the "Amendment", and together with the ATM Sales Agreement, the "Amended ATM Sales Agreement") to provide for an increase in the aggregate offering amount under the Amended ATM Sales Agreement, such that following the filing of a new prospectus supplement with respect to the ATM Shares on October 24, 2025, we may offer and sell ATM Shares having an aggregate offering price of up to $75.0 million, exclusive of ATM Shares previously sold in December 2024. The Agent will be entitled to a commission from the Company of up to 3.0% of the gross proceeds from the sale of ATM Shares sold under the Amended ATM Sales Agreement.

Private Placement

On May 1, 2024, we entered into a securities purchase agreement (the "Purchase Agreement") for the private placement (the "Private Placement") of (i) 59,032,259 shares (the "PIPE Shares") of our common stock at a purchase price of $1.55 per PIPE Share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase 5,482,741 shares of common stock (the "Warrant Shares") at a purchase price of $1.549 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The aggregate gross proceeds for the Private Placement were approximately $100 million, before deducting offering expenses of $5.2 million, and the Private Placement closed on May 6, 2024. In September 2025, 2,178,200 Pre-Funded Warrants were exercised on a cashless basis, resulting in the issuance of 2,174,983 shares of common stock. As of December 31, 2025, 3,304,541 Pre-Funded Warrants remained outstanding.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses have consisted primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred, including:

- expenses incurred to conduct the necessary discovery-stage laboratory work, preclinical studies and clinical trials required to obtain regulatory approval;
- personnel expenses, including salaries, benefits and share-based compensation expense for our employees and consultants engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with contract research organizations ("CROs") that conduct our clinical trials, as well as investigative sites, consultants and CROs that conduct our preclinical and clinical studies;
- expenses incurred under agreements with contract manufacturing organizations, including manufacturing scale-up expenses, milestone-based payments, and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- license payments and acquisitions of acquired in-process research and development assets that have no alternative future use;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities and maintenance.

We track outsourced development costs and other external research and development costs to specific product candidates on a program-by-program basis. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including share-based compensation, conduct our clinical trials, including later-stage clinical trials, for current and any future product candidates and prepare regulatory filings for our current and any future product candidates.

General and Administrative Expenses

General and administrative expenses have consisted primarily of personnel expenses, including salaries, benefits and share-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and business development functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expense, including rent, utilities and insurance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, legal support and accountants, among other expenses. Additionally, we will continue to incur significant costs associated with being a public company, including expenses related to services associated with

maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs. If any of our current or future product candidates obtain U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Other Income (Expense)

Other income (expense) is primarily due to the recognition of foreign currency gains or losses as a result of exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change	% Change
Operating expenses:				
Research and development	$ 31,856,252	$ 22,701,335	$ 9,154,917	40 %
General and administrative	7,846,379	7,222,565	623,814	9 %
Loss from operations	(39,702,631)	(29,923,900)	(9,778,731)	33 %
Interest income	3,378,545	3,200,224	178,321	6 %
Other income (expense)	200,471	(1,428)	201,899	*
Net loss	$ (36,123,615)	$ (26,725,104)	$ (9,398,511)	35 %

** Percentage not meaningful*

Research and Development Expenses

Research and development expenses increased by approximately $9.2 million for the year ended December 31, 2025 as compared to 2024. The following table summarizes our research and development expenses for the year ended December 31, 2025 as compared to 2024:

	Year ended December 31,			
	2025	2024	$ Change	% Change
CTIM-76	$ 6,843,564	$ 5,581,896	$ 1,261,668	23 %
CT-95	4,865,479	4,871,254	(5,775)	— %
CT-202	15,573,393	11,151,496	4,421,897	40 %
Personnel-related costs	4,368,441	1,032,516	3,335,925	323 %
Other research and development	205,375	64,173	141,202	220 %
	$ 31,856,252	$ 22,701,335	$ 9,154,917	40 %

CTIM-76 expenditures increased by $1.3 million, primarily due to an increase of $3.1 million in clinical costs as a result of continued progression of our ongoing Phase 1 clinical trial. This increase was partially offset by a decrease of $1.0 million in preclinical costs as a result of the completion of IND-enabling studies in early 2024 and a decrease of $0.8 million in contract manufacturing costs. CT-95 expense of $4.9 million for 2025 primarily represents $3.7 million in clinical costs and $1.2 million in preclinical, contract manufacturing, and diagnostic development expenses incurred. CT-95 expense of $4.9 million for 2024 primarily represents consideration paid of $3.75 million to acquire the asset from Link in July 2024 and approximately $1.1 million in other expenses, the majority of which was $0.6 million of clinical start up costs. CT-202 expense of $15.6 million for 2025 primarily represents $8.7 million in contract manufacturing costs, $4.7 million in preclinical expenses, and a $2.0 million

expense related to achieving a development milestone under the BioAtla License Agreement. CT-202 expense of $11.2 million for 2024 primarily represents the $11.0 million consideration paid under the BioAtla License Agreement entered into in September 2024. Personnel-related costs, which include salaries, benefits and stock-based compensation expense, increased by approximately $3.3 million, primarily due to higher headcount over the prior year as well as termination benefits incurred related to certain employee departures. Other research and development expense increased by approximately $0.1 million, due to allocated expenses as a result of higher headcount over the prior year.

General and Administrative Expenses

General and administrative expenses increased by $0.6 million from $7.2 million for the year ended December 31, 2024 to $7.8 million for the year ended December 31, 2025. The increase was primarily driven by a $0.7 million increase in salaries and personnel-related costs, including share-based compensation, mainly due to higher headcount and compensation adjustments. The increase was partially offset by a decrease in professional fees of $0.1 million.

Interest Income

Interest income increased by approximately $0.2 million for the year ended December 31, 2025 as compared to 2024, primarily due to additional interest earned from higher cash and cash equivalent balances following the Private Placement and other sales of common stock.

Other Income (Expense)

Other income was $0.2 million for the year ended December 31, 2025 as compared to other expense of $1,400 in 2024, primarily due to foreign currency gains in 2025 as a result of exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Liquidity and Capital Resources

Overview

Since our inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception through December 31, 2025, we have funded our operations through the sale of common stock, warrants, convertible debt and convertible preferred stock. As of December 31, 2025, we had $66.0 million in cash and cash equivalents and an accumulated deficit of $130.9 million.

We expect our cash and cash equivalents at December 31, 2025 to fund the estimated duration of the Phase 1a dose escalation portions of our CTIM-76 and CT-95 trials, the estimated expenses to initiate patient enrollment in a first-in-human trial for CT-202, as well as our operations into mid-2027. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

Funding Requirements

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures and various general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our current and any future product candidates that we may pursue;
- the costs of manufacturing our current and any future product candidates for clinical trials and in preparation for regulatory approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our current and any future product candidates that we may pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for our current and any future product candidates for which we receive regulatory approval; and
- revenue, if any, received from commercial sales of our current and any future product candidates, should any of our product candidates receive regulatory approval.

We will need additional funds to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic transactions and/or marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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 acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic transactions or marketing, or distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Year ended December 31,	
	2025	2024
Cash used in operating activities	$ (26,385,380)	$ (14,556,434)
Cash used in investing activities	(2,033,948)	(14,757,316)
Cash (used in) provided by financing activities	(15,268)	109,293,747
Net (decrease) increase in cash and cash equivalents	$ (28,434,596)	$ 79,979,997

Comparison of the Years Ended December 31, 2025 and 2024

Operating Activities

During the year ended December 31, 2025, we used $26.4 million of cash in operating activities. Cash used in operating activities reflected our net loss of $36.1 million, partially offset by a net change in our operating assets and liabilities of $6.3 million, in-process research and development charges of $2.0 million, and non-cash share-based compensation of $1.3 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

During the year ended December 31, 2024, we used $14.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $26.7 million and a net change in our operating assets and liabilities of $3.5 million, partially offset by in-process research and development charges of $14.8 million and non-cash share-based compensation of $0.8 million. The primary uses of cash were to fund our operations related to the development of our current and former product candidates.

Investing Activities

During the year ended December 31, 2025, cash used in investing activities was attributable to a payment of $2.0 million under the BioAtla License Agreement for the achievement of a development milestone for CT-202, and purchases of property and equipment totaling $34,000.

During the year ended December 31, 2024, cash used in investing activities was primarily attributable to a payment of $11.0 million under the BioAtla License Agreement for the development of CT-202 and a one-time payment of $3.75 million made to Link to acquire the assets associated with CT-95.

Financing Activities

During the year ended December 31, 2025, we used approximately $15,000, of cash in financing activities related to the payment of remaining offering costs from the sale of ATM Shares under our ATM Sales Agreement.

During the year ended December 31, 2024, financing activities provided $109.3 million, consisting of net proceeds of $94.8 million from the sale of common stock and Pre-Funded Warrants in the Private Placement, as well as net proceeds of $14.5 million from the sale of common stock under our ATM Sales Agreement..

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid/accrued research and development expenses and share-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.

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements included elsewhere in this Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs include external costs of outside vendors engaged to conduct clinical studies and other research and development activities, acquired in-process research and development, salaries, share-based compensation, and other operational costs related to our research and development activities.

Costs for certain development activities, such as the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, are estimated based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. Although we do not expect our estimates to be materially different from amounts actually incurred, our estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-Based Compensation

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our share-based awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards for which vesting is subject to market or performance conditions.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 7 to our audited consolidated financial statements included elsewhere in this Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our awards granted.

Recent Accounting Pronouncements

See Note 3 to our audited consolidated financial statements found elsewhere in this Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Other exemptions and reduced reporting requirements under the JOBS Act include, without limitation, the requirements for providing an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following October 19, 2026, (ii) in which we have total annual gross revenues of at least $1.235 billion or (iii) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means that we have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months and have filed at least one annual report pursuant to the Exchange Act and (b) either (i) the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We will continue to be a smaller reporting company while either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

Context Therapeutics Inc.
Index To Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of
Context Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Context Therapeutics Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024 and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ CohnReznick LLP

We have served as the Company's auditor since January 2021.

Parsippany, New Jersey
March 23, 2026

Context Therapeutics Inc.
Consolidated Balance Sheets

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 65,995,228	$ 94,429,824
Prepaid expenses and other current assets	2,358,474	3,466,160
Total current assets	68,353,702	97,895,984
Operating lease right-of-use asset	110,410	218,816
Property and equipment, net	29,656	11,959
Total assets	$ 68,493,768	$ 98,126,759
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,532,887	$ 1,452,188
Accrued expenses and other current liabilities	5,375,090	1,188,929
Operating lease liability - current	112,064	107,316
Total current liabilities	8,020,041	2,748,433
Operating lease liabilities - non-current	—	112,064
Total liabilities	8,020,041	2,860,497
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock—$0.001 par value; 200,000,000 shares authorized; 91,879,177 and 89,704,194 issued and outstanding at December 31, 2025 and December 31, 2024, respectively	91,879	89,704
Additional paid-in capital	191,285,157	189,956,252
Accumulated deficit	(130,903,309)	(94,779,694)
Total stockholders' equity	60,473,727	95,266,262
Total liabilities and stockholders' equity	$ 68,493,768	$ 98,126,759

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

Context Therapeutics Inc.
Consolidated Statements of Operations

	Year ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 31,856,252	$ 22,701,335
General and administrative	7,846,379	7,222,565
Loss from operations	(39,702,631)	(29,923,900)
Interest income	3,378,545	3,200,224
Other income (expense)	200,471	(1,428)
Net loss	$ (36,123,615)	$ (26,725,104)
Net loss per common share, basic and diluted	$ (0.38)	$ (0.46)
Weighted average shares outstanding, basic and diluted	95,185,683	58,416,141

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

Context Therapeutics Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2024	15,966,053	$ 15,966	$ 79,909,644	$ (68,054,590)	$ 11,871,020
Share-based compensation expense	—	—	841,867	—	841,867
Sale of common stock and prefunded warrants in private placement, net of offering costs of $5,234,020	59,032,259	59,032	94,699,715	—	94,758,747
Sale of common stock from ATM facility, net of offering costs of $480,268	14,705,882	14,706	14,505,026	—	14,519,732
Net loss	—	—	—	(26,725,104)	(26,725,104)
Balance at December 31, 2024	89,704,194	$ 89,704	$189,956,252	$ (94,779,694)	$ 95,266,262
Exercise of pre-funded warrants from private placement	2,174,983	2,175	(2,175)	—	—
Share-based compensation expense	—	—	1,331,080	—	1,331,080
Net loss	—	—	—	(36,123,615)	(36,123,615)
Balance at December 31, 2025	91,879,177	$ 91,879	$191,285,157	$(130,903,309	$ 60,473,727

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

Context Therapeutics Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (36,123,615)	$ (26,725,104)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development charge	2,000,000	14,750,000
Share-based compensation expense	1,331,080	841,867
Depreciation and amortization expense	16,251	10,881
Reduction in the carrying amount of operating lease right-of-use asset	108,406	41,822
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,107,686	(1,868,776)
Accounts payable	1,095,967	(946,096)
Accrued expenses and other current liabilities	4,186,161	(619,770)
Operating lease liability	(107,316)	(41,258)
Cash used in operating activities	(26,385,380)	(14,556,434)
Cash flows from investing activities:		
Acquired in-process research and development	(2,000,000)	(14,750,000)
Purchase of property and equipment	(33,948)	(7,316)
Cash used in investing activities	(2,033,948)	(14,757,316)
Cash flows from financing activities:		
Proceeds from the sale of common stock and prefunded warrants in private placement, net of offering costs	—	94,758,747
Payment of offering costs from the sale of common stock from ATM facility	(15,268)	—
Proceeds from the sale of common stock from ATM facility, net	—	14,535,000
Cash (used in) provided by financing activities	(15,268)	109,293,747
Net (decrease) increase in cash and cash equivalents	(28,434,596)	79,979,997
Cash and cash equivalents at beginning of year	94,429,824	14,449,827
Cash and cash equivalents at end of year	$ 65,995,228	$ 94,429,824
Supplemental disclosure of non-cash activities:		
Cashless exercise of prefunded warrants from private placement	$ 2,175	$ —
Unpaid offering costs in Accounts payable	$ —	$ 15,268
Right-of-use asset acquired under operating lease	$ —	$ 260,638

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

CONTEXT THERAPEUTICS INC.
Notes to Consolidated Financial Statements

(1) Organization and Description of Business

Context Therapeutics Inc. (the "Company") is a clinical-stage biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies ("bsAb") for solid tumors. The Company's product candidates include CTIM-76, a Claudin 6 ("CLDN6") x CD3 TCE, CT-95, a Mesothelin ("MSLN") x CD3 TCE, and CT-202, a Nectin cell adhesion protein 4 ("Nectin-4") x CD3 TCE.

The Company was organized in April 2015 under the laws of the State of Delaware. The Company is headquartered in Philadelphia, Pennsylvania.

(2) Risks and Liquidity

The Company has incurred losses and negative cash flows from operations since inception and had an accumulated deficit of $130.9 million as of December 31, 2025. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its current or any future product candidates. The Company believes its cash and cash equivalents of $66.0 million as of December 31, 2025 are sufficient to fund its projected operations for a period of at least 12 months from the issuance date of these consolidated financial statements. Substantial additional funding will be needed by the Company to fund its operations and to commercially develop its current and any future product candidates.

Management plans to seek additional capital in the future through a combination of equity offerings, debt financings, collaborations, strategic transactions and/or marketing, distribution or licensing arrangements to carry out the Company's planned development activities. If additional capital is not available when required, the Company may need to delay or curtail its operations until such funding is received. There is no assurance that such financing will be available when needed or on acceptable terms. Various internal and external factors will affect whether and when the Company's current or any future product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's current and any future product candidates, length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management, among others.

(3) Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The consolidated financial statements include the accounts of the Company, Context Therapeutics LLC, Context Biopharma, Inc. and Context Ireland Ltd., the Company's wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private

companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Use of Estimates

The preparation of consolidated 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 contingent liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates and assumptions are periodically reviewed, and the effects of the revisions are reflected in the accompanying consolidated financial statements in the period they are determined to be necessary. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, share-based compensation arrangements, the fair value of warrants, and in recording the prepayments, accruals and associated expense for research and development activities performed for the Company by third parties.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment which consists of the development of clinical and preclinical product candidates for the advancement of therapies to treat solid tumors. The Company's chief operating decision maker ("CODM") is the chief executive officer.

The accounting policies of the Company's segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the Company's segment based on net loss, which is reported on the statements of operations as net loss. The measure of segment assets is reported on the balance sheet as total assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. As such, the CODM uses cash forecast models in deciding how to deploy capital at the Company. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment, along with cash forecast models. The CODM is regularly provided with net loss and consolidated assets, which are reported on the consolidated statements of operations and consolidated balance sheets, respectively.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Operating Expenses:		
CTIM-76	$ 6,843,564	$ 5,581,896
CT-95	4,865,479	4,871,254
CT-202	15,573,393	11,151,496
Personnel-related costs	7,292,550	3,760,439
Professional fees	2,125,628	2,249,207
Share-based compensation	1,331,080	841,867
Other segment items (a)	1,670,937	1,467,741
Loss from operations	(39,702,631)	(29,923,900)
Interest income	3,378,545	3,200,224
Other income (expense)	200,471	(1,428)
Segment and Net loss	$ (36,123,615)	$ (26,725,104)

(a) Other segment items included in Segment loss mainly includes board fees, insurance, facilities and information technology costs.

The Company tracks outsourced development costs and other external research and development costs to specific product candidates on a program-by-program basis. However, it does not track internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents and accounts payable, approximate their fair values given their short-term nature.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have original maturities of three months or less when acquired to be cash equivalents. Cash equivalents consist of amounts invested in money market accounts. At December 31, 2025, the Company's cash and cash equivalent balances exceeded federally insured limits by approximately $65.5 million.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, the costs are recorded as a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of each of December 31, 2025 and December 31, 2024, there was $0.2 million of deferred offering costs included in prepaid expenses and other current assets.

Property and Equipment

Property and equipment consist of office equipment, furniture, and leasehold improvements and are recorded at cost. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. Leasehold improvements are amortized over the shorter of their economic lives or the remaining lease term.

Leases

The Company determines if an arrangement is a lease at inception. Balances recognized related to operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheets. Operating lease right-of-use assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments. The Company recognizes rent expense on a straight-line basis over the lease period and accrues for rent expense incurred but not yet paid.

Acquired In-Process Research and Development Costs

Acquired in-process research and development ("IPR&D") expense consists of payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under FASB ASC Topic 805, *Business Combinations*. Payments for acquired IPR&D as well as future product development milestones are initially treated as the acquisition of an asset but then immediately expensed as there is no future alternative use for the asset. These payments are reflected as a component of research and development expense as an investing activity outflow on the Company's consolidated statements of cash flows due to the nature of the underlying acquisition of an asset. See Note 8 for further discussion.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include external costs of outside vendors engaged to conduct clinical studies and other research and development activities, acquired IPR&D, salaries, share-based compensation, and other operational costs related to the Company's research and development activities.

Costs for certain development activities, such as the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, are estimated based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Share-Based Compensation

The Company measures and recognizes share-based compensation expense for both employee and non-employee awards based on the grant date fair value of the awards. The Company recognizes share-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Company recognizes forfeitures as they occur.

The Company classifies share-based compensation expense in its consolidated statements of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

The Company estimates the fair value of employee and non-employee stock awards as of the date of grant using the Black-Scholes option pricing model. The Company lacks Company-specific historical and implied volatility information. Therefore, management estimates the expected share price volatility based on the historical volatility of a publicly traded set of peer companies in addition to the Company's historical volatility information. Management expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own publicly traded share price. The expected term of the Company's stock awards has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" stock awards. The risk-free interest rate is determined by reference to the yield curve of a zero-coupon U.S. Treasury bond on the date of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, the Company has not taken any uncertain tax position or recorded any reserves, interest or penalties. Interest and penalties related to uncertain tax positions are included within the provision for income tax.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period, including outstanding pre-funded warrants to purchase shares of common stock that were issued in the private placement transaction in May 2024 (Note 6). Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as preferred stock, warrants (excluding pre-funded warrants) and share-based awards, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares of common stock outstanding, as they would be anti-dilutive:

	December 31,	
	2025	2024
Stock options	5,868,500	3,273,615
Warrants	5,860,000	5,860,000
	11,728,500	9,133,615

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands the disclosures required for income taxes. This ASU is effective for fiscal years

beginning after December 15, 2024, with early adoption permitted. The Company's adoption of this pronouncement did not have a material effect on the Company's disclosures.

Recently Issued but Not yet Adopted Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*. ASU 2024-03 requires additional disclosure of specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its disclosures.

(4) Fair Value Measurements

The Company utilizes a valuation hierarchy that prioritizes fair value measurements based on the types of inputs used for the various valuation techniques related to its financial assets and financial liabilities. The three levels of inputs used to measure fair value are described as follows:

Level 1 – Observable inputs such as quoted prices in active markets.

Level 2 – Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3 – Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In accordance with the fair value hierarchy described above, the following table sets forth the Company's assets and liabilities measured at fair value on a recurring basis:

	December 31, 2025			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents (Money Market Accounts)	$ 65,523,204	$ 65,523,204	$ —	$ —

	December 31, 2024			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents (Money Market Accounts)	$ 93,949,553	$ 93,949,553	$ —	$ —

(5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2025	2024
Compensation and benefits	$ 1,384,430	$ 891,917
Research and development costs	3,913,168	229,908
Professional fees	38,524	17,325
Other	38,968	49,779
Total	$ 5,375,090	$ 1,188,929

(6) Stockholders' Equity

Increase to Authorized Shares

On September 17, 2024, the Company held a Special Meeting of Stockholders (the "Special Meeting"). At the Special Meeting, the Company's stockholders approved, among other things, an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100,000,000 to 200,000,000.

Private Placement

On May 1, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") for the private placement (the "Private Placement") of (i) 59,032,259 shares (the "PIPE Shares") of the Company's common stock at a purchase price of $1.55 per PIPE Share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase 5,482,741 shares of common stock at a purchase price of $1.549 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. During the year ended December 31, 2025, 2,178,200 Pre-Funded Warrants were exercised on a cashless basis, resulting in the issuance of 2,174,983 shares of common stock. As of December 31, 2025, 3,304,541 Pre-Funded Warrants remained outstanding. The aggregate gross proceeds for the Private Placement were approximately $100 million, before deducting offering expenses of approximately $5.2 million, and the Private Placement closed on May 6, 2024.

At-the-Market Facility

On December 2, 2024, the Company entered into a Sales Agreement (the "ATM Sales Agreement") with Leerink Partners LLC (the "Agent"). Pursuant to the terms of the ATM Sales Agreement, the Company may offer and sell shares of the Company's common stock (the "ATM Shares"), having an aggregate offering amount of up to $75.0 million from time to time through the Agent. Sales of the ATM Shares may be made in sales deemed to be an "at-the-market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. On December 23, 2024, the Company sold 14,705,882 shares of its common stock under the ATM Sales Agreement for net proceeds of approximately $14.5 million. On October 24, 2025, the Company entered into Amendment No. 1 to Sales Agreement (the "Amendment", and together with the ATM Sales Agreement, the "Amended ATM Sales Agreement") to provide for an increase in the aggregate offering amount under the Amended ATM Sales Agreement, such that following the filing of a new prospectus supplement with respect to the ATM Shares on

October 24, 2025, the Company may offer and sell ATM Shares having an aggregate offering price of up to $75.0 million, exclusive of ATM Shares previously sold in December 2024.

Warrants for Common Stock

At December 31, 2025, the Company had the following warrants outstanding to acquire common stock:

	Outstanding	Exercise price	Expiration dates
Issued in connection with 2021 initial public offering	250,000	$ 6.25	October 2026
Issued in connection with 2021 private placement	5,250,000	$ 6.25	June 2027
Issued in 2022 for consulting services	360,000	$ 10.00	December 2027
Issued in connection with 2024 private placement	3,304,541	$ 0.001	No expiration
	9,164,541		

(7) Share-Based Compensation

In April 2021, the Company adopted the 2021 Long-Term Performance Incentive Plan ("2021 Incentive Plan"). Under the 2021 Incentive Plan, the Company can grant stock options, stock appreciation rights, restricted stock, restricted stock units ("RSUs") and stock grants. On its initial effective date, the 2021 Incentive Plan allowed for the issuance of up to 1,266,092 shares of common stock (the "Share Limit"). The Share Limit automatically increases on January 1st of each year, during the term of the 2021 Incentive Plan, commencing on January 1 of the year following the year in which the effective date occurs, in an amount equal to four percent (4%) of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year; provided that the board of directors may determine that there will be no such increase or a smaller increase for any particular year. As of December 31, 2025, 1,322,222 shares remained available for future grants.

In addition, from time to time, the Company makes inducement grants of stock options to new hires, which awards are made pursuant to the Nasdaq's inducement grant exception to the shareholder approval requirement for grants of equity compensation. During the year ended December 31, 2025, the Company granted inducement stock options covering 389,000 shares of the Company's common stock to new employees.

Share-based awards generally vest over a period of one year to four years, and share-based awards that lapse or are forfeited are available to be granted again. The contractual life of all share-based awards is 10 years. The expiration dates of the outstanding share-based awards range from January 2028 to October 2035.

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the service period of the awards. Share-based compensation is allocated to employees and consultants based on their respective departments. All board of directors' compensation is charged to general and administrative expense.

Share-based compensation expense related to the issuance of stock options was as follows for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Research and development	$ 235,779	$ 61,121
General and administrative	1,095,301	780,746
	$ 1,331,080	$ 841,867

The weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option awards granted during 2025 and 2024 were as follows:

	2025	2024
Expected stock price volatility	111.98%	95.54%
Expected term (in years)	5.94	6.00
Risk-free interest rate	4.29%	4.13%
Expected dividend yield	—	—

As the Company began trading publicly in October 2021, there is a lack of Company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to the Company's historical volatility information. Additionally, due to an insufficient history with respect to stock option activity and post-vesting cancellations, the expected term assumption for employee grants is based on a permitted simplified method, which is based on the vesting period and contractual term for each tranche of awards. The mid-point between the weighted-average vesting term and the expiration date is used as the expected term under this method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table summarizes the share-based award activity for the periods presented:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2025	3,273,615	$ 1.97	8.2	$ 176,045
Granted	3,284,660	$ 0.77		
Forfeited	(689,775)	$ 1.73		
Outstanding at December 31, 2025	5,868,500	$ 1.33	8.2	$ 2,941,679
Vested and exercisable at December 31, 2025	2,144,441	$ 2.19	6.8	$ 512,287
Vested and expected to vest at December 31, 2025	5,868,500	$ 1.33	8.2	$ 2,941,679

The aggregate intrinsic value in the above table is calculated as the difference between the fair market value of the Company’s common stock price and the exercise price of the stock options. The weighted average fair value of share-based awards granted during the years ended December 31, 2025 and 2024 was $0.65 and $1.19, respectively. As of December 31, 2025, the unrecognized compensation cost related to outstanding share-based awards was $2.0 million and is expected to be recognized as expense over a weighted-average period of approximately 2.6 years.

(8) Commitments and Contingencies, including License Agreements

Operating Leases

In March 2024, the Company amended its lease for corporate office space in Philadelphia, Pennsylvania that it initially entered into in March 2023, in order to extend the expiration date to November 30, 2024. In July 2024, the Company further amended the lease, which is now set to expire on November 30, 2026, thus making the arrangement no longer qualify for the short-term lease exception under ASC 842. The Company also retains the right to renew the lease for up to two consecutive 12-month terms upon at least nine months advance notice to the

landlord before any such successive renewal. These renewal options were not contemplated in the Company's calculation of its right of use asset and lease liability. See Note 10 for further discussion.

As of December 31, 2025, the operating lease right-of-use asset and the operating lease liabilities were each approximately $0.1 million, which were estimated using a discount rate of 11%. As of December 31, 2025, the remaining term of the Company's noncancellable operating lease was 0.92 years. Future minimum lease payments under the lease are $0.1 million at December 31, 2025.

The Company recognizes rent expense on a straight-line basis over the lease period and accrues for rent expense incurred but not yet paid. Rent expense related to the Company's operating lease was approximately $126,000 and $125,000 for the years ended December 31, 2025 and 2024, respectively.

Employee Benefit Plans

The Company established a defined contribution 401(k) plan in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company contributes a safe harbor minimum contribution equivalent to 3% of employees' compensation. For the years ended December 31, 2025 and 2024, the Company provided contributions of approximately $108,000 and $60,000, respectively.

Collaboration Agreement with Tyligand Bioscience

In March 2020, the Company entered into a process development agreement (the "Tyligand Process Development Agreement") with Tyligand Bioscience (Shanghai) Limited ("Tyligand") for the development, manufacturing, registration and future commercialization of onapristone extended release. In August 2024, the Company and Tyligand mutually agreed to terminate the license agreement previously entered into between the parties in August 2021, and further agreed to terminate any ongoing payment obligations the Company may have had to Tyligand under the Tyligand Process Development Agreement.

Collaboration and Licensing Agreement with Integral Molecular

In April 2021, the Company entered into a collaboration and licensing agreement with Integral Molecular, Inc. ("Integral") (the "Integral License Agreement") for the development of a CLDN6 bsAb for cancer therapy. Under the terms of the Integral License Agreement, Integral and the Company developed a CLDN6 bsAb that is intended to trigger the activation of T cells and eliminate cancer cells displaying CLDN6. The Company will conduct preclinical and all clinical development, as well as regulatory and commercial activities through exclusive worldwide rights to develop and commercialize the novel CLDN6 candidates. The payment for the initial upfront license fee as well as subsequent payments for milestones achieved were expensed to acquired IPR&D. As a part of the Integral License Agreement, Integral was eligible to receive remaining development and regulatory milestone payments totaling approximately $55.0 million, sales milestone payments totaling up to $130.0 million, and tiered royalties of up to 12% of net sales of certain products developed under the Integral License Agreement.

On March 20, 2023, the Company amended the Integral License Agreement (the "First Amendment") to remove the previously agreed to second milestone payment and to change the amount of the third milestone payment to increase such payment by the amount of the prior second milestone payment and to add payment for third-party research funding obtained and used by Integral in connection with the development of CTIM-76.

On February 29, 2024, the Company further amended the Integral License Agreement (the "Second Amendment") to reflect updated financial terms. Integral's right to receive certain future payments was reduced as follows: aggregate development and regulatory milestone payments were reduced from $55 million to $15 million, aggregate sales milestone payments were reduced from $130 million to $12.5 million, and a tiered royalty of 8-12% that commenced at first commercial sale was reduced to a flat royalty rate of 6% on net sales beginning no sooner than February 1, 2034. The Second Amendment also narrowed the license grant from Integral to the Company to only cover CTIM-76, removed any further obligation to reimburse Integral for any independently obtained research funding Integral applied against CTIM-76 research, and included mutual releases by the parties.

Asset Purchase Agreement

On July 9, 2024, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") pursuant to which the Company acquired CT-95 (formerly known as LNK-101), an MSLN x CD3 TCE bsAb, from Link (assignment for the benefit of creditors), LLC ("Link"), which succeeded to the assets of Link Immunotherapeutics Inc.

Pursuant to the Asset Purchase Agreement, the Company purchased all of the assets from Link associated with CT-95, including patent rights, know-how, regulatory filings, and inventory of drug substance and drug product (the "Transferred Assets"), on an "as is" and "where is" basis. CT-95 patents are currently being prosecuted and/or maintained in the United States, Europe, Canada, Australia, Taiwan and Japan. The Company also assumed certain liabilities relating to the Transferred Assets. In consideration of the purchase of the Transferred Assets, the Company made a one-time payment to Link of $3.75 million and is not obligated to make any other payments. This transaction qualified as an asset purchase as prescribed by ASC 805-50 and the assets purchased were determined to have no alternative future use under the accounting definition, and therefore the Company expensed the one-time payment as a component of research and development expense in the consolidated statements of operations for the year ended December 31, 2024.

Collaboration and Licensing Agreement with BioAtla

On September 23, 2024, the Company entered into a license agreement (the "BioAtla License Agreement") with BioAtla, Inc. ("BioAtla"), pursuant to which the Company obtained an exclusive, worldwide license to develop, manufacture and commercialize two licensed antibodies (the "BioAtla Assets"), including BA3362 (renamed by the Company as CT-202), BioAtla's Nectin-4 x CD3 T cell engaging bispecific antibody.

As partial consideration for the exclusive license under the BioAtla License Agreement, the Company made an upfront payment of $11.0 million for the IPR&D asset, which was determined to have no alternative future use under the accounting definition. Therefore, the upfront payment was expensed as a component of research and development expense in the consolidated statements of operations for the year ended December 31, 2024. The Company may be obligated to pay up to $122.5 million in additional milestone payments based upon the achievement of specified pre-clinical, clinical, development and commercial milestones, as well as tiered mid-single digit to low double-digit royalties on future net sales for products containing the BioAtla Assets, subject to standard reductions. In October 2025, the Company achieved a $2.0 million development milestone under the BioAtla License Agreement which was expensed as a component of research and development expense in the consolidated statements of operations for the year ended December 31, 2025. The BioAtla License Agreement will continue on a country-by-country, product-by-product basis until the expiration of the royalty term as defined in the BioAtla License Agreement, unless earlier terminated.

CTIM-76 and CT-202 Lonza License Agreements

The Company has obtained active pharmaceutical ingredients and drug product for its product candidates from several third-party contract manufacturers, including Lonza Sales AG ("Lonza Sales") and Lonza AG ("Lonza AG", and collectively with Lonza Sales, "Lonza").

On November 7, 2022, the Company entered into a license agreement (the "Lonza CTIM-76 License Agreement") with Lonza Sales in connection with Lonza's development and manufacturing services with respect to CTIM-76. Under the terms of the Lonza CTIM-76 License Agreement, to the extent Lonza's technology is incorporated into CTIM-76, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit CTIM-76.

On November 3, 2025, the Company entered into a license agreement (the "Lonza CT-202 License Agreement") with Lonza Sales in connection with Lonza's development and manufacturing services with respect to CT-202. Under the terms of the Lonza CT-202 License Agreement, to the extent Lonza's technology is incorporated into CT-202, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit CT-202.

The Company shall pay certain royalties and annual payments to Lonza under the applicable license agreement with respect to the manufacturing and sale of CTIM-76 or CT-202, as applicable, which amounts shall be

determined by the party manufacturing CTIM-76 or CT-202, as applicable, and ranges from a potential annual payment of up to less than $500,000 per asset and a royalty per asset on net sales from 0% up to a low single digit percentage. Under each respective license agreement, the royalty payments and annual payments would be reduced per asset in certain circumstances, including should the valid claims for any such patent rights not exist in the country in which CTIM-76 or CT-202, as applicable, is being sold, and the royalty payments per asset would expire upon the later of the expiration of the licensed patents in the country in which CTIM-76 or CT-202, as applicable, is being sold, the expiration of the licensed patents in the country in which CTIM-76 or CT-202, as applicable, is being manufactured, and 10 years from the first commercial sales of CTIM-76 or CT-202, as applicable, in such country of sale.

The Lonza CTIM-76 License Agreement and the Lonza CT-202 License Agreement each continue until respectively terminated. The Company or Lonza may terminate either the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement, as applicable, for uncured material breaches or insolvency of the other party. The Company can unilaterally terminate the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza CTIM-76 License Agreement or the Lonza CT-202 License Agreement upon certain actions by the Company.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with investigative sites and contract research organizations to assist in the performance of research and development activities and contract manufacturers to assist with chemistry, manufacturing, and controls-related expenses. Expenditures to contract research organizations represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of cash.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company believes no matters at either December 31, 2025 or 2024 that will have a material impact to the Company's financial position, results of operations or cash flows. See Note 10 for further discussion.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by applicable law. The Company currently has directors and officers insurance. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

(9) Income Taxes

The Company is a corporation and is subject to federal, state and local corporate income taxes which have been provided for in the consolidated financial statements based upon ASC 740. Context BioPharma, Inc. has always been subject to corporate income taxes.

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2025 and 2024. The Company had also not recorded any income tax benefits for the net operating losses incurred in

each period due to its uncertainty of realizing a benefit from those items. All of the Company's losses before income taxes were generated in the United States.

In July 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law. The OBBBA makes the following changes to the U.S. tax code: restores bonus depreciation to 100% for all qualified assets placed in service after January 19, 2025, allows for the option to expense all domestic research and experimental expenditures for tax years beginning after December 31, 2024, allows for the option to recaptures all unamortized domestic research and experimental expenditures from prior years, changes the adjusted taxable income formula for interest expense limitation to include depreciation and amortization expense. The provisions of the OBBBA became effective for the Company during the year ended December 31, 2025.

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets and liabilities were as follows:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 12,079,779	$ 9,318,875
Research and development credits	2,525,197	1,765,100
Capitalized research and development Section 174 expense	15,145,882	8,268,682
Share-based compensation	1,485,127	1,094,621
Amortization	4,514,521	4,258,804
Other accruals	431,201	299,517
Gross deferred tax assets	36,181,707	25,005,599
Deferred tax liabilities:		
Prepaid expenses	(271,578)	(243,408)
Property and equipment	(8,229)	(2,799)
Net deferred tax assets	35,901,900	24,759,392
Less: valuation allowance	(35,901,900)	(24,759,392)
	$ —	$ —

In assessing the need for a valuation allowance, management must determine that there will be sufficient taxable income to allow for the realization of deferred tax assets. Based upon the historical and anticipated future losses, management has determined that the deferred tax assets do not meet the more likely than not threshold for realizability. Accordingly, a full valuation allowance has been recorded against the Company's net deferred tax assets as of December 31, 2025 and 2024. The valuation allowance increased by $11.1 million and $8.2 million during the years ended December 31, 2025 and 2024, respectively.

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,			
	2025		2024	
Federal income tax benefit at statutory rate	$ (7,584,636)	21.0 %	$ (5,611,510)	21.0 %
State income tax, net of federal benefit (a)	(2,827,095)	7.8	(2,011,315)	7.5
Research and development credit	(760,097)	2.1	(533,785)	2.0
Change in valuation allowance	11,171,828	(30.9)	8,156,610	(30.5)
Effective income tax rate	$ —	— %	$ —	— %

(a) State taxes in Pennsylvania, Massachusetts and Philadelphia made up the majority (greater than 50 percent) of the tax effect in this category for 2025 and 2024.

The following table summarizes carryforwards of federal, state and local net operating losses ("NOL") and research tax credits:

	December 31,	
	2025	2024
NOL carryforwards—Federal	$ 44,031,473	$ 33,850,215
NOL carryforwards—State	44,413,810	33,934,258
NOL carryforwards—Local	23,792,092	18,967,829
Research tax credits—Federal	2,525,197	1,765,100

The NOL carryforwards begin expiring in 2037 for federal and state income tax purposes; however, all federal NOL carryforwards generated subsequent to January 1, 2018 are able to be carried forward indefinitely. Local NOL carryforwards expire after three years with the 2023 NOL set to expire in 2026. As of December 31, 2025 and 2024, the Company had federal research and development tax credit carryforwards of $2.5 million and $1.8 million, respectively, that will begin to expire in 2037, unless previously utilized.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. To date, the Company has not performed an analysis to determine whether or not ownership changes have occurred since inception. State and local NOLs may also be limited.

As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations. Due to NOLs and tax credit carryforwards that remain unutilized, income tax returns for tax years from all years remain subject to examination by the taxing jurisdictions. The NOL carryforwards remain subject to review until utilized.

(10) Subsequent Events

In January 2026, the Company further amended its lease for corporate office space in Philadelphia, Pennsylvania that it initially entered into in March 2023 in order to obtain additional office space and to renew the lease for one additional successive one-year period that expires on November 30, 2026. The Company also retains

the right to renew the lease for and additional 12-month term upon at least nine months advance notice to the landlord, including the right to remove the additional office space from that renewal.

On February 4, 2026, the Vladimir Gusinsky Revocable Trust filed a stockholder class action complaint (the "Action") against the Company and its directors in the Court of Chancery of the State of Delaware (the "Court") asserting that (i) Article V, Section 2 of the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), provides for a full term of three years for directors in violation of Section 211(b) of the General Corporation Law of the State of Delaware (the "DGCL") and (ii) Article VI, Section 1 of the Certificate of Incorporation limits removal of directors only for cause in violation of Section 141(k) of the DGCL.

On February 24, 2026, a stipulation and proposed consent judgment (the "Stipulated Judgment") was filed with the Court regarding the Action, and on March 11, 2026, the Court approved the Stipulated Judgment, pursuant to which Article V, Section 2 and Article VI, Section 1 of the Certificate of Incorporation were determined to be invalid and unenforceable. On March 11, 2026, the Company filed a Certificate of Correction with the Delaware Secretary of State reflecting such provisions as invalid, unenforceable and no longer part of the Certificate of Incorporation. Accordingly, the term of office of the current members of the Company's Board of Directors will expire at the Company's 2026 annual meeting of stockholders, with each serving until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. In addition, directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors.

On March 11, 2026, pursuant to the Stipulated Judgment, the Action was dismissed with prejudice with respect to the plaintiff; however, the Court retains jurisdiction to address any mootness fee application.

The Company does not believe this matter will have a material impact on its financial position, results of operations or cash flows.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of our Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

As of December 31, 2025, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013). Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on those criteria.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption provided by the JOBS Act for emerging growth companies.

Changes in Internal Control Over Financial Reporting

There has been no change 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 December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in the SEC's rules).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, under the captions "*Information regarding Committees of the Board of Directors,*" "*Information regarding the Board of Directors and Corporate Governance,*" "*Executive Officers*" and "*Delinquent Section 16(a) Reports.*"

As part of our system of corporate governance, our board of directors has adopted a code of business conduct and ethics. The code applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), contractors, consultants and agents and representatives, including our independent directors and consultants, who are not employees of ours, with regard to their Company-related activities. Our code of business conduct and ethics is available on our website at www.contexttherapeutics.com within the "Investors & News — Governance" section. We intend to post on this section of our website any amendment to our code of business conduct and ethics, as well as any waivers of our code of business conduct and ethics, that are required to be disclosed by the rules of the SEC or The Nasdaq Stock Market.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, under the captions "*Executive Compensation*" and "*Director Compensation*."

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

The information required by this item is incorporated by reference to our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, under the captions "*Equity Compensation Plan Information*" and "*Security Ownership of Certain Beneficial Owners and Management.*"

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

The information required by this item is incorporated by reference to our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, under the captions "*Transactions with Related Persons*" and "*Director Compensation.*"

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, under the caption "*Proposal 2–Ratification of Selection of Independent Registered Public Accounting Firm."*

PART IV.

Item 15. Exhibits and Financial Statement Schedules

We have filed the following documents as part of this Annual Report:

(a)(1) Financial Statements

The financial statements are included in Item 8. “Financial Statements and Supplementary Data.”

(a)(2) Financial Statement Schedules

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) The exhibits listed under Item 15(b), which are incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

(b) Exhibits.

Exhibit No.	Description of Exhibit
3.1*	Amended & Restated Certificate of Incorporation of Context Therapeutics Inc. as amended through March 11, 2026.
3.2	Certificate of Correction to the Amended and Restated Certificate of Incorporation, dated March 11, 2026 (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on March 13, 2026).
3.3	Amended & Restated Bylaws of Context Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 21, 2024).
4.1	Form of Stock Certificate of Common Stock (incorporated by reference to Exhibit 4.1 to the Company’s Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on May 2, 2024).
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company’s Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on December 2, 2021).
4.4*	Description of Securities of Context Therapeutics Inc.
10.1#	Research Collaboration and License Agreement, dated April 6, 2021, between Context Therapeutics LLC and Integral Molecular, Inc. (incorporated by reference to Exhibit 10.1 to the Company’s Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
10.2#	Amendment No. 1, dated March 20, 2023, to that certain Research Collaboration and License Agreement, dated April 6, 2021, between Context Therapeutics LLC and Integral Molecular, Inc. (incorporated by reference to Exhibit 10.23 to the Company’s Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 22, 2023).
10.3#	Amendment No. 2, dated February 29, 2024, to that certain Research Collaboration and License Agreement, dated April 6, 2021, between Context Therapeutics LLC and Integral Molecular, Inc. (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on March 6, 2024).
10.4†	Context Therapeutics LLC 2015 Option Plan (incorporated by reference to Exhibit 10.5 to the Company’s Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).

Exhibit No.	Description of Exhibit
10.5†	Context Therapeutics Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
10.6†	Form of Stock Option Agreement under the Context Therapeutics Inc. 2021 Incentive Award Plan (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
10.7†	Form of Stock Grant Agreement under the Context Therapeutics Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
10.8†	Form of Indemnification Agreement between Context Therapeutics Inc. and its officers and directors (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A (File No. 333-256572), as filed with the SEC on June 16, 2021).
10.9†	Amended and Restated Employment Agreement, dated October 22, 2021, between Context Therapeutics Inc. and Martin Lehr (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 22, 2021).
10.10†	Employment Agreement, dated November 1, 2021, between Context Therapeutics Inc. and Jennifer Minai-Azary (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on November 1, 2021).
10.11†	Employment Agreement, dated October 22, 2021, between Context Therapeutics Inc. and Alex Levit (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 23, 2022).
10.12†	Employment Agreement, dated June 9, 2025, between Context Therapeutics Inc. and Karen Chagin, M.D. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on August 6, 2025).
10.13	Registration Rights Agreement, dated December 1, 2021, by and between Context Therapeutics Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on December 2, 2021).
10.14#	Development and Manufacturing Services Agreement, dated November 7, 2022, between Lonza Sales AG, Lonza AG and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on November 9, 2022).
10.15#	First Amendment to the Development and Manufacturing Services Agreement, dated January 9, 2025, between Lonza Sales AG, Lonza AG and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 20, 2025).
10.16#	License Agreement, dated November 7, 2022, between Lonza Sales AG and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on November 9, 2022).
10.17#	Amendment No. 1 to License Agreement, dated November 3, 2025, between Lonza Sales AG and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on November 5, 2025).
10.18#	License Agreement, dated November 3, 2025, between Lonza Sales AG and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on November 5, 2025).
10.19	Registration Rights Agreement, dated May 1, 2024, by and between the Company and the Purchasers named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on May 2, 2024).
10.20#	Master Services Agreement, dated October 8, 2021, by and between Link Immunotherapeutics, Inc. and Just - Evotec Biologics, Inc. (as assigned to the Company on July 9, 2024) (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 20, 2025).

Exhibit No.	Description of Exhibit
10.21#	Asset Purchase Agreement, dated July 9, 2024, by and between Company and Link (assignment for the benefit of creditors), LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on July 10, 2024).
10.22†	Form of Stock Option Agreement (Inducement Grant) of Context Therapeutics Inc. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on August 7, 2024).
10.23†	Form of Stock Option Agreement under the Context Therapeutics Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on August 7, 2024).
10.24#	License Agreement, dated September 23, 2024, by and between the Company and BioAtla, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on September 23, 2024).
10.25	Sales Agreement, dated as of December 2, 2024, by and between Context Therapeutics Inc. and Leerink Partners LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on December 2, 2024).
10.26	Amendment No. 1 to Sales Agreement, dated as of October 24, 2025, by and between Context Therapeutics Inc. and Leerink Partners LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 24, 2025).
19	Context Therapeutics Inc. Insider Trading Policy (incorporated by reference to Exhibit 19 to the Company's Annual Report on Form 10-K (File No. 001-40654), as filed with the SEC on March 20, 2025).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).
23.1*	Consent of CohnReznick LLP.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1*+	Certification pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.
97	Context Therapeutics Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K, as filed with the SEC on March 21, 2024).
101	The following financial statements from Context Therapeutics Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2025, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; (v) Notes to the Consolidated Financial Statements and (vi) information regarding trading arrangements set forth in Part II, Item 9B.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith

† Executive Compensation Plan or Agreement

Certain information has been excluded from the exhibit because it both (i) is not material and (ii) is the type that the registrant treats as private or confidential.

+ This certification is being furnished pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CONTEXT THERAPEUTICS INC.

By: /s/ Martin Lehr
Martin Lehr
Chief Executive Officer

March 23, 2026

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

SIGNATURE	TITLE	DATE
/s/ Martin Lehr Martin Lehr	Chief Executive Officer and Director (*Principal Executive Officer*)	March 23, 2026
/s/ Jennifer Minai-Azary Jennifer Minai-Azary	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 23, 2026
/s/ Andy Pasternak Andy Pasternak	Chairman of the Board and Director	March 23, 2026
/s/ Philip Kantoff Philip Kantoff	Director	March 23, 2026
/s/ Karen Smith Karen Smith	Director	March 23, 2026
/s/ Jennifer Evans Stacey Jennifer Evans Stacey	Director	March 23, 2026
/s/ Luke Walker Luke Walker	Director	March 23, 2026
/s/ Linda West Linda West	Director	March 23, 2026