UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2024

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

For the transition period from _____ to _____.

Commission file number: 001-40654

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 code)

(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

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 and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

The number of shares of common stock outstanding at November 4, 2024 was 74,998,312 shares.

INDEX TO FORM 10-Q

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

Trademark Notice

Context Therapeutics® is a trademark of ours in the United States. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes "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. 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 any other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the periods during which the data and 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 applications and final U.S. Food and Drug Administration (“FDA”) approval 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 any other product candidates we may develop, our ability to obtain extensions of existing patent terms, 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 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, as well as research and development activities;
- 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 any 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 any 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;
- 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”;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. 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-Q. 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.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the reports that we file with the U.S. Securities and Exchange Commission (“SEC”).

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Market, Industry and Other Data

This Form 10-Q may contain estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning markets for CTIM-76, our Claudin 6 (“CLDN6”) x CD3 bispecific antibody (“bsAb”), CT-95, our Mesothelin (“MSLN”) x CD3 bsAb, and CT-202, our Nectin cell adhesion protein 4 (“Nectin-4”) x CD3 bsAb. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to

uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances reflected in this information. As a result, you are cautioned not to give undue weight to such information.

This Form 10-Q also may contain certain data and information, which we obtained from various government and private publications. Although we believe that the publications and reports are reliable, we have not independently verified the data. Statistical data in these publications include 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.

Part I - Financial Information

Item 1. Financial Statements

Context Therapeutics Inc.
Condensed Consolidated Balance Sheets

	September 30, 2024 (Unaudited)	December 31, 2023 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 84,801,556	$ 14,449,827
Prepaid expenses and other current assets	1,269,265	1,597,384
Total current assets	86,070,821	16,047,211
Property and equipment, net	14,893	15,524
Operating lease right-of-use lease assets	244,135	—
Total assets	$ 86,329,849	$ 16,062,735
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,028,667	$ 2,383,016
Accrued expenses and other current liabilities	1,199,205	1,808,699
Operating lease liabilities - current	104,160	—
Total current liabilities	2,332,032	4,191,715
Operating lease liabilities - non-current	140,200	—
Total liabilities	2,472,232	4,191,715
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 and 100,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 74,998,312 and 15,966,053 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	74,998	15,966
Additional paid-in capital	175,219,405	79,909,644
Accumulated deficit	(91,436,786)	(68,054,590)
Total stockholders' equity	83,857,617	11,871,020
Total liabilities and stockholders' equity	$ 86,329,849	$ 16,062,735

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

Context Therapeutics Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 16,825,198	$ 4,485,223	$ 20,182,960	$ 12,480,836
General and administrative	1,876,230	1,695,272	5,430,518	5,658,575
Loss from operations	(18,701,428)	(6,180,495)	(25,613,478)	(18,139,411)
Interest income	1,243,687	290,440	2,236,188	939,256
Other (expense) income	(2,152)	15,369	(4,906)	5,830
Net loss	$ (17,459,893)	$ (5,874,686)	$ (23,382,196)	$ (17,194,325)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.37)	$ (0.46)	$ (1.08)
Weighted average shares outstanding, basic and diluted	80,481,053	15,966,053	50,578,115	15,966,053

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

Context Therapeutics Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Nine Months Ended September 30, 2024				
	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	—	—	240,007	—	240,007
Net loss	—	—	—	(3,667,797)	(3,667,797)
Balance at March 31, 2024	15,966,053	15,966	80,149,651	(71,722,387)	8,443,230
Sale of common stock and prefunded warrants, net of offering costs of $5,234,020	59,032,259	59,032	94,699,715	—	94,758,747
Share-based compensation expense	—	—	157,037	—	157,037
Net loss	—	—	—	(2,254,506)	(2,254,506)
Balance at June 30, 2024	74,998,312	74,998	175,006,403	(73,976,893)	101,104,508
Share-based compensation expense	—	—	213,002	—	213,002
Net loss	—	—	—	(17,459,893)	(17,459,893)
Balance at September 30, 2024	74,998,312	$ 74,998	$ 175,219,405	$ (91,436,786)	$ 83,857,617

	Nine Months Ended September 30, 2023				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2023	15,966,053	$ 15,966	$ 78,832,779	$ (44,090,379)	$ 34,758,366
Share-based compensation expense	—	—	282,762	—	282,762
Net loss	—	—	—	(6,308,318)	(6,308,318)
Balance at March 31, 2023	15,966,053	15,966	79,115,541	(50,398,697)	28,732,810
Share-based compensation expense	—	—	283,103	—	283,103
Net loss	—	—	—	(5,011,321)	(5,011,321)
Balance at June 30, 2023	15,966,053	15,966	79,398,644	(55,410,018)	24,004,592
Share-based compensation expense	—	—	254,949	—	254,949
Net loss	—	—	—	(5,874,686)	(5,874,686)
Balance at September 30, 2023	15,966,053	$ 15,966	$ 79,653,593	$ (61,284,704)	$ 18,384,855

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

Context Therapeutics Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (23,382,196)	$ (17,194,325)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development charge	14,750,000	—
Share-based compensation expense	610,046	820,814
Depreciation and amortization expense	7,947	9,476
Reduction in the carrying amount of operating lease right-of-use asset	16,503	51,967
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	328,119	1,062,681
Other assets	—	32,750
Accounts payable	(1,354,349)	891,478
Accrued expenses and other current liabilities	(609,494)	559,791
Operating lease liability	(16,278)	(55,078)
Cash used in operating activities	(9,649,702)	(13,820,446)
Cash flows from investing activities:		
Acquired in-process research and development	(14,750,000)	—
Purchase of property and equipment	(7,316)	—
Cash used in investing activities	(14,757,316)	—
Cash flows from financing activities:		
Proceeds from the sale of common stock and prefunded warrants, net	94,758,747	—
Cash provided by financing activities	94,758,747	—
Net increase (decrease) in cash and cash equivalents	70,351,729	(13,820,446)
Cash and cash equivalents at beginning of period	14,449,827	35,497,445
Cash and cash equivalents at end of period	$ 84,801,556	$ 21,676,999
Supplemental disclosure of non-cash activities:		
Right-of-use asset obtained in exchange for lease obligation	$ 260,638	$ —

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

CONTEXT THERAPEUTICS INC.
Notes to Unaudited Condensed Consolidated Financial Statements

(1) Organization and Description of Business

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

The Company had also been developing onapristone extended release ("ONA-XR"). However, in March 2023, the Company announced its plan to discontinue the development of this product candidate and focus its efforts on the development of CTIM-76. All estimated close-out costs associated with the ONA-XR program were recognized in research and development expense during the first quarter of 2023. The Company does not expect to incur future expenses related to this program.

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 $91.4 million as of September 30, 2024. 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 $84.8 million as of September 30, 2024 are sufficient to fund its projected operations for a period of at least 12 months from the issuance date of these unaudited condensed 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 unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading. 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").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the unaudited condensed consolidated

financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2024, and its results of operations and cash flows for the three and nine months ended September 30, 2024 and 2023. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. The unaudited condensed consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2023. The consolidated financial information as of December 31, 2023 included herein has been derived from the annual audited consolidated financial statements.

The unaudited condensed 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.

Use of Estimates

The preparation of the unaudited condensed 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 unaudited condensed 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 unaudited condensed consolidated financial statements in the period they are determined to be necessary. Significant estimates and assumptions made in the accompanying unaudited condensed 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.

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 September 30, 2024, the Company's cash and cash equivalent balances exceeded federally insured limits by approximately $84.3 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 condensed consolidated statements of operations.

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 condensed 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 the 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 under the accounting guidance for the asset. These payments are reflected as a component of research and development expense as well as an investing activity outflow on the Company's condensed 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 unaudited condensed 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 condensed 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 and 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.

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 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 convertible promissory notes, 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:

	September 30,	
	2024	2023
Stock options	3,259,615	2,238,609
Warrants	5,860,000	5,860,000
	9,119,615	8,098,609

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 unaudited condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Issued but Not yet Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is currently evaluating the effect of this pronouncement on its disclosures.

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 amendment should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the effect of this pronouncement 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:

	September 30, 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)	$ 84,304,470	$ 84,304,470	$ —	$ —

	December 31, 2023			
	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)	$ 14,017,306	$ 14,017,306	$ —	$ —

(5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Compensation and benefits	$ 627,400	$ 652,804
Research and development costs	458,271	1,084,009
Professional fees	23,776	63,393
Other	89,758	8,493
Total	$ 1,199,205	$ 1,808,699

(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 "Shares") of the Company's common stock at a purchase price of $1.55 per 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. As of September 30, 2024, the Pre-Funded Warrants had not been exercised. 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.

Warrants for Common Stock

In connection with the Company's initial public offering ("IPO") and private placement in 2021, the Company issued warrants to purchase shares of common stock.

In March 2022, the Company issued 360,000 warrants to purchase common stock with an exercise price of $10.00 per share and a term of 5.76 years as compensation for professional consulting services performed in 2021.

At September 30, 2024, the Company had the following warrants outstanding to acquire common stock:

	Outstanding	Exercise price	Expiration dates
Issued in connection with 2021 IPO	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	5,482,741	$ 0.001	No expiration
	11,342,741		

(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. The 2021 Incentive Plan allows 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 September 30, 2024, 223,115 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 nine months ended September 30, 2024, the Company granted inducement stock options covering 317,407 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 ten years. The expiration dates of the outstanding share-based awards range from January 2028 to September 2034.

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 three and nine months ended September 30, 2024 and 2023:

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Research and development	$ 25,811	$ 13,506	$ 21,765	$ 48,675
General and administrative	187,191	241,443	588,281	772,139
	$ 213,002	$ 254,949	$ 610,046	$ 820,814

The weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of share-based awards granted to employees during the nine months ended September 30, 2024 and 2023 were as follows:

	2024	2023
Expected stock price volatility	95.52%	91.98%
Risk-free interest rate	4.13%	3.86%
Expected term (in years)	6.00	6.00
Expected dividend yield	—	—

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, 2024	2,164,031	$ 2.20	8.4	$ 260,688
Granted	1,230,604	$ 1.51		
Forfeited	(135,020)	$ 1.30		
Outstanding at September 30, 2024	3,259,615	$ 1.97	8.4	$ 1,715,314
Vested and exercisable at September 30, 2024	1,383,123	$ 2.77	7.5	$ 519,934
Vested and expected to vest at September 30, 2024	3,259,615	$ 1.97	8.4	$ 1,715,314

The weighted average fair value of share-based awards granted during the nine months ended September 30, 2024 and 2023 was $1.19 and $0.65, respectively. As of September 30, 2024, the unrecognized compensation cost related to outstanding share-based awards was $1.8 million and is expected to be recognized as expense over a weighted-average period of approximately 2.8 years.

(8) Commitments and Contingencies, including License Agreements

Operating Lease

In February 2022, the Company commenced a noncancellable operating sublease for corporate office space in Philadelphia, Pennsylvania. In March 2023, the Company entered into a direct lease for this same office space that commenced on August 1, 2023. In March 2024, the Company amended the lease, which extended 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.

As of September 30, 2024, the operating lease right-of-use asset and the operating lease liabilities were each $0.2 million, which were estimated using a discount rate of 11%. As of September 30, 2024, the remaining term of the Company's noncancellable operating lease was 2.2 years. Future minimum lease payments under the sublease are $0.3 million at September 30, 2024.

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 $31,000 and $18,000 for the three months ended September 30, 2024 and 2023, respectively. Rent expense related to the Company's operating lease was approximately $93,000 and $63,000 for the nine months ended September 30, 2024 and 2023, 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. The Company generally assumes all administrative costs of the plan. For the three months ended September 30, 2024 and 2023, the Company provided contributions of approximately $9,000 and $7,000, respectively. For the nine months ended September 30, 2024 and 2023, the Company provided contributions of approximately $50,000 and $62,000, 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 ONA-XR. Upon completion of specific performance-based milestones under the Tyligand Process Development Agreement, in August 2021, the Company and Tyligand entered into a license agreement (the "Tyligand License Agreement") whereby Tyligand was granted the exclusive right to ONA-XR and was solely responsible for the development and commercialization of ONA-XR in China, Hong Kong and Macau. The Company retained rights in the rest of the world to commercialize ONA-XR. In August 2024, the Company and Tyligand mutually agreed to terminate the Tyligand License Agreement, and 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 bispecific antibody for cancer therapy. Under the terms of the agreement, Integral and the Company will develop CLDN6 bispecific antibodies that 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 in-process research and development. As a part of the 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 this agreement.

On March 20, 2023, the Company amended the Integral License Agreement ("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 ("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 third-party 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 T cell engaging bispecific antibody, 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 and Taiwan. 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 condensed consolidated statements of operations for the three and nine months ended September 30, 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 condensed consolidated statements of operations for the three and nine months ended September 30, 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. 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.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and other financial information included in this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 21, 2024. In addition to historical information, the following discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks referred to under Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K. Please also see the section entitled "Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies for solid tumors. We are building an innovative portfolio of TCE bispecific therapeutics, including CTIM-76, a CLDN6 x CD3 bsAb, CT-95, an MSLN x CD3 bsAb, and CT-202, a Nectin-4 x CD3 bsAb.

CTIM-76 is a CLDN6 x CD3 bispecific antibody 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. Investigational New Drug ("IND")-enabling studies on CTIM-76 have been completed. On May 2, 2024, we announced 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 anticipate dosing the first patient in the CTIM-76 Phase 1 trial by the end of 2024. We expect to share initial data for the CTIM-76 Phase 1 trial in the first half of 2026.

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.

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 Conditionally Active Biologic T cell engager that is designed to be preferentially active within the tumor microenvironment. We expect to file an IND application for CT-202 in the middle of 2026.

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 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.

CT-95 is an MSLN x CD3 bispecific antibody 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, 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 relatively low affinity but high avidity for membrane-bound MSLN, minimizing the impact

of the shed MSLN. CT-95 is being developed as a therapy for advanced cancers associated with MSLN expression, including ovarian, lung, pancreatic, and mesothelioma. We expect to dose the first patient in the CT-95 Phase 1 trial in the first quarter of 2025. We expect to share initial data for the CT-95 Phase 1 trial in the middle of 2026.

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 "Shares") of our common stock at a purchase price of $1.55 per 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. We expect to have sufficient cash and cash equivalents to fund the estimated duration of the dose escalation portions of our CTIM-76 and CT-95 Phase 1 trials, the estimated expenses through IND filing for CT-202, as well as our operations into 2027.

In addition, pursuant to a registration rights agreement dated May 1, 2024 (the "Registration Rights Agreement"), we filed a registration statement for purposes of registering the resale of the Shares (including the Warrant Shares) (the "Registration Statement"), which was declared effective by the SEC on May 31, 2024. We agreed to use our reasonable best efforts to keep the Registration Statement effective until the date that all registrable securities covered by the Registration Statement (i) have been sold, thereunder or pursuant to Rule 144, or (ii) may be sold by a non-affiliate without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for us to be in compliance with the current public information requirement under Rule 144.

On February 29, 2024, we amended the Research Collaboration and License Agreement (the "Integral License Agreement") with Integral Molecular, Inc. ("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, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 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 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.

On March 22, 2023, we announced a portfolio prioritization and capital allocation strategy, including discontinuing the development of ONA-XR and focusing on the development of CTIM-76. Based upon the challenging market conditions for emerging companies, the increasingly competitive landscape for breast cancer treatments, recent study findings, and other factors, we decided to cease development and explore strategic options for ONA-XR. As a result, we no longer primarily focus on female cancers.

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 $23.4 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $91.4 million.

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.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue nonclinical studies and initiate clinical trials for CTIM-76, CT-95, CT-202, and for any additional product candidates that we may pursue;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidate and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies, including related upfront, milestone and royalty payments;
- attract, hire and retain additional executive officers, clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States and to other geographies; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

As of September 30, 2024, we had cash and cash equivalents of $84.8 million, which we expect will be sufficient to fund our operations into 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.

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 IPR&D 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 (Expense) Income

Other (expense) income 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 Three Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,			
	2024	**2023**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 16,825,198	$ 4,485,223	$ 12,339,975	275 %
General and administrative	1,876,230	1,695,272	180,958	11 %
Loss from operations	(18,701,428)	(6,180,495)	(12,520,933)	203 %
Interest income	1,243,687	290,440	953,247	328 %
Other (expense) income	(2,152)	15,369	(17,521)	(114)%
Net loss	$ (17,459,893)	$ (5,874,686)	$ (11,585,207)	197 %

Research and Development Expenses

Research and development expenses increased by approximately $12.3 million for the three months ended September 30, 2024 as compared to the same period in 2023. The following table summarizes our research and development expenses for the three months ended September 30, 2024 as compared to the same period in 2023:

	Three Months Ended September 30,			
	2024	**2023**	**$ Change**	**% Change**
ONA-XR	$ —	$ (17,363)	$ 17,363	(100)%
CTIM-76	1,431,387	4,191,008	(2,759,621)	(66)%
CT-95	4,008,841	—	4,008,841	*
CT-202	11,016,442	—	11,016,442	*
Personnel-related costs	349,414	295,323	54,091	18 %
Other research and development	19,114	16,255	2,859	18 %
	$ 16,825,198	$ 4,485,223	$ 12,339,975	275 %

** Percentage not meaningful*

ONA-XR income of $17,363 for the three months ended September 30, 2023 was due to actual closeout costs incurred being less than the estimated close out costs recorded as of June 30, 2023, following our decision in March 2023 to discontinue the development of ONA-XR and focus on the development of CTIM-76. CTIM-76 expenditures decreased by $2.8 million, primarily due to a decrease of $3.5 million in contract manufacturing costs and preclinical costs, partially offset by an increase of $0.8 million in clinical costs as a result of initiating our Phase 1 clinical trial. CT-95 expense of $4.0 million primarily represents consideration paid of $3.75 million to acquire the asset from Link in July 2024 and approximately $0.2 million in other preclinical expenses incurred. CT-202 expense of $11.0 million primarily represents 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 $0.1 million, primarily due to higher headcount over the prior year period.

General and Administrative Expenses

General and administrative expenses increased by approximately $0.2 million for the three months ended September 30, 2024 as compared to the same period in 2023. The increase was primarily driven by an increase in professional fees of $0.2 million for legal services incurred during the three months ended September 30, 2024.

Interest Income

Interest income increased by approximately $1.0 million for the three months ended September 30, 2024 as compared to the same period in 2023 primarily due to higher cash and cash equivalent balances due to the Private Placement.

Other (expense) income

Other expense was $2,152 for the three months ended September 30, 2024 as compared to other income of $15,369 for the same period in 2023, primarily due to higher foreign currency losses as a result of exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,			
	2024	**2023**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 20,182,960	$ 12,480,836	$ 7,702,124	62 %
General and administrative	5,430,518	5,658,575	(228,057)	(4)%
Loss from operations	(25,613,478)	(18,139,411)	(7,474,067)	41 %
Interest income	2,236,188	939,256	1,296,932	138 %
Other (expense) income	(4,906)	5,830	(10,736)	(184)%
Net loss	$ (23,382,196)	$ (17,194,325)	$ (6,187,871)	36 %

Research and Development Expenses

Research and development expenses increased by approximately $7.7 million for the nine months ended September 30, 2024 as compared to the same period in 2023. The following table summarizes our research and development expenses for the nine months ended September 30, 2024 as compared to the same period in 2023:

	Nine Months Ended September 30,			
	2024	**2023**	**$ Change**	**% Change**
ONA-XR	$ —	$ 1,904,088	$ (1,904,088)	(100)%
CTIM-76	4,659,764	9,599,509	(4,939,745)	(51)%
CT-95	4,008,841	—	4,008,841	*
CT-202	11,016,442	—	11,016,442	*
Personnel-related costs	470,771	928,330	(457,559)	(49)%
Other research and development	27,142	48,909	(21,767)	(45)%
	$ 20,182,960	$ 12,480,836	$ 7,702,124	62 %

** Percentage not meaningful*

The decrease in ONA-XR expense of $1.9 million was due to the decision in March 2023 to discontinue the development of ONA-XR and focus on the development of CTIM-76. CTIM-76 expenditures decreased by $4.9 million, primarily due to a decrease of $6.8 million in preclinical and contract manufacturing costs, partially offset by an increase of $1.7 million in clinical and regulatory costs as a result of initiating our Phase 1 clinical trial. CT-95 expense of $4.0 million primarily represents consideration paid of $3.75 million to acquire the asset from Link in July 2024 and approximately $0.2 million in other preclinical expenses incurred. CT-202 expense of $11.0 million primarily represents consideration paid under the BioAtla License Agreement entered into in September 2024. Personnel-related costs, which include salaries, benefits and stock-based compensation expense, decreased by approximately $0.5 million, primarily due to lower average headcount over the prior year period.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.2 million for the nine months ended September 30, 2024 as compared to the same period in 2023. The decrease was primarily driven by decreases in compensation and share-based compensation costs of $0.3 million and insurance expense of $0.2 million. These decreases were partially offset by an increase in professional fees of $0.2 million in the nine months ended September 30, 2024.

Interest Income

Interest income increased by approximately $1.3 million for the nine months ended September 30, 2024 as compared to the same period in 2023 primarily due to higher cash and cash equivalent balances due to the Private Placement.

Other expense

Other expense was $4,906 for the nine months ended September 30, 2024 as compared to other income of $5,830 for the same period in 2023, primarily due to higher foreign currency losses 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 September 30, 2024, we have funded our operations through the sale of common stock, warrants, convertible debt, and convertible preferred stock. As of September 30, 2024, we had $84.8 million in cash and cash equivalents and an accumulated deficit of $91.4 million.

We expect our cash and cash equivalents at September 30, 2024 to fund the estimated duration of the dose escalation portions of our CTIM-76 and CT-95 Phase 1 trials, the estimated expenses through IND filing for CT-202, as well as our operations into 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, 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:

	Nine Months Ended September 30,	
	2024	**2023**
Cash used in operating activities	$ (9,649,702)	$ (13,820,446)
Cash used in investing activities	(14,757,316)	—
Cash provided by financing activities	94,758,747	—
Net increase (decrease) in cash and cash equivalents	$ 70,351,729	$ (13,820,446)

Comparison of the Nine Months Ended September 30, 2024 and 2023

Operating Activities

During the nine months ended September 30, 2024, we used $9.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $23.4 million and a change in our operating assets and liabilities of $1.7 million, partially offset by in-process research and development charges of $14.8 million and non-cash share-based compensation expense of $0.6 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

During the nine months ended September 30, 2023, we used $13.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of $17.2 million, partially offset by a change in our operating assets and liabilities of $2.5 million and non-cash share-based compensation expense of $0.8 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

Investing Activities

During the nine months ended September 30, 2024, cash used in investing activities was primarily attributable to a one-time payment of $3.75 million made to Link to acquire the assets associated with CT-95 and a payment of $11.0 million under the BioAtla License Agreement for the development of CT-202. In addition, we used $7,000 of cash to purchase property and equipment.

We did not have cash flows from investing activities during the nine months ended September 30, 2023.

Financing Activities

During the nine months ended September 30, 2024, financing activities provided $94.8 million, consisting of net proceeds from the sale of common stock and Pre-Funded Warrants in the Private Placement.

We did not have cash flows from financing activities during the nine months ended September 30, 2023.

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

During the three and nine months ended September 30, 2024, there were no material changes to our critical accounting policies and estimates from those described in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 21, 2024.

Recent Accounting Pronouncements

See Note 3 to our unaudited condensed consolidated financial statements found elsewhere in this Quarterly Report for a description of recent accounting pronouncements applicable to our unaudited condensed consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, 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 of 1933, as amended, 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 Securities Exchange Act of 1934, as amended (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 was 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 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate 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 their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024. There have been no material changes to the risk factors described in that report. The occurrence of any of the events or developments described in our Risk Factors could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

During the third quarter of 2024, the Company granted inducement stock options outside of the 2021 Long-Term Performance Incentive Plan covering 317,407 shares of the Company’s common stock to new employees (the "Inducement Grants") with a weighted average exercise price of $2.25 per share. Each respective Inducement Grants 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 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2024, 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 6. Exhibits

Exhibit No.	Exhibit Description
3.1	Amended & Restated Certificate of Incorporation of Context Therapeutics Inc. as amended through September 17, 2024 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on September 17, 2024).
3.2	Amended and 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).
10.1#	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).
10.2†	Employment Agreement, dated August 1, 2024, between Context Therapeutics Inc. and Claudio Alberto Dansky Ullmann, M.D. (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 August 7, 2024).
10.3#	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).
10.4†	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 10-Q (File No. 001-40654), as filed with the SEC on August 7, 2024).
10.5†	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 10-Q (File No. 001-40654), as filed with the SEC on August 7, 2024).
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.
101*	The following financial statements from Context Therapeutics Inc.'s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; (v) Notes to the Condensed Consolidated Financial Statements; and (vi) the information under Part II, Item 5, "Other Information."
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 hereto)

* 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 Company, whether made before or after the date hereof.

SIGNATURES

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

Date: November 6, 2024

CONTEXT THERAPEUTICS INC.

By: /s/ Martin Lehr

Martin Lehr

Chief Executive Officer (Principal Executive Officer)

By: /s/ Jennifer Minai-Azary

Jennifer Minai-Azary

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Martin Lehr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Context Therapeutics Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

By: /s/ Martin Lehr
Martin Lehr
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Jennifer Minai-Azary, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Context Therapeutics Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

By: /s/ Jennifer Minai-Azary
Jennifer Minai-Azary
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350, as adopted), Martin Lehr, Chief Executive Officer (Principal Executive Officer) of Context Therapeutics Inc. (the "Company"), and Jennifer Minai-Azary, Chief Financial Officer (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Quarterly Report"), and to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and

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

/s/ Martin Lehr
Date: November 6, 2024
Martin Lehr
Chief Executive Officer (Principal Executive Officer)

/s/ Jennifer Minai-Azary
Date: November 6, 2024
Jennifer Minai-Azary
Chief Financial Officer (Principal Financial Officer)

"This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Context Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."