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, 2023

o **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 o

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 o

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 o No ☒

The number of shares of common stock outstanding at November 6, 2023 was 15,966,053 shares.

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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 and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of U.S. and foreign regulatory filings and approvals, including timing of Investigational New Drug applications and final U.S. Food and Drug Administration (“FDA”) approval of CTIM-76 and any other future product candidates;
- our ability to develop and advance CTIM-76 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 develop a sales team;
- any disagreements or disputes with our licensee and other counterparties relating to onapristone extended release (“ONA-XR”), which may be time consuming and costly;
- 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 intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering CTIM-76, ONA-XR, and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct and support clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;

- our ability to obtain, and negotiate favorable terms of, collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of CTIM-76 and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of CTIM-76 and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our current plans to seek additional capital in the future through equity and/or debt financings, partnerships, collaborations, licensing agreements or other strategic arrangements, or other sources and the availability of such future sources of capital;
- our financial performance;
- 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 our anti-CD3 x anti-Claudin 6 (“CLDN6”) antigen bispecific monoclonal antibody (“bsAb”), CTIM-76. 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, 2023	December 31, 2022
	(Unaudited)	(Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 21,676,999	$ 35,497,445
Prepaid expenses and other current assets	1,293,532	2,356,213
Total current assets	22,970,531	37,853,658
Operating lease right-of-use asset	—	51,967
Property and equipment, net	18,092	27,568
Other assets	—	32,750
Total assets	$ 22,988,623	$ 37,965,943
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,827,808	$ 936,330
Accrued expenses and other current liabilities	2,775,960	2,216,169
Operating lease liability - current	—	55,078
Total current liabilities	4,603,768	3,207,577
Total liabilities	4,603,768	3,207,577
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; 100,000,000 shares authorized; 15,966,053 shares issued and outstanding at September 30, 2023 and December 31, 2022	15,966	15,966
Additional paid-in capital	79,653,593	78,832,779
Accumulated deficit	(61,284,704)	(44,090,379)
Total stockholders' equity	18,384,855	34,758,366
Total liabilities and stockholders' equity	$ 22,988,623	$ 37,965,943

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Acquired in-process research and development	$ —	$ —	$ —	$ 500,000
Research and development	4,485,223	2,077,566	12,480,836	4,946,304
General and administrative	1,695,272	1,970,521	5,658,575	6,052,556
Loss from operations	(6,180,495)	(4,048,087)	(18,139,411)	(11,498,860)
Interest income	290,440	192,245	939,256	219,405
Other income	15,369	1,532	5,830	297
Net loss	$ (5,874,686)	$ (3,854,310)	$ (17,194,325)	$ (11,279,158)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.24)	$ (1.08)	$ (0.71)
Weighted average shares outstanding, basic and diluted	15,966,053	15,966,053	15,966,053	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, 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

	Nine Months Ended September 30, 2022				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2022	15,966,053	$ 15,966	$ 77,510,809	$ (29,254,440)	$ 48,272,335
Fair value of warrants issued for services	—	—	345,530	—	345,530
Share-based compensation expense	—	—	214,958	—	214,958
Net loss	—	—	—	(3,438,337)	(3,438,337)
Balance at March 31, 2022	15,966,053	15,966	78,071,297	(32,692,777)	45,394,486
Share-based compensation expense	—	—	241,324	—	241,324
Net loss	—	—	—	(3,986,511)	(3,986,511)
Balance at June 30, 2022	15,966,053	15,966	78,312,621	(36,679,288)	41,649,299
Share-based compensation expense	—	—	276,521	—	276,521
Net loss	—	—	—	(3,854,310)	(3,854,310)
Balance at September 30, 2022	15,966,053	$ 15,966	$ 78,589,142	$ (40,533,598)	$ 38,071,510

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (17,194,325)	$ (11,279,158)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development charge	—	500,000
Share-based compensation expense	820,814	732,803
Depreciation and amortization expense	9,476	6,074
Reduction in the carrying amount of operating lease right-of-use asset	51,967	56,736
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,062,681	(891,912)
Other assets	32,750	(39,313)
Accounts payable	891,478	(229,228)
Accrued expenses and other current liabilities	559,791	1,576,728
Operating lease liability	(55,078)	(52,291)
Cash used in operating activities	(13,820,446)	(9,619,561)
Cash flows from investing activities:		
Acquired in-process research and development	—	(500,000)
Purchase of property and equipment	—	(36,836)
Cash used in investing activities	—	(536,836)
Cash flows from financing activities:		
Payments for offering costs related to the private placement sale of common stock	—	(102,071)
Cash used in financing activities	—	(102,071)
Net decrease in cash, cash equivalents and restricted cash	(13,820,446)	(10,258,468)
Cash, cash equivalents and restricted cash at beginning of period	35,497,445	49,685,586
Cash and cash equivalents at end of period	$ 21,676,999	$ 39,427,118
Supplemental disclosure of non-cash activities:		
Issuance of warrants for services provided	$ —	$ 345,530
Right-of-use asset obtained in exchange for lease obligation	$ —	$ 130,488

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 medicines for solid tumors. The Company's preclinical product candidate, CTIM-76, is an anti-CD3 x anti-Claudin 6 ("CLDN6") antigen bispecific monoclonal antibody ("bsAb") that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6.

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 closeout 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 material 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 $61.3 million as of September 30, 2023. 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 $21.7 million as of September 30, 2023 are not 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. As a result, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the unaudited condensed consolidated financial statements are issued. The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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 equity and/or debt financings, partnerships, collaborations, or other sources 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 condensed consolidated financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2023, and its results of operations and cash flows for the three and nine months ended September 30, 2023 and 2022. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. 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, 2022. The consolidated financial information as of December 31, 2022 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 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 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 amount of the Company's financial instruments, which include cash and cash equivalents, restricted cash, and accounts payable, approximate their fair values given their short-term nature.

Cash, Cash Equivalents and Restricted Cash

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, 2023, the Company's cash and cash equivalent balances exceeded federally insured limits by approximately $21.2 million.

The Company maintained approximately $50,000 as collateral for the Company's credit card program at December 31, 2021, which was previously reported as restricted cash on its condensed consolidated balance sheets. There were no amounts restricted as of September 30, 2023 and December 31, 2022, as the collateral was released to the Company in the first quarter of 2022.

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.

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 product development milestones are initially treated as the acquisition of an asset but then immediately expensed as there is no future alternative use for the asset. These development milestone payments are reflected 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, 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 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 unaudited 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. 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 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,	
	2023	2022
Stock options	2,238,609	1,341,504
Warrants	5,860,000	5,860,000
	8,098,609	7,201,504

The amounts in the above table reflect common stock equivalents.

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 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.

(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, 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)	$ 21,104,648	$ 21,104,648	$ —	$ —

		December 31, 2022		
	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)	$ 1,723,893	$ 1,723,893	$ —	$ —

(5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Compensation and benefits	$ 632,850	$ 770,055
Research and development costs	2,063,903	1,358,707
Professional fees	21,988	3,951
Other	57,219	83,456
Total	$ 2,775,960	$ 2,216,169

(6) Stockholders' Equity

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. The estimated fair value of the warrants of $0.3 million was recorded in general and administrative expense during the year ended December 31, 2021 and was also reflected as a liability on the condensed consolidated balance sheets as of December 31, 2021. The liability was reclassified into additional paid-in capital in March 2022 upon the issuance of the warrants.

At September 30, 2023, 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
	5,860,000			

(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, 2023, 288,072 shares remained available for future grants.

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 May 2033.

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, 2023 and 2022:

	Three months ended September 30,				Nine months ended September 30,			
	2023		2022		2023		2022	
Research and development	$	13,506	$	14,349	$	48,675	$	74,256
General and administrative		241,443		262,172		772,139		658,547
	$	254,949	$	276,521	$	820,814	$	732,803

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, 2023 and 2022 were as follows:

	2023	2022
Expected stock price volatility	91.98%	87.02%
Risk-free interest rate	3.86%	2.17%
Expected term (in years)	6.00	5.95
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, 2023	1,341,504	$ 3.27	8.9	$ —
Granted	949,142	$ 0.84		
Forfeited	(52,037)	$ 1.40		
Outstanding at September 30, 2023	2,238,609	$ 2.28	8.4	$ 610,076
Vested and exercisable at September 30, 2023	839,347	$ 3.80	7.5	$ —
Vested and expected to vest at September 30, 2023	2,238,609	$ 2.28	8.4	$ 610,076

The weighted average fair value of share-based awards granted during the nine months ended September 30, 2023 and 2022 was $0.65 and $1.38, respectively. As of September 30, 2023, the unrecognized compensation cost related to outstanding share-based awards was $1.3 million and is expected to be recognized as expense over a weighted-average period of approximately 2.2 years.

(8) Commitments and Contingencies

Operating Lease

In January 2022, the Company entered into a noncancellable operating sublease for corporate office space in Philadelphia, Pennsylvania. The sublease for this space commenced on February 1, 2022 and expired on July 31, 2023. In March 2023, the Company entered into a direct lease for this same office space that commenced on August 1, 2023 and is set to expire on August 31, 2024, pursuant to which the Company retains the right to renew the lease for an additional one-year term.

As of September 30, 2023, the operating lease right-of-use asset and the operating lease liabilities were immaterial. The remaining term of the Company's noncancellable operating lease is 11 months. Future minimum lease payments under the sublease are $114,000 at September 30, 2023.

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 $18,000 and $23,000 for the three months ended September 30, 2023 and 2022, respectively, and $63,000 and $60,000 for the nine months ended September 30, 2023 and 2022, respectively.

Employee Benefit Plans

In the first quarter of 2022, 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, 2023 and 2022, the Company provided contributions of approximately $7,000 and $12,000, respectively. For the nine months ended September 30, 2023 and 2022, the Company provided contributions of approximately $62,000 and $54,000, 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.

Under the terms of the Tyligand Process Development Agreement, Tyligand was solely responsible for the design and optimization of an improved manufacturing process for ONA-XR. Upon completion of specific performance-based milestones, Tyligand and the Company entered into a license agreement (the “Tyligand License Agreement”) whereby Tyligand was granted the exclusive right to ONA-XR and is solely responsible for the development and commercialization of ONA-XR in China, Hong Kong and Macau (the “Territory”). The Company retained rights in the rest of the world to commercialize ONA-XR.

Under the Tyligand Process Development Agreement, the Company paid Tyligand certain milestone payments upon successful completion of the manufacturing development plan in 2021. In addition, $2.0 million would be payable upon the completion of scale-up of the first cumulative 100 kilograms of the Good Manufacturing Practices (“GMP”)-grade compound and $3.0 million upon the Company’s completion of scale-up of the first cumulative 300 kilograms of the GMP-grade compound. In consideration of and upon Tyligand’s successful completion of the development plan, within 30 days at the end of each calendar quarter, the Company shall pay Tyligand 1% of net sales of finished product utilizing the compound substantially manufactured in accordance with the process and specifications outlined in the Tyligand Process Development Agreement. Due to the Company's decision to discontinue the development of ONA-XR, the Company does not anticipate any further payments will become due to Tyligand under the Tyligand Process Development Agreement.

Per the Tyligand License Agreement, Tyligand shall pay the Company a non-refundable, non-creditable royalty at a rate in the mid-single digits of the net sales of each product in the Territory in each calendar quarter commencing with the first commercial sale of such product in the field in the Territory and ending upon the latest of (i) the sale of a generic product in the Territory and (ii) 15 years after the date of the first commercial sale of product in the Territory.

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 monoclonal 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 CLND6. 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. See Note 3 for further discussion. As a part of the agreement, Integral will be 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 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.

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, 2022, as filed with the SEC on March 22, 2023. 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 medicines for solid tumors.

Our preclinical program, CTIM-76, is an anti-CLDN6 bsAb 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, including ovarian, lung and testicular, and absent from or expressed at low levels in healthy adult tissues. Investigational new drug ("IND")-enabling studies on CTIM-76 are in process, and we expect to submit an IND application to support human clinical trials to the FDA late in the first quarter of 2024. We also presented additional preclinical data at the Society for Immunotherapy of Cancer’s (SITC) annual meeting in November 2023. The additional preclinical data indicated that CTIM-76 showed high potency and target selectivity in both binding and cytotoxicity assays, CTIM-76 induced dose-proportional tumor regressions and was well tolerated in in vivo xenograft experiments, CTIM-76 was well tolerated in IND-enabling toxicology studies, a potential first-in-human dose was identified, and certain benchmarking data was positive when comparing CTIM-76 to clones of certain competitors' clinical-stage molecules.

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 also expect to have sufficient cash and cash equivalents to fund our operations into late 2024.

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 convertible debt, convertible preferred stock, common stock and warrants. Our net loss was $17.2 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $61.3 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 candidates, 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 that we did not incur as a private company. 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 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, 2023, we had cash and cash equivalents of $21.7 million, which we expect will be sufficient to fund our operations into late 2024. 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 the sale of equity, debt financings and/or other capital sources, which may include collaborations with other companies or other strategic transactions. 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;
- 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 future product candidates and prepare regulatory filings for our 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table sets forth our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	$ Change	% Change
Operating expenses:				
Research and development	$ 4,485,223	$ 2,077,566	$ 2,407,657	116 %
General and administrative	1,695,272	1,970,521	(275,249)	(14)%
Loss from operations	(6,180,495)	(4,048,087)	(2,132,408)	53 %
Interest income	290,440	192,245	98,195	*51 %*
Other income	15,369	1,532	13,837	*(a)*
Net loss	$ (5,874,686)	$ (3,854,310)	$ (2,020,376)	52 %

(a) Percentage not meaningful

Research and Development Expenses

Research and development expenses increased by approximately $2.4 million for the three months ended September 30, 2023 as compared to the same period in 2022. The following table summarizes our research and development expenses for the three months ended September 30, 2023 as compared to the same period in 2022:

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	$ Change	% Change
ONA-XR	$ (17,363)	$ 1,422,477	$ (1,439,840)	(101)%
CTIM-76	4,191,008	299,686	3,891,322	*(a)*
Personnel-related costs	295,323	331,263	(35,940)	(11)%
Other research and development	16,255	24,140	(7,885)	(33)%
	$ 4,485,223	$ 2,077,566	$ 2,407,657	116 %

(a) Percentage not meaningful

The decrease in ONA-XR expense of $1.4 million was primarily due to the decision in March 2023 to discontinue the development of ONA-XR and focus on the development of CTIM-76. Actual closeout costs incurred as well as estimated remaining closeout costs as of September 30, 2023 were less than estimated closeout costs recorded as of March 31, 2023. CTIM-76 expenditures increased by $3.9 million, primarily due to an increase of $2.2 million in contract manufacturing costs and $1.7 million in preclinical costs as a result of ongoing IND-enabling studies.

General and Administrative Expenses

General and administrative expenses decreased for the three months ended September 30, 2023 as compared to the same period in 2022. The decrease was primarily driven by decreases in insurance expense of $0.2 million, in professional fees of $44,000, and in compensation and share-based compensation costs of $28,000.

Interest Income

Interest income increased by approximately $0.1 million for the three months ended September 30, 2023 as compared to the same period in 2022 primarily due to higher interest income earned on cash and cash equivalent balances.

Other income

Other income increased by approximately $14,000 for the three months ended September 30, 2023 as compared to the same period in 2022 primarily due to higher foreign currency gains 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, 2023 and 2022

The following table sets forth our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,			
	2023	2022	$ Change	% Change
Operating expenses:				
Acquired in-process research and development	$ —	$ 500,000	$ (500,000)	(100)%
Research and development	12,480,836	4,946,304	7,534,532	152 %
General and administrative	5,658,575	6,052,556	(393,981)	(7)%
Loss from operations	(18,139,411)	(11,498,860)	(6,640,551)	58 %
Interest income	939,256	219,405	719,851	*(a)*
Other income	5,830	297	5,533	*(a)*
Net loss	$ (17,194,325)	$ (11,279,158)	$ (5,915,167)	52 %

(a) Percentage not meaningful

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense ("IPR&D") of $0.5 million for the nine months ended September 30, 2022 reflects the expense recognized related to a development milestone achieved in the second quarter of 2022 under the Integral License Agreement for the development of our CLDN6 bsAb for solid tumors. There was no IPR&D expense recognized for the nine months ended September 30, 2023.

Research and Development Expenses

Research and development expenses increased by approximately $7.5 million for the nine months ended September 30, 2023 as compared to the same period in 2022. The following table summarizes our research and development expenses for the nine months ended September 30, 2023 as compared to the same period in 2022:

	Nine Months Ended September 30,			
	2023	2022	$ Change	% Change
ONA-XR	$ 1,904,088	$ 3,283,887	$ (1,379,799)	(42)%
CTIM-76	9,599,509	452,646	9,146,863	(a)
Personnel-related costs	928,330	1,101,291	(172,961)	(16)%
Other research and development	48,909	108,480	(59,571)	(55)%
	$ 12,480,836	$ 4,946,304	$ 7,534,532	152 %

(a) Percentage not meaningful

The decrease in ONA-XR expense of $1.4 million was primarily due to a decrease of $1.2 million in contract manufacturing costs and $0.1 million in clinical costs largely due to the decision in March 2023 to discontinue development of ONA-XR. CTIM-76 expenditures increased by $9.1 million, primarily due to an increase of $5.6 million in contract manufacturing costs and $3.4 million in preclinical costs as a result of ongoing IND-enabling studies.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.4 million for the nine months ended September 30, 2023 as compared to the same period in 2022. The decrease was primarily driven by a decrease in insurance expense of $0.7 million and other administrative costs of $0.1 million, partially offset by increases in compensation and share-based compensation cost of $0.3 million and spending on professional fees of $0.2 million.

Interest Income

Interest income increased by approximately $0.7 million for the nine months ended September 30, 2023 as compared to the same period in 2022 primarily due to higher interest income earned on cash and cash equivalent balances.

Other income

Other income increased by approximately $6,000 for the nine months ended September 30, 2023 as compared to the same period in 2022 primarily due to higher foreign currency gains 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, 2023, we have funded our operations through the sale of convertible debt, convertible preferred stock, common stock and warrants. As of September 30, 2023, we had $21.7 million in cash and cash equivalents and an accumulated deficit of $61.3 million.

While we expect our existing cash and cash equivalents will be sufficient to fund our operations into late 2024, we have concluded that there is substantial doubt about our ability to continue as a going concern for a period of at least 12 months from the issuance date of these accompanying unaudited condensed consolidated financial statements. 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 alliances 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 alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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,	
	2023	**2022**
Cash used in operating activities	$ (13,820,446)	$ (9,619,561)
Cash used in investing activities	—	(536,836)
Cash used in financing activities	—	(102,071)
Net decrease in cash, cash equivalents and restricted cash	$ (13,820,446)	$ (10,258,468)

Comparison of the Nine Months Ended September 30, 2023 and 2022

Operating Activities

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.

During the nine months ended September 30, 2022, we used $9.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $11.3 million, partially offset by in-process research and development charges of $0.5 million, non-cash share-based compensation of $0.7 million, and a change in our operating assets and liabilities of $0.4 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

Investing Activities

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

During the nine months ended September 30, 2022, cash used in investing activities was primarily attributable to the payment of a development milestone of $0.5 million under the Integral License Agreement for the development of CLDN6 BsAb for gynecologic cancer therapy. In addition, we used $37,000 of cash to purchase property and equipment.

Financing Activities

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

During the nine months ended September 30, 2022, cash used in financing activities was $0.1 million, consisting of the payment of offering costs related to our December 2021 private placement.

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

During the three and nine months ended September 30, 2023, 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, 2022, as filed with the SEC on March 22, 2023.

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 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 controls 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, 2023, 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, 2023 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, 2022, filed with the SEC on March 22, 2023. Except as set forth below, 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.

The following risk factor is added:

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

The continuation of our business is dependent upon raising additional capital. We will need additional funding to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital. We believe our cash and cash equivalents of $21.7 million as of September 30, 2023 are not sufficient to fund our projected operations for a period of at least the 12 months from the issuance date of the accompanying unaudited condensed consolidated financial statements. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the accompanying unaudited condensed consolidated financial statements are issued.

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. Moreover, the carrying amounts of assets and liabilities presented in the accompanying unaudited condensed consolidated financial statements (i) do not necessarily purport to represent realizable or settlement values and (ii) do not include any adjustment that might result from the outcome of this uncertainty or any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.

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 alliances and/or marketing, distribution or licensing arrangements. There can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or, if available, to obtain funds through financing transactions with unfavorable terms.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

None.

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, 2023, 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. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 22, 2021).
3.2	Amended and Restated Bylaws of Context Therapeutics Inc. (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 October 22, 2021).
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, 2023, 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

+ 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 9, 2023

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 9, 2023

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 9, 2023

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, 2023 (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 9, 2023	Martin Lehr
	Chief Executive Officer (Principal Executive Officer)
	/s/ Jennifer Minai-Azary
Date: November 9, 2023	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.”