Context Therapeutics Reports Full Year 2022 Financial Results and Recent Pipeline Updates

March 22, 2023

Company prioritizing pipeline to focus on CTIM-76 development and discontinuing ONA-XR program

Cash runway extended into late 2024

CTIM-76 preclinical data to be presented at AACR Annual Meeting 2023

PHILADELPHIA, March 22, 2023 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a biopharmaceutical company developing novel treatments for solid tumors, today announced financial results for the year ended December 31, 2022. Additionally, the Company announced a portfolio prioritization and capital allocation strategy that is expected to extend its cash runway into late 2024. The resulting changes include discontinuing the development of onapristone extended release (ONA-XR) and focusing on the development of CTIM-76, its Claudin 6 (CLDN6) bispecific antibody clinical candidate.

“Given the challenging market conditions for emerging companies, the increasingly competitive landscape for breast cancer treatments, and recent study findings, we have decided to discontinue the development of ONA-XR,” said Martin Lehr, CEO of Context. “We are shifting our development focus to our compelling preclinical asset CTIM-76, a CLDN6 x CD3 bispecific antibody. Additionally, we’re pleased that preclinical data regarding CTIM-76 will be presented at the upcoming American Association for Cancer Research (AACR) Annual Meeting 2023 in April and look forward to hosting an investor R&D webinar on the data following that presentation.”

Context ended the fourth quarter of 2022 with approximately $35.5 million in cash and cash equivalents. Based on its pipeline prioritization and related expense reduction, the Company expects to have sufficient financial resources to fund CTIM-76 beyond the filing of its Investigational New Drug (IND) Application, which is expected to occur in Q1 2024. The Company does not anticipate any headcount reductions related to its portfolio prioritization.

CTIM-76 Program Overview

There is a large unmet need for targeted therapies to treat solid tumors. CTIM-76 is a CLDN6 x CD3 bispecific antibody that simultaneously binds to CLDN6 expressing cancer cells and CD3 expressing immune T cells. In this manner, CTIM-76 functions as an immunotherapy that recruits a patient’s own immune system to attack cancer cells. CLDN6 is a developmental gene that is required for cell growth and that is silenced after birth. Some cancers, including ovarian, lung, and testicular, reactivate this developmental gene to promote cancer cell growth and survival. Therefore, therapeutic inhibition of CLDN6 via CTIM-76 immunotherapy may restrict the growth of CLDN6-positive cancer cells. Preclinical studies suggest the potential for convenient dosing and scalable manufacturing to address the significant number of patients who have CLDN6-positive disease.

ONA-XR Recent Study Findings

In the ongoing Phase 2 OATH trial evaluating ONA-XR in combination with anastrozole, elevated liver function tests (LFT) were identified in three patients, including in one patient who discontinued treatment, although none of the elevated LFTs were considered serious adverse events. The Company determined that significant incremental program costs and delays were likely to be required to analyze and potentially mitigate future LFT abnormalities. Based upon the challenging market conditions for emerging companies, the increasingly competitive landscape for breast cancer treatments, recent study findings, and other factors, the Company decided to cease development and explore strategic options for ONA-XR. As a result, the Company will no longer primarily focus on female cancers.

Strategy and Recent Pipeline Updates

- In March 2023, announced research regarding CTIM-76 will be presented on Monday, April 17 at 9 a.m. ET at the AACR Annual Meeting 2023, taking place April 14-19 in Orlando, FL. Details about the presentations can be found here. Additionally on April 17 at 4:30 p.m. ET, Context will host an investor R&D webinar with the Company’s management team and AACR presenter to discuss the presentation. To register for this event, please click here.
- In January 2023, announced a collaboration with Lonza, a global development and manufacturing partner to the pharma, biotech, and nutrition industries, to manufacture CTIM-76, Context’s clinical development candidate. CTIM-76 is a CLDN6 x CD3 T-cell engaging bispecific antibody targeting CLDN6-positive tumors.
- In November 2022, announced the selection of CTIM-76 as the Company’s lead clinical development candidate to target CLDN6-positive cancers, resulting from Context’s research collaboration and licensing agreement with Integral Molecular. IND-enabling studies have been initiated and Context expects to submit an IND Application to support human clinical trials for CTIM-76 in Q1 2024.

Full Year 2022 Financial Results

- Cash, cash equivalents, and restricted cash were $35.5 million at December 31, 2022, compared to $49.7 million at December 31, 2021.
- Acquired in-process research and development expense was $0.5 million for 2022, as compared to $3.1 million for the same period in 2021. The 2022 expense was due to a development milestone achieved under our collaboration and

license agreement with Integral Molecular for the development of CTIM-76, while the 2021 expense reflects the fair value of consideration paid/equity issued under that same agreement.

- Research and development (R&D) expenses were $7.1 million for 2022, as compared to $3.8 million for the same period in 2021. The increase in R&D expenses was primarily driven by higher contract manufacturing costs and clinical trial costs related to our ONA-XR program and increased preclinical costs for CTIM-76.
- General and administrative (G&A) expenses were $7.8 million for 2022, as compared to $3.6 million for the same period in 2021. The increase in G&A expenses was primarily due to higher employee compensation expense as a result of an increase in headcount and changes to compensation arrangements, as well as higher insurance and professional fees to support ongoing business operations and compliance obligations associated with being a publicly traded company.
- Context reported a net loss of $14.8 million for 2022, as compared to $10.5 million for the same period in 2021.

2023 Cash Guidance
The Company expects its cash and cash equivalents will be sufficient to fund its operations into late 2024.

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a biopharmaceutical company committed to advancing medicines for solid tumors. Context is developing CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6-positive tumors, currently in preclinical development. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on Twitter and LinkedIn.

Forward-looking Statements
This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the ability of the Company, its employees and certain AACR presenters to participate in and present at conferences and webinars, (ii) the expectation to have an IND submission for CTIM-76 in the first quarter of 2024, (iii) having sufficient cash to fund our current operations into late 2024, (iv) the intention to cease development and explore strategic options for ONA-XR, (v) the intention to no longer primarily focus on female cancers, (vi) the expectation that there will be no headcount reductions related to our portfolio prioritization, (vii) the timing, enrollment and results of our clinical trials, (viii) the potential benefits and side effect profile of our product candidates, (ix) the likelihood data will support future development, and (x) the likelihood of obtaining regulatory approval of our product candidates. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Context Therapeutics Inc.
Condensed Statements of Operations
(Unaudited)

	Year Ended December 31,	
	2022	**2021**
Operating Expenses		
Acquired in-process research and development	$ 500,000	$ 3,087,832
Research and development	7,091,163	3,805,067
General and administrative	7,790,040	3,632,920
Loss from operations	(15,381,203)	(10,525,819)
Other income (expense), net	545,264	68,949
Net loss	$ (14,835,939)	$ (10,456,870)
Net loss per common share, basic and diluted	($0.93)	($3.69)
Weighted average shares outstanding, basic and diluted	15,966,053	2,833,674

Context Therapeutics Inc.
Condensed Balance Sheets Data
(Unaudited)

	December 31, 2022	December 31, 2021

Cash, cash equivalents and restricted cash	$ 35,497,445	$ 49,685,586
Other assets	2,468,498	1,620,164
Total assets	$ 37,965,943	$ 51,305,750
Total liabilities	$ 3,207,577	$ 3,033,415
Total stockholders' equity	34,758,366	48,272,335
Total liabilities and stockholders' equity	$ 37,965,943	$ 51,305,750

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