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): January 10, 2022

Context Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction of incorporation)

001-40654

86-3738787 (I.R.S. Employer Identification ?

3675 Market Street, Suite 200 Philadelphia, Pennsylvania 19104 (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	230.4	25)
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☐ 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))

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

Trading Name of exchange
Title of each class Symbol on which registered
Common Stock CNTX The Nasdag Stock Market

\$0.001 par value per share

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 \boxtimes

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 8.01. Other Events.

On January 10, 2022, Context Therapeutics Inc. updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibits. (d)

Exhibit No. Description
99.1 Context Therapeutics Inc. Corporate Presentation January 2022

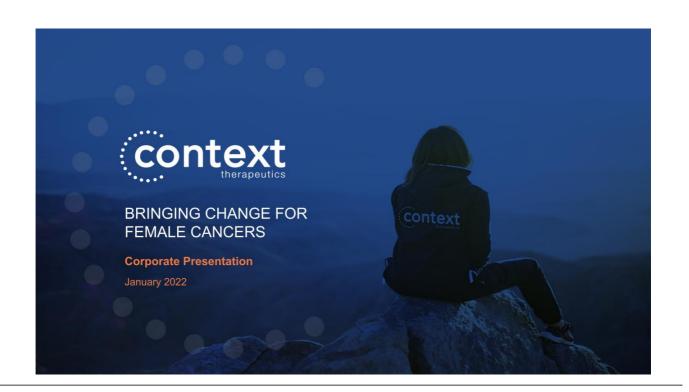
SIGNATURES

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: January 10, 2022

Context Therapeutics Inc.

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



Forward Looking Statement

Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects the Company's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "plan", "predict", "expect," "estimate," "anticipate," "intend," "goal," "strategy," "believe," "could", "would", "potential", "project", "continue" and similar expressions and variations thereof.

Forward-looking statements may include statements regarding the Company's business strategy, cash flows and funding status, potential growth opportunities, clinical development activities, the timing and results of preclinical research, clinical trials and potential regulatory approval and commercialization of product candidates.

Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in documents the Company has filed with the SEC. These forward-looking statements speak only as of the date of this presentation and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Certain information contained in this presentation may be derived from information provided by industry sources. The Company believes such information is accurate and that the sources from which it has been obtained are reliable. However, the Company cannot guarantee the accuracy of, and has not independently verified, such information.

Trademarks: The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

Company Highlights

Focus on Women's Oncology	→ Unmet clinical need in breast, ovarian, and endometrial cancers
Lead Asset: ONA-XR oral PR antagonist	 → Progesterone receptor (PR) oncogenic signaling is associated with breast, ovarian, and endometrial cancer¹ → Onapristone is a progesterone receptor (PR) antagonist that suppresses PR oncogenic signaling² → Onapristone extended release (ONA-XR) is a proprietary, oral, extended-release form of onapristone → ONA-XR has been administered in over 128 subjects-to-date → ONA-XR being evaluated in four ongoing mid-stage clinical trials
Second Asset: CLDN6 x CD3 bispecific antibody	 → Claudin 6 (CLDN6) is a protein expressed in ovarian and endometrial cancer, but not in normal adult tissues → Developing a highly selective CLDN6 x CD3 bispecific antibody
Path Forward	 → Multiple clinical inflection points in 2022 → Cash runway into 2024

3 Nasdaq: CNTX

(1) Chiebowski, JAMA, 2010; Daniel, Oncogene, 2015 (2) Knutson, J Hem & Onc, 2017

Pipeline

Cancer	Clinical Indication	Research Phase 1	Phase 2	Phase 3	Upcoming Milestones	FDA Fast Track
ONA-XR (PR antagonist) ¹						
Breast	1L ER+,PR+,HER2- ctDNA ^{high}	Phase 1b/2 Trial			Phase 1b data Mid 2022	
Cancer	2L/3L ER+,PR+,HER2- Post-CDK4/6 inhibitor	Phase 2 Trial			Preliminary data 2H 2022	
Ovarian Cancer	Recurrent PR+ Granulosa Cell	Phase 2 Trial			Preliminary data 2H 2022	\oslash
Endometrial Cancer	Recurrent PR+ Endometrioid	Phase 2 Trial			Preliminary data Mid 2022	
CLDN6xCD3 b	ispecific antibody					
	Ovarian & Endometrial Cancer				IND enabling studies 2022	
4 Nasdaq: CNTX (1) Tyligand Biosciences Ltd licensed rights to ONA-XR in China, Hk						China, HK, Macau

Market Opportunity

- · We target large, underserved markets
- · Within the G7 countries, over 362,000 patients are living with metastatic breast, ovarian, or endometrial cancer

Prevalence of Metastatic Female Hormone-Driven Cancers in G7 Countries (EU5, Japan, US)



5 Nasdaq: CNTX

*Source: secondary epidemiologic estimates, 2020 estimates

Experienced Team









ReedSmith



Evan Dick, PhD SVP R&D



aclaris

C CEPTARIS

CEPTION





KPMG





Mark Fletcher, PhD









Focus on Execution

- We believe that clinical development of ONA-XR is primarily a function of exacting clinical execution
- Our CMO led the clinical development of multiple blockbuster drugs for female cancers, including Kisqali, Arimidex, and Afinitor
- Our management team is supported by a Board with strong public company operating and governance experience



Tarek Sahmoud, MD, PhD Chief Medical Officer









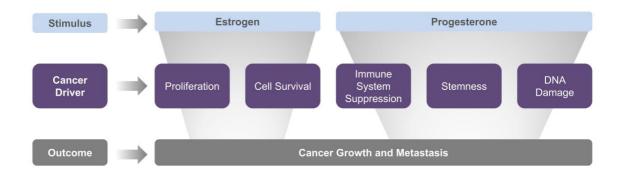


Onapristone Extended Release (ONA-XR)

Mechanism of Action	 → Onapristone is a progesterone receptor (PR) antagonist that suppresses PR oncogenic signaling → PR oncogenic signaling is associated with breast, ovarian, and endometrial cancer → Onapristone is the only known clinical-stage full PR antagonist
Market Opportunity	 → Breast, ovarian, and endometrial cancers are large and growing markets → Up to 70% of these cancer patients have progesterone receptor positive disease
Dosing and Administration	 → ONA-XR is an extended-release (XR) tablet form of onapristone (ONA) → 50 mg tablets administered orally twice per day
Focus on Clinical Execution	 → ONA-XR has been administered in over 128 subjects-to-date → ONA-XR is currently the subject of three ongoing Phase 2 trials and one ongoing Phase 1b/2 trial → Preliminary clinical data in 2022, with more advanced data in 2023
Intellectual Property	→ IP protection through at least 2034

Clinical Development Strategy

Blocking cancer growth by combining antiestrogen and antiprogestin therapies



ONA-XR Evaluation in Breast Cancer Trials

Treatment Line	Context Trial	Clinical Collaborator	Trial Status		Estimated Patients (US) ⁴	Standard of Care (SOC)	Medical Need
Adjuvant (after primary disease treatment)	Window of Opportunity ¹	SOLTI	Completed	\Rightarrow	>>250,000	Antiestrogen	Enhance antiestrogen potency
First-Line Metastatic	1L ER+,PR+,HER2- (ctDNA ^{high}) ²	Memorial Sloan Kettering Cancer Center.	Enrolling Patients	>	75,000	Antiestrogen + CDK4/6i	Treat patients who are at high risk of early progression
Second / Third Line Metastatic	2L/3L ER+,PR+,HER2- (post-CDK4/6i) ³	Carbone Cancer Center UNIVERSITY OF WISCORDS SCHOOL OF MEDICINE AND FULL FRAITH	Enrolling Patients	\Rightarrow	35,000	Fulvestrant or Fulvestrant + PI3Ka	Improve response rate and progression free survival

Developing ONA-XR as an Add-on to Antiestrogen Therapy Across Treatment Lines

10 Nasdaq: CNTX

(1) NCT04142892; (2) NCT04872608; (3) NCT04738292 (4) Source: secondary epidemiologic estimates, 2020 estimates

ONA-XR Evaluation in Gynecologic Trials

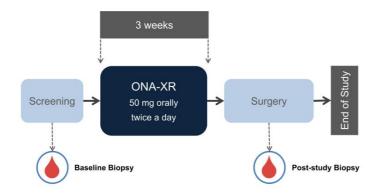
Cancer	Context Trial	Clinical Collaborator	Trial Status		Estimated Patients (US) ³	Standard of Care (SOC)	Medical Need
Recurrent Endometrial	Combination with Anastrozole in PR+ patients ¹	Jefferson	Enrolling Patients	→	25,000	Lenvima + Keytruda	Limited treatment options after recurrence
Recurrent Granulosa Cell Tumor of Ovary	Combination with Anastrozole in PR+ patients ²	Memorial Sloan Kettering Cancer Center	Monotherapy Phase Complete; Combination Study Enrolling Patients	→	5,000	Physician's Choice	No FDA approved products in recurrent setting

Developing ONA-XR as an Add-on to Antiestrogen Therapy Across Gynecologic Cancers

(1) NCT04719273; (2) NCT03909152 (3) Source: secondary epidemiologic estimates, 2020 estimates



Window of Opportunity Trial in Primary Breast Cancer



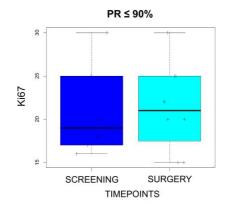
Key Eligibility Criteria

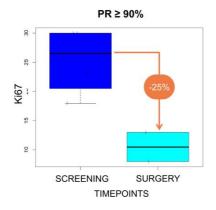
- Post-menopausal women
- Histologically confirmed invasive breast carcinoma
- PR+, ER+, HER2- as per local assessment
- Local Ki67 ≥15%

13 Nasdaq: CNTX

Bellet et al., San Antonio Breast Cancer Symposium 2021

High PR Expression Associated with Treatment Response





Post-ONA-XR reduction in cell proliferation marker

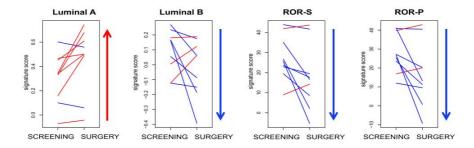
ONA-XR treatment response was seen in the high PR patient population

14 Nasdaq: CNTX

Ki67 = marker of cell proliferation Bellet et al., San Antonio Breast Cancer Symposium 2021

ONA-XR Shifted Tumors to a More Hormone-sensitive State

A post-treatment switch to a more hormone-sensitive phenotype was observed, as shown by the increase Luminal A score at surgery (post-3 weeks of ONA-RX) and risk of recurrence (ROR) scores



The shift implies an increased chance of tumor responsiveness to combined anti-estrogen and ONA-XR therapy

ROR-S: risk of recurrence based on gene expression; ROR-P: risk of recurrence based on tumor cell proliferation
Bellet et al., San Antonio Breast Cancer Symposium 2021



CLDN6 x CD3 Bispecific Antibody Program



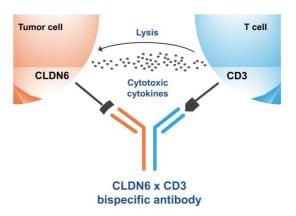
Claudin-6 is a tumor-specific protein in adults



Integrating Claudin-6 binding with the CD3 T-cell engager couples immunotherapy to tumor specific targeting



Opportunity to be 1st/2nd in market based on current competition



The bispecific antibody simultaneously binds to a CLDN6-expressing tumor cell and a cytotoxic T-cell. This brings the T-cell into proximity to the tumor cell. The T-cell, activated by CD3, releases cytotoxic cytokines that drive tumor cell death.

Competitive Landscape/Advantage

	Context	Xencor	BioNTech
Asset	Confidential	Confidential	BNT211
Format	CLDN6xCD3 Bispecific	CLDN6xCD3 Bispecific	CLDN6 CAR-T
Stage	Preclinical	Preclinical	Phase 1
Status	Active	Active	Active ²
Selectivity CLDN6:9	>100x	10x ¹	7x

- Based on internal studies and published data, Context anti-CLDN6 binding is at least 10x more selective vs. CLDN9 than competitive anti-CLDN6 mAbs and bispecifics
- CLDN6:CLDN9 binding selectivity is a critical safety factor for CLDN6targeted bispecific antibodies

Claudin 9 (CLDN9) is expressed in normal adult tissues, including the inner ear, olfactory epithelium, and pituitary gland. It is involved in hearing – a key reason for the importance of CLDN6:CLDN 9 selectivity.

The Company has performed head-to-head in vitro studies comparing BioNTech CLDN6 monoclonal antibodies. These antibodies were derived from publicly available reports published independent of the Company and may differ in material ways from the actual antibody that is in development.



Upcoming Milestones

ONA-XR	Q4 2021	1H 2022	2H 2022		
Breast – Window of Opportunity data presentation	❤				
Breast – mechanism of action data presentation					
Breast – 1L (ctDNA enriched) Phase 1b trial update					
Endometrial – Phase 2 trial update	•				
Breast – 2L/3L (post-CDK4/6) Phase 2 trial update					
Granulosa Cell – combination Phase 2 trial update					
Claudin 6	Q4 2021	1H 2022	2H 2022		
Preclinical update					

Investment Highlights



Large Unmet Need

Female Cancers



High Value Targets

Progesterone Receptor and Claudin 6



Near-Term Milestones

Multiple Data Readouts in 2022



Strong Team

Deep Domain Experience, Track Record of Success



Financial Strength

Expected cash runway into 2024

