UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 7, 2022

Context Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-40654	86-3738787
(State of other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock $0.001 par value per share	**CNTX**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01. Regulation FD Disclosure.

On December 8, 2022, Context Therapeutics Inc. ("Context") issued a press release announcing preliminary Phase 2 data from the ongoing SMILE trial of onapristone extended release (ONA-XR), Context's novel, first-in-class, potent, orally administered progesterone receptor (PR) antagonist, in metastatic breast cancer. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 attached hereto are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On December 7, 2022, data was presented at the 2022 San Antonio Breast Cancer Symposium® (SABCS®) noting preliminary Phase 2 findings of the SMILE trial, highlighting a 4-month progression free survival (PFS) rate of 44%, and favorable safety and tolerability.

Item 9.01. Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Context Therapeutics Inc., dated December 8, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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

Dated: December 8, 2022

Context Therapeutics Inc.

By: /s/ Martin A. Lehr
Name: Martin A. Lehr
Title: Chief Executive Officer

Context Therapeutics® Reports Encouraging Preliminary Phase 2 Data for ONA-XR in Metastatic Breast Cancer

Data presented at San Antonio Breast Cancer Symposium® demonstrate preliminary 4-month PFS rate of 44% in ongoing Phase 2 trial in second- or third-line metastatic breast cancer

PFS follows recently disclosed positive preliminary data in ongoing Phase 2 endometrial cancer trial

PHILADELPHIA, PA— December 8, 2022—Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a women's oncology company developing novel treatments for breast and gynecologic cancers, announced preliminary Phase 2 data from the ongoing SMILE trial of onapristone extended release (ONA-XR), the company's novel, first-in-class, potent, orally administered progesterone receptor (PR) antagonist, in metastatic breast cancer.

Being conducted in collaboration with the Wisconsin Oncology Network, the Phase 2 SMILE trial is evaluating ONA-XR in combination with fulvestrant in patients with ER+, HER2- advanced or metastatic breast cancer who progressed on prior CDK4/6 inhibitor therapy. Preliminary Phase 2 findings highlight a 4-month progression free survival (PFS) rate of 44%, and favorable safety and tolerability. The data were presented at the 2022 San Antonio Breast Cancer Symposium® (SABCS®).

Also at SABCS, an initial look at the trial design of the recently initiated ELONA Phase 1b/2 clinical trial evaluating the combination of ONA-XR with The Menarini Group's oral selective estrogen degrader, elacestrant, in patients with second- or third-line advanced or metastatic ER+, PR+, HER2- breast cancer was presented. Data from the Phase 1b portion of the trial is expected in Q4 2023.

"We are pleased to be building a robust package of data supporting the safety and tolerability of ONA-XR and its potentially meaningful improvement over single agent standards of care," said Martin Lehr, CEO of Context Therapeutics. "We're encouraged by the improvement in preliminary PFS observed in the SMILE trial presented at SABCS this week, which is consistent with the significant improvement in PFS recently reported in the ongoing Phase 2 endometrial cancer trial. We look forward to the continued evaluation of ONA-XR across multiple ongoing breast cancer clinical trials, including the SMILE and ELONA trials."

The Company also recently announced preliminary Phase 2 findings for ONA-XR in combination with anastrozole in progesterone receptor-positive (PR+) metastatic endometrial cancer, highlighting a 4-month PFS rate of 77% and favorable safety and tolerability.

"There is a clear unmet need in metastatic endometrial cancer for a therapeutic option after primary or secondary chemotherapy treatment that can meaningfully delay disease progression without debilitating side effects prior to the next round of cytotoxic therapy," said Lehr. "We believe that dual targeting of both the progesterone receptor and estrogen receptor at efficacious doses without dose limiting toxicities could potentially result in a competitive product profile for ONA-XR. It is our hope that ONA-XR will one day address this unmet need."

For additional clinical updates, read the Company's third quarter 2022 operating and financial results release.

About ONA-XR
ONA-XR (onapristone extended release) is a potent and specific antagonist of the progesterone receptor (PR) that is orally administered. Currently, there are no approved therapies that selectively target PR+ cancers. Preliminary preclinical and clinical data suggest that ONA-XR has anticancer activity by inhibiting progesterone receptor binding to chromatin, downregulating cancer stem cell mobilization and blocking immune evasion. ONA-XR is currently being evaluated in three Phase 2 clinical trials and one Phase 1b/2 clinical trial in PR+ breast, ovarian and endometrial cancers. ONA-XR is an investigational drug that has not been approved for marketing by any regulatory authority.

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 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancers. Context is also 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 expectation to report Phase 1b data for the ELONA trial in the fourth quarter of 2023, (ii) the results of our clinical trials, (iii) the potential benefits and side effect profile of our product candidates, (iv) the likelihood data will support future development, and (v) 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.

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