**Filed Pursuant to Rule 424(b)(3)**
**Registration No. 333-261599**

**PROSPECTUS SUPPLEMENT NO. 6**
**(to prospectus dated April 12, 2022)**

# 10,000,000 Shares

# Common Stock

# Context Therapeutics Inc.

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This prospectus supplement is being filed to update and supplement the information contained in the prospectus dated April 12, 2022 (the "Prospectus"), related to the disposition, from time to time, by the selling stockholders identified in the Prospectus under the caption "Selling Stockholders" of up to 10,000,000 shares of our common stock, with the information contained in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (the "SEC") on November 9, 2022 (the "Quarterly Report"). Accordingly, we have attached the Quarterly Report to this prospectus supplement.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on this prospectus supplement.

Our common stock is traded on the Nasdaq Capital Market under the symbol "CNTX." On November 8, 2022, the last reported closing sale price of our common stock on the Nasdaq Capital Market was $1.15 per share.

We are an "emerging growth company" under the federal securities laws and have elected to comply with certain reduced public company reporting requirements.

**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11 of the Prospectus to read about factors you should consider before buying shares of our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is November 9, 2022

# 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, 2022**

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 4, 2022 was 15,966,053 shares.

**INDEX TO FORM 10-Q**



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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.

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Trademark Notice

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report (including, for purposes of this Note Regarding Forward-Looking Statements, any information or documents incorporated herein by reference) includes express and implied forward-looking statements. 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 clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing of preliminary results for our ongoing Company-sponsored trial and investigator-sponsored trials;
- the timing, progress and results of preclinical studies and clinical trials for onapristone extended release ("ONA-XR"), anti-claudin 6 ("CLDN6") bispecific monoclonal antibody ("BsAb"), 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 approval of ONA-XR, CLDN6 BsAb and any other future product candidates;
- our ability to develop and advance ONA-XR, CLDN6 BsAb, and any other future product candidates, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities, implementations thereof, and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus, sales strategy, and our ability to grow a sales team;
- the impact of the COVID-19 pandemic and other 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 expectations regarding the approval and use of our product candidates in combination with other drugs;
- our dependence on collaborations with third parties for certain research, development and commercialization activities;
- 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 ONA-XR, CLDN6 BsAb, 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 additional 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 ONA-XR, CLDN6 BsAb and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of ONA-XR, CLDN6 BsAb and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our current plans and ability to seek additional capital in the future through equity and/or debt financings, partnerships, collaborations, or other sources and the availability and terms 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 contains estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning markets for ONA-XR and CLDN6 BsAb. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances reflected in this information. As a result, you are cautioned not to give undue weight to such information.

This Form 10-Q also contains 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, 2022 (Unaudited) | December 31, 2021 (Note 3) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 39,427,118 | $ 49,635,197 |
| Prepaid expenses and other current assets | 2,512,076 | 1,620,164 |
| Total current assets | 41,939,194 | 51,255,361 |
| Operating lease right-of-use asset | 73,752 | — |
| Property and equipment, net | 30,762 | — |
| Other assets | 39,313 | — |
| Restricted cash | — | 50,389 |
| Total assets | $ 42,083,021 | $ 51,305,750 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,494,995 | $ 1,826,294 |
| Accrued expenses and other current liabilities | 2,438,319 | 1,207,121 |
| Operating lease liability - current | 78,197 | — |
| Total current liabilities | 4,011,511 | 3,033,415 |
| Total liabilities | 4,011,511 | 3,033,415 |
| Commitments and contingencies (Note 9) | | |
| 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, 2022 and December 31, 2021 | 15,966 | 15,966 |
| Additional paid-in capital | 78,589,142 | 77,510,809 |
| Accumulated deficit | (40,533,598) | (29,254,440) |
| Total stockholders' equity | 38,071,510 | 48,272,335 |
| Total liabilities and stockholders' equity | $ 42,083,021 | $ 51,305,750 |

*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, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Operating expenses: | | | | |
| Acquired in-process research and development | $ — | $ — | $ 500,000 | $ 3,087,832 |
| Research and development | 2,077,566 | 739,598 | 4,946,304 | 2,511,438 |
| General and administrative | 1,970,521 | 828,464 | 6,052,556 | 1,834,645 |
| Loss from operations | (4,048,087) | (1,568,062) | (11,498,860) | (7,433,915) |
| Interest income (expense), net | 192,245 | (1,261) | 219,405 | (64,555) |
| Change in fair value of convertible promissory notes | — | — | — | 9,317 |
| Other income | 1,532 | 126,531 | 297 | 124,148 |
| Net loss | $ (3,854,310) | $ (1,442,792) | $ (11,279,158) | $ (7,365,005) |
| Net loss per common share, basic and diluted | $ (0.24) | $ (4.00) | $ (0.71) | $ (20.74) |
| Weighted average shares outstanding, basic and diluted | 15,966,053 | 361,067 | 15,966,053 | 355,087 |

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

**Context Therapeutics Inc.**
**Condensed Consolidated Statement of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Deficit**
**(Unaudited)**

| | Series A Preferred Stock | | Series Seed Preferred Stock | | Redeemable Common Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Deficit |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| Balance at January 1, 2021 | 210,715 | $ 1,400,935 | 2,624,324 | $ 6,341,288 | 16,666 | $ 29,000 | 331,789 | $ 332 | $ 1,876,159 | $ (18,797,570) | $ (16,921,079) |
| Sale of Series A preferred stock, net of offering costs of $213,073 | 453,094 | 3,034,526 | — | — | — | — | — | — | — | — | — |
| Conversion of Senior Convertible Notes, including accrued interest, to Series A preferred stock | 844,824 | 5,728,793 | — | — | — | — | — | — | 137,497 | — | 137,497 |
| Fair value of warrants issued in conjunction with the Series A preferred stock | — | (158,658) | — | — | — | — | — | — | 158,658 | — | 158,658 |
| Fair value of warrants issued as placement agent fees | — | (13,388) | — | — | — | — | — | — | 13,388 | — | 13,388 |
| Share-based compensation expense, including vesting of restricted stock and issuance of common stock | — | — | — | — | — | — | 4,218 | 4 | 25,509 | — | 25,513 |
| Net loss | — | — | — | — | — | — | — | — | — | (892,049) | (892,049) |
| Balance at March 31, 2021 | 1,508,633 | 9,992,208 | 2,624,324 | 6,341,288 | 16,666 | 29,000 | 336,007 | 336 | $ 2,211,211 | (19,689,619) | (17,478,072) |
| Sale of Series A preferred stock, net of offering costs of $96,948 | 285,351 | 1,948,309 | — | — | — | — | — | — | — | — | — |
| Fair value of Series A preferred stock issued in conjunction with collaboration and licensing agreement | 418,559 | 2,837,832 | — | — | — | — | — | — | — | — | — |
| Fair value of warrants issued in conjunction with the Series A preferred stock | — | (106,935) | — | — | — | — | — | — | 106,935 | — | 106,935 |
| Fair value of warrants issued as placement agent fees | — | (30,409) | — | — | — | — | — | — | 30,409 | — | 30,409 |
| Share-based compensation expense, including vesting of restricted stock and issuance of common stock | — | — | — | — | — | — | 6,262 | 6 | 119,357 | — | 119,363 |
| Change in fair value of redeemable common stock to redemption value | — | — | — | — | — | 53,330 | — | — | (53,330) | — | (53,330) |
| Net loss | — | — | — | — | — | — | — | — | — | (5,030,164) | (5,030,164) |
| Balance at June 30, 2021 | 2,212,543 | 14,641,005 | 2,624,324 | 6,341,288 | 16,666 | 82,330 | 342,269 | 342 | 2,414,582 | (24,719,783) | (22,304,859) |
| Fair value of warrants issued for services | — | — | — | — | — | — | — | — | 371,895 | — | 371,895 |
| Share-based compensation expense, including vesting of restricted stock and issuance of common stock | — | — | — | — | — | — | 6,262 | 6 | 161,817 | — | 161,823 |
| Net loss | — | — | — | — | — | — | — | — | — | (1,442,792) | (1,442,792) |
| Balance at September 30, 2021 | 2,212,543 | $ 14,641,005 | 2,624,324 | $ 6,341,288 | 16,666 | $ 82,330 | 348,531 | $ 348 | $ 2,948,294 | $ (26,162,575) | $ (23,213,933) |

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

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

| | 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, | |
|---|---|---|
| | **2022** | **2021** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (11,279,158) | $ (7,365,005) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development charge | 500,000 | 3,087,832 |
| Fair value of warrants for services provided | — | 371,895 |
| Share-based compensation expense | 732,803 | 306,699 |
| Depreciation and amortization expense | 6,074 | — |
| Non-cash interest expense | — | 64,555 |
| Change in fair value of convertible promissory notes | — | (9,317) |
| Reduction in the carrying amount of operating lease right-of-use asset | 56,736 | — |
| Gain on extinguishment of debt | — | (125,577) |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (891,912) | (9,707) |
| Other assets | (39,313) | — |
| Accounts payable | (229,228) | (179,199) |
| Accrued expenses and other current liabilities | 1,576,728 | 20,021 |
| Operating lease liability | (52,291) | — |
| Cash used in operating activities | (9,619,561) | (3,837,803) |
| **Cash flows from investing activities:** | | |
| Acquired in-process research and development | (500,000) | (250,000) |
| Purchase of property and equipment | (36,836) | — |
| Cash used in investing activities | (536,836) | (250,000) |
| **Cash flows from financing activities:** | | |
| Payments for offering costs related to the private placement sale of common stock | (102,071) | — |
| Proceeds from the sale of Series A preferred stock, net | — | 4,982,835 |
| Payment of offering costs related to initial public offering | — | (816,917) |
| Cash (used in) provided by financing activities | (102,071) | 4,165,918 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (10,258,468) | 78,115 |
| Cash, cash equivalents and restricted cash at beginning of period | 49,685,586 | 341,037 |
| Cash, cash equivalents and restricted cash at end of period | $ 39,427,118 | $ 419,152 |
| **Supplemental disclosure of non-cash activities:** | | |
| Conversion of convertible promissory notes, including accrued interest, to Series A preferred stock | $ — | $ 5,866,290 |
| Issuance of warrants in conjunction with Series A preferred stock | $ — | $ 309,390 |
| Series A preferred stock issued for acquired in-process research and development | $ — | $ 2,837,832 |
| Deferred offering costs in accounts payable and accrued expenses | $ — | $ 1,004,856 |
| Issuance of warrants for services provided | $ 345,530 | $ — |
| Right-of-use asset obtained in exchange for lease obligation | $ 130,488 | $ — |
| Change in fair value of redeemable common stock to redemption value | $ — | $ 53,330 |

*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 clinical-stage biopharmaceutical company dedicated to improving the lives of women living with cancer. The Company was organized in April 2015 under the laws of the State of Delaware. The Company's operations are located in Philadelphia, Pennsylvania. In April 2021, the Company completed a reverse triangular merger, which resulted in Context Therapeutics Inc. becoming the sole holder of 100% of the membership interests in Context Therapeutics LLC. In connection with the merger, all common units, preferred units, options, warrants or other rights to purchase common or preferred units of Context Therapeutics LLC converted into common stock, preferred stock, options, warrants or other rights to purchase common or preferred stock of Context Therapeutics Inc. As this was a transaction between entities under common control, the carryover basis of accounting was used to record the assets, liabilities and equity of Context Therapeutics LLC. Further, as a common control transaction the condensed consolidated financial statements of the Company reflect the merger transaction as if it had occurred as of the earliest period presented herein.

**(2) Risks and Liquidity**

The Company has incurred losses and negative cash flows from operations since inception and had an accumulated deficit of $40.5 million as of September 30, 2022. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its product candidates currently in development. The Company believes its cash and cash equivalents of $39.4 million as of September 30, 2022 are sufficient to fund its projected operations for at least the next 12 months from the issuance date of these condensed consolidated financial statements. However, substantial additional financing will be needed by the Company to fund its operations and to commercially develop its current and future product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

In the first half of 2021, the Company raised $5.0 million in net proceeds related to the sale of its Series A convertible preferred stock ("Series A Stock") and warrants for common stock.

In October 2021, the Company closed an initial public offering ("IPO"), in which it issued and sold 5,750,000 shares at a public offering price of $5.00 per share. In addition, at the closing of the IPO, the Company issued warrants to purchase up to 250,000 shares of common stock to designees of the placement agent. The placement agent's warrants have an exercise price of $6.25 per share and a term of five years from the date of issuance. Immediately prior to the completion of the IPO, all of the Company's preferred stock and redeemable common stock converted into an aggregate of 4,853,533 shares of common stock and 480,415 warrants converted into 9,816 shares of common stock. The Company received net proceeds of approximately $24.4 million as a result of the offering.

In December 2021, the Company sold 5,000,000 shares of its common stock together with warrants to purchase 5,000,000 shares of common stock in a private placement and received net proceeds of approximately $28.9 million. Each share of common stock and accompanying warrant were sold together at a combined offering price of $6.25. The warrants have a term of 5.5 years and an exercise price of $6.25 per share. In addition, at the closing of the private placement, the Company issued warrants to purchase up to 250,000 shares of common stock to designees of the placement agent. The placement agent's warrants have an exercise price of $6.25 per share and a term of 5.5 years from the date of issuance.

The Company 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. Various internal and external factors will affect whether and when the Company's product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's 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.

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The spread of COVID-19 has caused worldwide economic downturn and significant volatility in the financial markets. There is significant uncertainty as to the likely effects of this disease which may, among other things, materially impact the Company's planned clinical trials. This pandemic or outbreak could result in difficulty securing clinical trial site locations, contract research organizations, and/or trial monitors and other critical vendors and consultants supporting the trials. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company's ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in the Company's clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company's business and its financial condition. At the current time, the Company is unable to quantify the potential effects of this pandemic on its future consolidated financial statements.

**(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 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 financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2022, and its results of operations for the three and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. 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, 2021. The consolidated financial information as of December 31, 2021 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, the fair value of common stock, share-based compensation arrangements, the fair value of convertible debt 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 and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

***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.

The Company maintained approximately $50,000 as collateral for the Company's credit card program at December 31, 2021, which is reported as restricted cash on its condensed consolidated balance sheets. There were no amounts restricted as of September 30, 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 Equipmen***t

Property and equipment consist of office equipment, furniture, and leasehold improvements and is recorded at cost. Property and equipment is 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.

***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 subject 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.

In addition, the Company measures and recognizes share-based compensation expense for advisors, officers and director restricted share-based awards based on the grant date fair value of the awards.

***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, | |
|---|---|---|
| | 2022 | 2021 |
| Series Seed convertible preferred stock | — | 2,624,324 |
| Series A convertible preferred stock | — | 2,212,543 |
| Stock options | 1,341,504 | 436,437 |
| Unvested restricted stock awards | — | 33,397 |
| Warrants | 5,860,000 | 480,415 |
| | 7,201,504 | 5,787,116 |

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.

***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) the lease classification or (c) the determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted this standard on January 1, 2022 and the adoption did not have a material impact on its condensed consolidated financial statements due to the fact that the Company did not have any material long-term leasing arrangements as of the date of adoption.

**(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, 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) | $ 1,921,341 | $ 1,921,341 | $ — | $ — |

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | 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) | $ 49,051,061 | $ 49,051,061 | $ — | $ — |

**(5) Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Compensation and benefits | $ 564,989 | $ 436,990 |
| Research and development costs | 1,801,041 | 339,072 |
| Professional fees | 12,000 | 345,530 |
| Other | 60,289 | 85,529 |
| Total | $ 2,438,319 | $ 1,207,121 |

**(6) Convertible Promissory Notes and Other Debt**

*Senior Convertible Notes*

The Company previously issued certain convertible promissory notes to various investors which were converted into Senior Convertible Notes (the “Senior Convertible Notes”, and collectively, the “Convertible Promissory Notes”).

All of the outstanding principal and accrued but unpaid interest associated with the Senior Convertible Notes converted into 844,824 shares of Series A Stock in February 2021, of which 430,467 shares were issued to the Company's Chief Executive Officer and an immediate family member (the "Related Party"). Due to certain embedded features within the Senior Convertible Notes, the Company elected to account for these notes and all their embedded features under the fair value option. At the time of conversion, the estimated fair value of the Senior Convertible Notes was $5.7 million and was reclassified to Series A Stock. The Company recorded a non-cash credit of $9,000 in the condensed consolidated statement of operations for the nine months ended September 30, 2021 related to the decrease in fair value of the Senior Convertible Notes. For the nine months ended September 30, 2021, the Company recognized $46,000 of interest expense in connection with the Senior Convertible Notes, including $23,000 payable to the Related Party, respectively.

*Paycheck Protection Program*

In May 2020, the Company entered into an original loan agreement with Pacific Western Bank as the lender for a loan in an aggregate principal amount of $0.1 million (the “Loan”) pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security (CARES) Act implemented by the U.S. Small Business Administration. In June 2020, the Paycheck Protection Program Flexibility Act was enacted, which among other things, extended the deferral period for loan payments to either (1) the date that the Small Business Administration remits the borrower’s loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, 10 months after the end of the borrower’s loan forgiveness covered period. The Loan was set to mature in two years and bore interest at a rate of 1.0% per year, with all payments deferred through September 5, 2021. The outstanding principal balance of the Loan of $0.1 million was forgiven in July 2021 and was recognized as a gain on extinguishment of debt within other income in the condensed consolidated statements of operations during the three and nine months ended September 30, 2021.

**(7) Convertible Preferred Stock, Redeemable Common Stock and Common Stock**

***Series A convertible preferred stock and Series Seed convertible preferred stock***

In February, March and April 2021, the Company sold 738,445 shares of Series A Stock for $7.168 per share for net proceeds of $5.0 million. The Company also issued 184,597 warrants to purchase common stock at an exercise price of $7.168 to the Series A stockholders as part of the Series A Stock financing. Additionally, the Company issued 24,134 warrants to purchase common stock at an exercise price of $7.168 to placement agents as a part of the Series A Stock financing.

In February 2021, the Company converted $6.1 million of principal and interest related to Senior Convertible Notes into 844,824 shares of Series A Stock at a price of $7.168 per share. In addition, warrants with a fair value of $0.1 million associated with the Senior Convertible Notes were reclassified into additional paid-in capital.

In October 2021, the Company completed its IPO in which the Company sold 5,750,000 shares at a public offering price of $5.00 per share. Immediately prior to the completion of the IPO, all of the Company's preferred stock and redeemable common stock converted into an aggregate of 4,853,533 shares of common stock and all of the outstanding warrants converted into 9,816 shares of common stock. The Company received net proceeds of $24.4 million as a result of the offering. The Company issued 250,000 warrants to a placement agent as part of the offering with an exercise price of $6.25 per share and a term of 5.0 years.

In December 2021, the Company sold 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock and received net proceeds of $28.9 million in a private placement. Each share of common stock and accompanying warrant were sold together at a combined offering price of $6.25. The warrants have a term of 5.5 years and an exercise price of $6.25 per share. The Company also issued 250,000 warrants to a placement agent as part of the offering with an exercise price of $6.25 per share and a term of 5.5 years.

***Warrants for 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, 2022, 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 | | | |

**(8) 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 will automatically increase 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 may determine that there will be no such increase or a smaller increase for any particular year. As of September 30, 2022, 546,535 shares remained available for future grants.

Share-based awards generally vest over a period of one 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 August 2032.

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, 2022 and 2021:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | $ 14,349 | $ 17,775 | $ 74,256 | $ 56,677 |
| General and administrative | 262,172 | 133,300 | 658,547 | 224,049 |
| | $ 276,521 | $ 151,075 | $ 732,803 | $ 280,726 |

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, 2022 and 2021, respectively, were as follows:

| | 2022 | 2021 |
|---|---|---|
| Expected stock price volatility | 87.02% | 97.50% |
| Risk-free interest rate | 2.17% | 1.03% |
| Expected term (in years) | 5.95 | 5.77 |
| Expected dividend yield | — | — |

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

| | Number of Options | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (years) |
|---|---|---|---|
| Outstanding at January 1, 2022 | 506,691 | $ 5.68 | 9.3 |
| Granted | 890,058 | $ 1.85 | |
| Forfeited | (55,245) | $ 2.52 | |
| Outstanding at September 30, 2022 | 1,341,504 | $ 3.27 | 9.1 |
| Vested and exercisable at September 30, 2022 | 275,061 | $ 5.90 | 8.5 |
| Vested and expected to vest at September 30, 2022 | 1,341,504 | $ 3.27 | 9.1 |

The weighted average fair value of share-based awards granted during the nine months ended September 30, 2022 and 2021 was $1.38 and $3.76, respectively. As of September 30, 2022, the unrecognized compensation cost related to outstanding share-based awards was $1.9 million and is expected to be recognized as expense over a weighted-average period of approximately 2.25 years.

***Restricted Stock Units***

The Company issues RSUs to employees and consultants that generally vest monthly over one to three-year periods. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is amortized straight-line over the service period.

The Company recorded share-based compensation expense of approximately $10,000 and $25,000 in research and development expense for the three and nine months ended September 30, 2021, respectively, related to RSUs. There were no RSUs outstanding as of September 30, 2022 or December 31, 2021.

**(9) 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 is set to expire on July 30, 2023.

As of September 30, 2022, the operating lease right-of-use asset and the operating lease liabilities were $74,000 and $78,000, respectively. The weighted average discount rate used to account for the Company's operating leases under Topic 842 is the Company's estimated incremental borrowing rate of 5.0%. The remaining term of the Company's noncancellable operating lease is 0.83 years.

Rent expense related to the Company's operating lease was approximately $23,000 and $60,000 for the three and nine months ended September 30, 2022, respectively. The Company recognizes rent expense on a straight-line basis over the lease period and accrues for rent expense incurred but not yet paid.

Future minimum lease payments under the sublease are $80,000 at September 30, 2022.

***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 and nine months ended September 30, 2022, the Company provided contributions of approximately $12,000 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 onapristone extended release ("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" and, together with the Tyligand Process Development Agreement, the "Tyligand Agreements") 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 retains rights in the rest of the world to commercialize ONA-XR.

Under the Tyligand Process Development Agreement, the Company paid Tyligand $0.8 million and issued 111,576 warrants to purchase shares of common stock at an exercise price of $7.17 per share upon successful completion of the manufacturing development plan in 2021. The warrants were cancelled in connection with the Company's IPO. In addition, $2.0 million will 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.

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") for the development of an anti-claudin 6 ("CLDN6") bispecific monoclonal antibody ("BsAb") 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 Company paid an upfront license fee of $0.3 million, granted 418,559 shares of Series A Stock with a fair market value of approximately $2.8 million, and expensed these costs to acquired in-process research and development during the year ended December 31, 2021. As a part of the agreement, Integral will be eligible to receive remaining development and regulatory milestone payments totaling approximately $55 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. In the second quarter of 2022, the Company expensed $0.5 million in acquired in-process research and development related to a development milestone achieved under the agreement with Integral.

***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.

**(10) Subsequent Event**

On November 7, 2022, the Company entered into a Development and Manufacturing Services Agreement (the "Lonza Development Agreement"), with Lonza Sales AG ("Lonza Sales") and Lonza AG (collectively, "Lonza"). Under the terms of the Lonza Development Agreement, Lonza will provide services relating to the development and manufacture of the Company's anti-claudin 6 bispecific monoclonal antibody product (the "Product") in accordance with the project plan attached to the Lonza Development Agreement and any other work as may be agreed to between the Company and Lonza. The Lonza Development Agreement will terminate upon the completion of the agreed upon services, unless earlier terminated by the Company or Lonza for uncured material breaches, insolvency of the other party, or if a party determines that it is not possible to complete the services for material scientific or material technical reasons.

In addition, on November 7, 2022, the Company entered into a License Agreement (the "Lonza License Agreement") with Lonza Sales. Under the terms of the Lonza License Agreement, to the extent incorporated into the Product, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit the Product.

**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, 2021 as filed with the Securities and Exchange Commission ("SEC"), on March 23, 2022. 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 "Special Note Regarding Forward-Looking Statements."*

**Overview**

We are a clinical-stage biopharmaceutical company dedicated to improving the lives of women living with cancer. Our development team is advancing a pipeline of innovative therapies with a primary focus on treating female cancers, including breast, ovarian, and endometrial (uterine) cancer. Our most advanced product candidate, onapristone extended-release ("ONA-XR"), builds upon a foundation of successful drug development by our management team and advisors in the field of hormone-dependent cancers. ONA-XR is a potent and selective antagonist of the progesterone receptor, which has been linked to resistance to multiple classes of cancer therapeutics, including anti-estrogen therapies, across female hormone-dependent cancers.

Our first program, ONA-XR, is being advanced across various investigator-sponsored trials and a Company-sponsored trial:

- An ongoing Phase 2 investigator-sponsored trial is being conducted in collaboration with Jefferson Health to evaluate ONA-XR in combination with anastrozole to treat women with progesterone receptor positive ("PR+") endometrial adenocarcinoma who have failed front line therapy with a platinum/taxane-based chemotherapy regimen. As of September 30, 2022, we note the following:
  - The trial has enrolled 12 of 25 planned patients.
  - The preliminary 4-month progression free survival ("PFS") rate was 77.7%, based on nine evaluable patients.
  - Three patients received treatment for greater than 12 months.
  - Overall, seven patients remain in the trial.
  - There have been no treatment-related serious adverse events reported.

  This trial is ongoing and updated trial results are expected in mid-2023.
- An ongoing Phase 2 investigator-sponsored basket trial is being conducted in collaboration with Memorial Sloan Kettering Cancer Center to evaluate ONA-XR in combination with anastrozole to treat women with PR+ recurrent gynecologic cancers. As of September 30, 2022, we note the following:
  - Cohort 1, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR as a single agent, completed accrual to stage 1 and has shown a 12-month PFS rate of 20.1% and a Clinical Benefit Rate (stable disease) of 35.7%. Two patients continued on active treatment for greater than 18 months. One patient remains on trial.
  - Cohort 4, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR in combination with anastrozole, enrolled 14 patients in stage 1 and will expand to stage 2 when greater than or equal to one response is observed. Seven patients remain on trial.
  - There have been no treatment-related serious adverse events reported.

  This trial is ongoing and updated trial results are expected in mid-2023.
- An ongoing Phase 2 investigator-sponsored trial is being conducted in collaboration with Wisconsin Oncology Network to evaluate ONA-XR in combination with fulvestrant in second line or third line advanced or metastatic estrogen receptor positive ("ER+"),PR+,HER2- breast cancer (the "SMILE" trial). This trial is intended to evaluate potential ONA-XR plus fulvestrant drug synergy after treatment failure of CDK4/6 and/or PIK3α inhibitors, with initial clinical data expected in December 2022.
- The SMILE trial will also evaluate radiolabeled progesterone ("$^{18}$F-FFNP") distribution in PR target tissues and quantify available PR binding sites via positron emission tomography (PET)/computed tomography (CT) imaging in breast tumors when co-treated with ONA-XR. Data is expected in 2023.

- On August 1, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement (the “Menarini Agreement”) with Berlin-Chemie AG - Menarini Group - (“Menarini”). Pursuant to the Menarini Agreement, we will conduct a Phase 1b/2 study of elacestrant in combination with ONA-XR in patients with advanced or metastatic ER+,PR+,HER2- breast cancer (the “ELONA” trial). Menarini will provide, at no cost to us, elacestrant, its nonsteroidal combined selective estrogen receptor modulator and selective estrogen receptor degrader therapy, for use in combination with our investigational drug, ONA-XR, in the ELONA trial. Under the Menarini Agreement, we will sponsor, fund and conduct the ELONA trial, and Menarini has agreed to manufacture and supply elacestrant at Menarini's cost and for no charge to us for use in the ELONA trial and to provide cell-free nucleic acid analysis of the anonymized blood samples of all ELONA trial patients.
- In November 2022, we initiated the ELONA trial, with Phase 1b data expected in the fourth quarter of 2023.

The observations from the ongoing clinical trials noted above are based on information available as of September 30, 2022. These trials are still actively enrolling patients and these preliminary clinical findings may materially fluctuate on a month-to-month basis as the trials progress and may not be representative of results after all patients complete the respective trial and all data is collected and analyzed. Further, this data is subject to continuing audit and verification procedures that will not be complete until the conclusion of the respective trial and therefore the interim data is subject to change.

Our second program, CLDN6xCD3 bispecific antibody, is being advanced toward an Investigational New Drug Application ("IND") submission. CLDN6xCD3 BsAb 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. CLDN6 is a tight junction membrane protein target expressed in multiple cancers, including ovarian and endometrial tumors, and absent from or expressed at very low levels in normal adult tissues. We reached the first development milestone under our collaboration and license agreement with Integral Molecular ("Integral") in the second quarter of 2022. We expect to select a candidate to support Investigational New Drug ("IND")-enabling studies for CLDN6xCD3 BsAb in December 2022 and an IND submission is planned in the first quarter of 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 issuance of convertible debt, convertible preferred stock and sale of common stock. Our net loss was $11.3 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $40.5 million.

In October 2021, we closed an initial public offering (“IPO”) on the Nasdaq Stock Market, in which we issued and sold 5,750,000 shares at a public offering price of $5.00 per share. We received gross proceeds of approximately $28.8 million as a result of the offering. In December 2021, we sold 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock in a private placement for gross proceeds of approximately $31.3 million. We expect our existing cash and cash equivalents will be sufficient to fund our operations into the first quarter of 2024. 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 future product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, in connection with the closing of our IPO, we have incurred and continue to incur additional costs associated with operating as a public company, including significant 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 ongoing and planned 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 our ongoing and planned research and development of our most advanced product candidate ONA-XR;

- continue nonclinical studies and initiate clinical trials for our CLDN6 BsAb product 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 candidates 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.

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.

**The COVID-19 Pandemic and its Impacts on Our Business**

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The spread of COVID-19 has caused worldwide economic instability and significant volatility in the financial markets. There is significant uncertainty as to the likely effects of this disease which may, among other things, materially impact our ongoing or planned clinical trials. This pandemic or outbreak could result in difficulty securing clinical trial site locations, contract research organizations (“CROs”), and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact our ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and financial condition. At the current time, we are unable to quantify the potential effects of this pandemic on our future consolidated financial statements.

**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 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 ("CMOs"), 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, fees paid to CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. 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.

*Interest Expense*

Interest expense has consisted primarily of interest related to our convertible promissory notes that converted to Series A stock in 2021. All of the previously outstanding convertible promissory notes of the Company were converted as of February 2021.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2022 and 2021***

The following table sets forth our results of operations for the three months ended September 30, 2022 and 2021:

| | Three months ended September 30, | | | |
|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** |
| Operating expenses: | | | | |
| Research and development | $ 2,077,566 | $ 739,598 | $ 1,337,968 | 181 % |
| General and administrative | 1,970,521 | 828,464 | 1,142,057 | 138 % |
| Loss from operations | (4,048,087) | (1,568,062) | (2,480,025) | 158 % |
| Interest income (expense), net | 192,245 | (1,261) | 193,506 | (15345)% |
| Other income | 1,532 | 126,531 | (124,999) | (99)% |
| Net loss | $ (3,854,310) | $ (1,442,792) | $ (2,411,518) | 167 % |

*Research and Development Expenses*

Research and development expenses increased by approximately $1.3 million for the three months ended September 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the three months ended September 30, 2022 as compared to the same period in 2021:

| | Three months ended September 30, | | | |
|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** |
| ONA-XR | $ 1,422,477 | $ 331,872 | $ 1,090,605 | 329 % |
| CLDN6 | 299,686 | 207,398 | 92,288 | 44 % |
| Personnel-related costs | 331,263 | 199,216 | 132,047 | 66 % |
| Other research and development | 24,140 | 1,112 | 23,028 | 2071 % |
| | $ 2,077,566 | $ 739,598 | $ 1,337,968 | 181 % |

The increase in ONA-XR expense of $1.1 million was primarily due to an increase of $0.6 million in contract manufacturing costs and an increase of $0.4 million in clinical trial costs, mostly as a result of preparing to initiate our Phase 1b/2 ELONA trial. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.1 million, primarily due to higher headcount over the prior year period.

*General and Administrative Expenses*

General and administrative expenses increased by approximately $1.1 million for the three months ended September 30, 2022 as compared to the same period in 2021. The increase was primarily due to an increase of $0.4 million in compensation and share-based compensation as a result of an increase in our general and administrative headcount and changes to compensation arrangements, higher insurance costs of $0.4 million and $0.3 million of other costs associated with operating as a public company.

*Interest Income (Expense), net*

Interest income (expense), net, increased by approximately $0.2 million for the three months ended September 30, 2022 as compared to the same period in 2021 primarily due to higher interest income earned as a result of higher cash and cash equivalent balances and higher interest rates.

*Other Income*

Other income of $0.1 million for the three months ended September 30, 2021 was primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

***Comparison of the Nine Months Ended September 30, 2022 and 2021***

The following table sets forth our results of operations for the nine months ended September 30, 2022 and 2021:

| | Nine months ended September 30, | | | |
|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** |
| Operating expenses: | | | | |
| Acquired in-process research and development | $ 500,000 | $ 3,087,832 | $ (2,587,832) | (84)% |
| Research and development | 4,946,304 | 2,511,438 | 2,434,866 | 97 % |
| General and administrative | 6,052,556 | 1,834,645 | 4,217,911 | 230 % |
| Loss from operations | (11,498,860) | (7,433,915) | (4,064,945) | 55 % |
| Interest income (expense), net | 219,405 | (64,555) | 283,960 | (440)% |
| Change in fair value of convertible promissory notes | — | 9,317 | (9,317) | (100)% |
| Other income | 297 | 124,148 | (123,851) | (100)% |
| Net loss | $ (11,279,158) | $ (7,365,005) | $ (3,914,153) | 53 % |

*Acquired In-Process Research and Development Expenses*

Acquired in-process research and development expense 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 collaboration and licensing agreement with Integral for the development of CLDN6 BsAb.

Acquired in-process research and development expense of $3.1 million for the nine months ended September 30, 2021 reflects the fair value of the initial consideration paid/issued under the collaboration and licensing agreement with Integral for the development of CLDN6 BsAb.

*Research and Development Expenses*

Research and development expenses increased by approximately $2.4 million for the nine months ended September 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the nine months ended September 30, 2022 as compared to the same period in 2021:

| | Nine months ended September 30, | | | |
|---|---|---|---|---|
| | **2022** | **2021** | **$ Change** | **% Change** |
| ONA-XR expenses | $ 3,283,887 | $ 1,423,277 | $ 1,860,610 | 131 % |
| CLDN6 expenses | 452,646 | 523,462 | (70,816) | (14)% |
| Personnel-related costs | 1,101,291 | 545,583 | 555,708 | 102 % |
| Other research and development | 108,480 | 19,116 | 89,364 | 467 % |
| | $ 4,946,304 | $ 2,511,438 | $ 2,434,866 | 97 % |

The increase in ONA-XR expenses of $1.9 million was primarily due to an increase of $1.1 million in contract manufacturing costs and an increase of $0.5 million in clinical trial costs, mostly as a result of preparing to initiate our Phase

1b/2 ELONA trial. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.6 million, primarily due to higher headcount over the prior year period.

*General and Administrative Expenses*

General and administrative expenses increased by approximately $4.2 million for the nine months ended September 30, 2022 as compared to the same period in 2021. The increase was mainly due to an increase of $1.8 million in compensation and share-based compensation as a result of an increase in our general and administrative headcount and changes to compensation arrangements. Additionally, expenses increased due to higher insurance costs of $1.3 million and $0.9 million of other costs associated with operating as a public company.

*Interest Income (Expense), net*

Interest income (expense), net, increased by approximately $0.3 million for the nine months ended September 30, 2022 as compared to the same period in 2021 primarily due to higher interest income earned as a result of higher cash and cash equivalent balances and higher interest rates. In addition, interest expense was lower for the nine months ended September 30, 2022 due to the conversion of all convertible promissory notes during 2021.

*Change in Fair Value of Convertible Promissory Notes*

The change in fair value of convertible promissory notes was $9,317 for the nine months ended September 30, 2021. This change was attributable to a decrease in the fair value of our common stock.

*Other Income*

Other income of $0.1 million for the nine months ended September 30, 2021 was primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

**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, 2022, we have funded our operations through the sale of convertible debt, convertible preferred stock and common stock. As of September 30, 2022, we had $39.4 million in cash and cash equivalents and had an accumulated deficit of $40.5 million.

In October 2021, we closed an IPO on the Nasdaq Stock Market, in which we issued and sold 5,750,000 shares at a public offering price of $5.00 per share. We received gross proceeds of approximately $28.8 million as a result of the offering. In December 2021, we sold 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock in a private placement for gross proceeds of approximately $31.3 million. We expect our existing cash and cash equivalents will be sufficient to fund our operations into the first quarter of 2024. 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 product candidates;

- the costs of manufacturing our product candidates for clinical trials and in preparation for regulatory approval and commercialization;
- the extent to which we enter into additional collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- 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 any of our product candidates for which we receive regulatory approval; and
- revenue, if any, received from commercial sales of our 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, | |
|---|---|---|
| | **2022** | **2021** |
| Cash used in operating activities | $ (9,619,561) | $ (3,837,803) |
| Cash used in investing activities | (536,836) | (250,000) |
| Cash (used in) provided by financing activities | (102,071) | 4,165,918 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (10,258,468) | $ 78,115 |

***Comparison of the Nine Months Ended September 30, 2022 and 2021***

*Operating Activities*

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.

During the nine months ended September 30, 2021, we used $3.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of $7.4 million, a gain of $0.1 million from the extinguishment of debt and an increase in our operating assets and liabilities of $0.2 million. This was offset by non-cash in-process research and development charges of $3.1 million, the non-cash fair value measurement of warrants for services of $0.4 million and non-cash interest expense and share-based compensation of $0.4 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

*Investing Activities*

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

During the nine months ended September 30, 2021, cash used in investing activities was attributable to the initial upfront license fee of $0.3 million related to our acquired in-process research and development.

*Financing Activities*

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.

During the nine months ended September 30, 2021, financing activities provided $4.2 million, primarily consisting of net proceeds of $5.0 million from the sale of Series A preferred stock and warrants for common stock, partially offset by the payment of $0.8 million of offering costs related to our IPO.

**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, 2022, 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, 2021, as filed with the SEC on March 23, 2022.

**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 Jumpstart Our Business Startups Act of 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.

We also rely on other exemptions and reduced reporting requirements under the JOBS Act, including without limitation, exemption from the requirements to provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of our IPO (December 31, 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 either (a) the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company until 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, 2022, 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, 2022 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, 2021, filed with the SEC on March 23, 2022. Other than 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 passage of the Inflation Reduction Act of 2022 may negatively impact our ability to sell our product candidates, if approved, profitably.**

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

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

None.

### Item 3. Defaults upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

Because we are filing this Quarterly Report on Form 10-Q within four business days after the triggering event, we are making the following disclosure under this Item 5 instead of filing a Current Report on Form 8-K under Item 1.01, Entry into a Material Definitive Agreement:

Development and Manufacturing Services Agreement

On November 7, 2022, Context Therapeutics Inc. (the “Company”) entered into a Development and Manufacturing Services Agreement (the “Lonza Development Agreement”), with Lonza Sales AG (“Lonza Sales”) and Lonza AG (collectively, “Lonza”). Under the terms of the Lonza Development Agreement, Lonza will provide services relating to the development and manufacture of the Company’s anti-claudin 6 bispecific monoclonal antibody product (the “Product”) in accordance with the project plan attached to the Lonza Development Agreement and any other work as may be agreed to between the Company and Lonza. The Lonza Development Agreement will terminate upon the completion of the agreed upon

services, unless earlier terminated by the Company or Lonza for uncured material breaches, insolvency of the other party, or if a party determines that it is not possible to complete the services for material scientific or material technical reasons.

The Company can terminate certain services under the Lonza Development Agreement, but in addition to payment for certain non-cancellable commitments, the Company would be required to pay a cancellation fee, such fee to be determined depending on the timing of such notice prior to the commencement of the related services.

The License Development Agreement requires the Company to obtain a license from Lonza prior to receipt of the Product or in vivo clinical studies or any other commercial use or sale of the Product, which the Company entered into concurrently with the License Development Agreement, as further described below. Additionally, should the Company desire to either manufacture the Product itself or have it manufactured by a third party, the Company would be required to obtain Lonza's consent (not to be unreasonably withheld, conditioned or delayed) and would need to enter into a separate technology transfer agreement with Lonza for a non-exclusive license to the extent necessary to manufacture, have manufactured and supply the Product at a licensing fee up to £750,000.

The Lonza Development Agreement also contains customary representations, warranties, indemnification and other obligations of the Company and Lonza.

License Agreement

On November 7, 2022, the Company entered into a License Agreement (the "Lonza License Agreement") with Lonza Sales. Under the terms of the Lonza License Agreement, to the extent incorporated into the Product, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit the Product.

The Company shall pay certain royalties and annual payments in respect of the manufacturing and sale of Product, which amounts shall be determined by the party manufacturing the Product and ranges from a potential annual payment of up to less than $500,000 and a royalty on net sales from 0% up to a low single digit percentage. The royalty payments and annual payments would be reduced in certain circumstances, including should the valid claims for any such patent rights not exist in the country in which such Product is being sold, and the royalty payments would expire upon the later of the expiration of the licensed patents in the country in which such Product is being sold, the expiration of the licensed patents in the country in which such Product is being manufactured, and ten years from the first commercial sales of the Product in such country of sale.

The Lonza License Agreement continues until terminated, and the Company or Lonza may terminate the Lonza License Agreement for uncured material breaches or insolvency of the other party. The Company can unilaterally terminate the Lonza License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza License Agreement upon certain actions by the Company.

The Lonza License Agreement also contains customary representations, warranties, indemnification and other obligations of the Company and Lonza.

The foregoing description of the Lonza Development Agreement and Lonza License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Lonza Development Agreement and Lonza License Agreement, which will be filed as exhibits to a subsequent filing with the Securities and Exchange Commission (the "Commission"), as permitted by the rules of the Commission.

**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). |
| 10.1# | Clinical Trial Collaboration and Supply Agreement, dated August 1, 2022, by and between Context Therapeutics Inc. and Berlin-Chemie AG - Menarini Group (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on August 11, 2022). |
| 10.2* | Amendment No. 3 to Process Development Agreement & Amendment No. 1 to License, Development, Manufacturing & Marketing Agreement, dated November 7, 2022, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited. |
| 10.3*# | Development and Manufacturing Services Agreement, dated November 7, 2022, between Lonza Sales AG, Lonza AG and Context Therapeutics Inc. |
| 10.4*# | License Agreement, dated November 7, 2022, between Lonza Sales AG and Context Therapeutics Inc. |
| 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, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statement of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Deficit; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to the Condensed Consolidated Financial Statements. |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 hereto) |

* Filed herewith
# Certain confidential information contained in this agreement has been omitted because it is both not material and is the type that the registrant treats as private or confidential

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

**SIGNATURES**

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

Date: November 9, 2022

**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)