



Context Therapeutics® Reports Second Quarter 2022 Operating and Financial Results

August 11, 2022

Announced new clinical trial collaboration with Menarini Group to evaluate ONA-XR plus elacestrant in metastatic breast cancer

Results of the monotherapy portion of Phase 2 ONA-XR clinical trial in granulosa cell tumors of the ovary presented at the 2022 ASCO Annual Meeting

Preliminary results from multiple clinical trials planned for Q4 2022

On track for development candidate selection of CLDN6xCD3 bispecific in Q4 2022

PHILADELPHIA, Aug. 11, 2022 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a women's oncology company developing novel treatments for breast and gynecological cancers, today announced financial results for the second quarter ended June 30, 2022, and highlighted recent corporate accomplishments.

"During the second quarter, Context continued to advance its two pipeline programs, onapristone extended release ("ONA-XR") and Claudin 6 x CD3 ("CLDN6xCD3") bispecific antibody. We are encouraged by the data from the initial phase of our ongoing Phase 2 clinical trial of ONA-XR in granulosa cell tumors ("GCT") of the ovary presented at the 2022 American Society of Clinical Oncology ("ASCO") Annual Meeting and enrollment continues for the second portion of the trial evaluating the combination of ONA-XR with an oral antiestrogen," said Martin Lehr, CEO of Context Therapeutics.

Lehr continued, "Context recently announced its Clinical Trial Collaboration and Supply Agreement with The Menarini Group ("Menarini") for a Phase 1b/2 ELONA trial evaluating ONA-XR in combination with Menarini's oral selective estrogen receptor degrader ("SERD"), elacestrant, in ER+, PR+, HER2- metastatic breast cancer ("mBCa") patients who have previously been treated with a CDK4/6 inhibitor. The ELONA trial is expected to initiate in the fourth quarter of this year. Additionally, Context's CLDN6xCD3 bispecific antibody program continues to advance as the program achieved its first development milestone under Context's collaboration and license agreement with Integral Molecular. Looking ahead, we anticipate reporting initial data from three of our ongoing ONA-XR Phase 2 clinical studies in the fourth quarter of this year and remain on track to announce the selection of our CLDN6xCD3 candidate by year-end, bringing us closer to realizing the potential of our pipeline to transform how female cancers are treated."

Second Quarter 2022 and Recent Corporate Highlights

Pipeline Updates

- In June 2022, results of the monotherapy portion of an ongoing Phase 2 trial of ONA-XR in GCT of the ovary were presented at the 2022 ASCO Annual Meeting. The results showed that ONA-XR was well tolerated and exhibited a 12-month progression-free survival rate of 20.1% and a clinical benefit rate of 35.7% in patients with GCT. The abstract can be viewed [here](#). Enrollment continues for the second stage of the clinical trial which will evaluate the combination of ONA-XR with an oral antiestrogen. Additional details on the clinical trial can be found at <http://www.clinicaltrials.gov> using the identifier [NCT03909152](https://clinicaltrials.gov/ct2/show/study/NCT03909152).
- Enrollment continues in the Phase 2 clinical trials of ONA-XR – [second or third line \(2L/3L\) ER+, PR+, HER2- mBCa](#), [PR+ recurrent granulosa cell tumor of the ovary](#), and [PR+ recurrent endometrial cancer](#) – and Context expects to report preliminary data from all three trials in the fourth quarter of this year.
- Enrollment continues in the Phase 1b/2 clinical trial of ONA-XR in [first line \(1L\) ER+, PR+, HER2- mBCa](#) and, primarily due to slower than anticipated patient enrollment, Context currently expects to report preliminary data from the Phase 1b portion of the trial in mid 2023.

Corporate Updates

- In August 2022, announced that Context entered into a Clinical Trial Collaboration and Supply Agreement with Menarini for its oral SERD, elacestrant. This agreement will support the upcoming ELONA trial, a Phase 1b/2 clinical proof-of-concept trial that will evaluate ONA-XR in combination with elacestrant in ER+, PR+, HER2- mBCa patients who have previously been treated with a CDK4/6 inhibitor. Context expects to initiate the ELONA trial in the fourth quarter of this year.

Second Quarter Financial Results

- Cash, cash equivalents, and restricted cash were \$42.9 million at June 30, 2022, compared to \$49.7 million at December 31, 2021.
- Acquired in-process research and development (IPR&D) expense was \$0.5 million for the second quarter 2022, as compared to \$3.1 million for the same period in 2021. The second quarter 2022 expense was due to a development milestone achieved under the collaboration and license agreement with Integral Molecular, while the second quarter 2021 expense reflects the fair value of the initial consideration paid/issued under that same agreement.
- Research and development (R&D) expenses were \$1.5 million for second quarter 2022, as compared to \$1.3 million for

the same period in 2021. The increase in R&D expenses was primarily driven by increased ONA-XR contract manufacturing and clinical costs and an increase in salaries and related benefits due to a higher employee headcount, offset by lower CLDN6 preclinical costs.

- General and administrative (G&A) expenses were \$2.0 million for second quarter 2022, as compared to \$0.6 million for the same period in 2021. The increase in G&A expenses was primarily driven by increased salaries and related benefits due to a higher employee headcount, 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 \$4.0 million for second quarter 2022, as compared to \$5.0 million for the same period in 2021.

2022 Financial Guidance

Context expects that its cash and cash equivalents will be sufficient to fund its operations into the fourth quarter of 2023.

About Context Therapeutics®

Context Therapeutics Inc. (Nasdaq: CNTX) is a clinical-stage biopharmaceutical company committed to advancing medicines for female cancers. The Company's pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Onapristone extended release (ONA-XR), a novel, first-in-class potent and selective progesterone receptor antagonist, is currently in three Phase 2 trials and one Phase 1/2 trial in hormone-driven breast, ovarian, and endometrial cancers. Context and The Menarini Group have also entered a Clinical Trial Collaboration and Supply Agreement for a Phase 1b/2 clinical proof-of-concept trial evaluating ONA-XR in combination with Menarini's oral selective estrogen receptor degrader (SERD), elacestrant. Context is also developing 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 expectation to report preliminary data from our currently ongoing clinical trials in fourth quarter 2022 and in mid-2023, (ii) the expectation to select a development candidate for our CLDN6xCD3 program before the end of 2022, (iii) the expectation to initiate the combination study of ONA-XR and elacestrant in the fourth quarter of 2022, (iv) having sufficient cash to fund our operations into the fourth quarter 2023, (v) the results of our clinical trials, (vi) the potential benefits of the product candidates, (vii) the likelihood data will support future development, and (viii) 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating Expenses:				
Acquired in-process research and development	\$ 500,000	\$ 3,087,832	\$ 500,000	\$ 3,087,832
Research and development	1,517,243	1,333,101	2,868,738	1,771,840
General and administrative	1,990,568	604,602	4,082,035	1,006,181
Loss from operations	(4,007,811)	(5,025,535)	(7,450,773)	(5,865,853)
Other income (expense), net	21,300	(4,629)	25,925	(56,360)
Net loss	<u>\$ (3,986,511)</u>	<u>\$ (5,030,164)</u>	<u>\$ (7,424,848)</u>	<u>\$ (5,922,213)</u>
Net loss per common share, basic and diluted	\$ (0.25)	\$ (14.18)	\$ (0.47)	\$ (16.82)
Weighted average shares outstanding, basic and diluted	15,966,053	354,829	15,966,053	352,048

Context Therapeutics Inc. Condensed Balance Sheets Data (Unaudited)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Cash, cash equivalents and restricted cash	\$ 42,921,214	\$ 49,685,586
Other assets	1,775,579	1,620,164
Total assets	<u>\$ 44,696,793</u>	<u>\$ 51,305,750</u>
Total liabilities	\$ 3,047,494	\$ 3,033,415
Total stockholders' equity	41,649,299	48,272,335
Total liabilities and stockholders' equity	<u>\$ 44,696,793</u>	<u>\$ 51,305,750</u>

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