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): August 1, 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. ☐

1

Item 1.01 Entry into a Material Definitive Agreement

On August 1, 2022, Context Therapeutics Inc. (the "Company"), entered into a Clinical Trial Collaboration and Supply Agreement (the "Agreement") with Berlin-Chemie AG - Menarini Group - ("Menarini"). Pursuant to the Agreement, Menarini will provide, at no cost to the Company, elacestrant, its nonsteroidal combined selective estrogen receptor modulator and selective estrogen receptor degrader therapy, for use in combination with the Company's investigational drug, onapristone extended-release ("ONA-XR"), in a planned Phase 1/2 clinical trial (the "Study"). Under the Agreement, the Company will sponsor, fund and conduct the Study. Under the Agreement, Menarini has agreed to manufacture and supply elacestrant at Menarini's cost and for no charge to the Company for use in the Study and to provide cfNA analysis of the anonymized blood samples of all Study patients. The Company will own any data and sample testing results produced in the Study. The Company and Menarini will jointly own any rights to inventions relating to the combined use of elacestrant and ONA-XR, while Menarini will own certain inventions solely related to elacestrant and the Company will own certain inventions solely related to ONA-XR. Additionally, should the Study be successful such that the Company or Menarini desires to pursue a Phase 3 study, the other party would be obligated to use commercially reasonable efforts to provide a reasonable supply of such study drug for a Phase 3 study at a reasonable cost. The Company and Menarini will form a joint development committee responsible for coordinating all activities between the parties under the Agreement. Additionally, should the Company receive a bona-fide third-party offer to sell, divest or license ONA-XR, the Company shall, subject to certain exceptions, inform Menarini of the receipt of an offer and, if Menarini timely provides proposed terms for such a transaction in writing, the Company shall consider such terms in good faith.

Until the earlier of (i) Study completion, (ii) the termination of the Study or the Agreement, (iii) the FDA providing a complete response letter ("CRL") to the application for approval for elacestrant that does not ultimately lead to approval of elacestrant within six (6) months of such initial CRL, or (iv) Menarini's breach of the terms of the Agreement, Context will not conduct a clinical trial in humans with an orally administered selective estrogen receptor degrader, other than elacestrant, in patients with advanced or metastatic estrogen receptor-positive, progesterone receptor-positive, HER2-negative breast cancer. The Agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) for safety reasons, (iii) should any regulatory authority take certain actions that suspend or terminate the Study or the other party's ability to provide its Study drug, or (iv) should either party reasonably believe that the Study data shows evidence of lack of efficacy and/or futility that is agreed to by the parties or confirmed by a third-party expert. Further, the Agreement may be terminated by the Company should the Study budget exceed or be anticipated to exceed the initial budget with the primary contract research organization engaged by Context to perform the Study and the Company reasonably determines not to cover the additional costs and expenses. Upon termination other than due to Menarini's material breach, the Company shall return or destroy all unused elacestrant. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

The foregoing is only a summary description of the terms of the Agreement, does not purpose to be complete and is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2022.

Item 7.01. Regulation FD Disclosure.

On August 2, 2022, the Company issued a press release announcing its execution of the Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. Additionally, on August 02, 2022, the Company updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01, and Exhibits 99.1 and 99.2 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 9.01. Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release issued by Context Therapeutics Inc., dated August 2, 2022.
99.2	Context Therapeutics Inc. Corporate Presentation - August 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: August 2, 2022

Context Therapeutics Inc.

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

Context Therapeutics and The Menarini Group Announce Clinical Trial Collaboration and Supply Agreement to Evaluate ONA-XR and Elacestrant Combination

Preclinical data support the potential of ONA-XR plus estrogen receptor degraders in endocrine resistant disease models

Context to initiate Phase 1b/2 clinical trial in Q4 2022

PHILADELPHIA, PA and FLORENCE, Italy— August 02, 2022—Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a women's oncology company developing small molecule and immunotherapy treatments for breast and gynecological cancers, and The Menarini Group ("Menarini") today announced a clinical trial collaboration and supply agreement for Menarini's oral selective estrogen receptor degrader (SERD), elacestrant.

This agreement will support the upcoming Phase 1b/2 ELONA clinical proof-of-concept trial evaluating onapristone extended release (ONA-XR), an oral progesterone receptor (PR) antagonist, in combination with elacestrant in estrogen receptor positive (ER+), PR+ HER2- metastatic breast cancer (mBC) patients who have previously been treated with a CDK4/6 inhibitor. Context will sponsor the clinical trial and Menarini will supply elacestrant at no cost.

According to the American Cancer Society, breast cancer is the second most common cancer among women occurring in 1 in 8 women (13%) over the course of a woman's lifetime, with ~280,000 new cases of invasive breast cancer and 51,400 cases of non-invasive breast cancer expected in 2022. Elacestrant is the first oral SERD to demonstrate a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus standard-of-care (SOC) endocrine therapy in a Phase 3 trial in patients with ER+, HER2- mBC, with 30% reduction in the risk of progression or death in all patients. Data also showed that 22% of patients were alive and progression-free at 12 months after elacestrant treatment initiation vs. 9% with SOC in the overall population. Therefore, elacestrant may become the new backbone endocrine therapy for ER+, HER2- mBC.

Preliminary data from preclinical studies suggest that a dual ER and PR blockade may be associated with enhanced tumor control. The ELONA clinical trial will be evaluating this important hypothesis.

"We are grateful to Menarini for their collaboration as we explore the therapeutic potential of adding ONA-XR, our oral PR antagonist, to elacestrant," said Tarek Sahmoud, MBBCh, Ph.D., Context's Chief Medical Officer. "We hope that this combination will further improve the clinical outcome in patients with ER+, PR+, HER2- mBC."
"ONA-XR's ability to restore hormone sensitivity and its tolerability profile positions it well for combination with elacestrant," said Nassir Habboubi, M.D., Menarini's Global Head of R&D.

Context anticipates initiating the Phase 1b/2 clinical trial in the fourth quarter of 2022. The two companies will form a joint committee to review results.

About Menarini Group

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for oncology, cardiology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

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 women's oncology company developing small molecule and immunotherapy treatments to transform care for breast and gynecological cancers. The Company's robust clinical program for lead candidate onapristone extended release (ONA-XR) comprises three Phase 2 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancer. ONA-XR is a novel, first-in-class small molecule under development as a potent and specific antagonist of the progesterone receptor, a key unchecked mechanism in hormone-driven women's cancers. Context is headquartered in Philadelphia, PA. For more information, visit www.contexttherapeutics.com.

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 timing to initiate, enroll, and obtain initial data for our clinical trials, (ii) the results of our clinical trials, (iii) the potential benefits of the product candidates, (iv) the likelihood data will support future development, and (v) the likelihood of obtaining regulatory approval of the 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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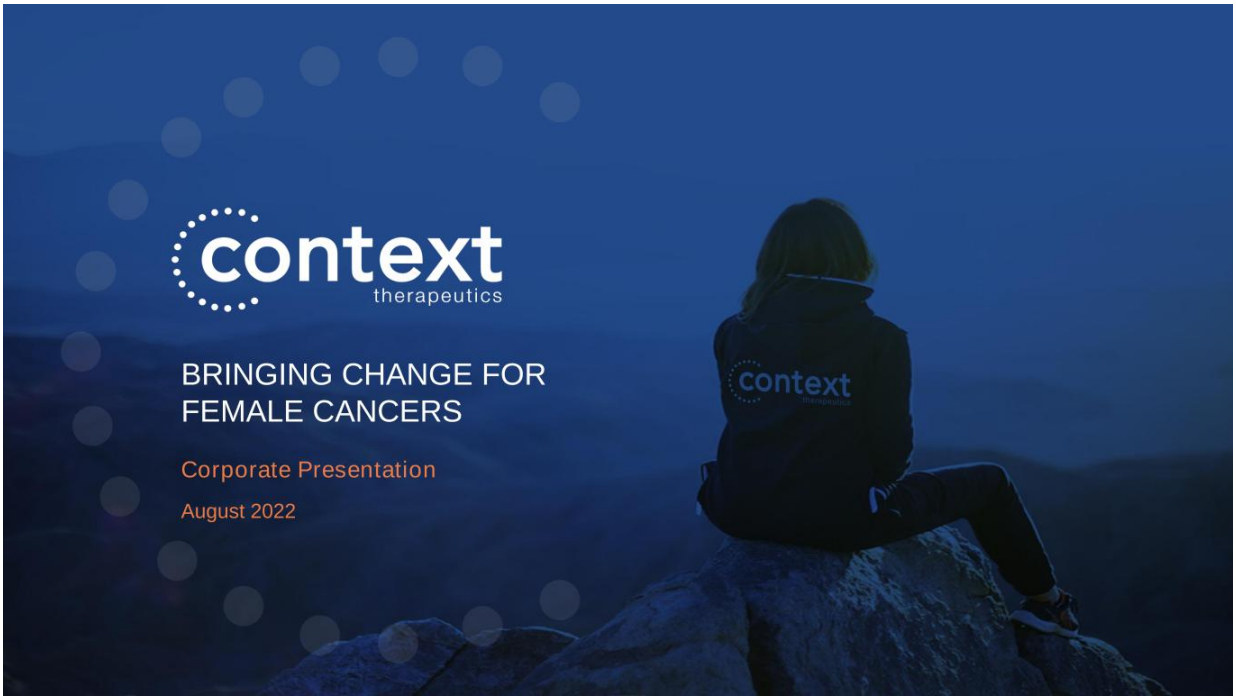
Context Therapeutics

Media Contact:
Gina Cestari
6 Degrees
917-797-7904
gcestari@6degreespr.com

Investor Relations Contact:
Laine Yonker
Edison Group
lyonker@edisongroup.com

Menarini Group

Media Contact:
Valeria Speroni Cardi
pressoffice@menarini.com


context
therapeutics
BRINGING CHANGE FOR
FEMALE CANCERS
Corporate Presentation
August 2022
context

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
Financial Strength	→ Expected cash runway into Q4 2023
ONA-XR oral PR antagonist	→ Progesterone receptor (PR) oncogenic signaling is associated with breast, ovarian, and endometrial cancer[1] → ONA-XR is a proprietary, oral, extended-release form of onapristone, a potent PR antagonist → ONA-XR is being evaluated in one Phase 1b/2 and three Phase 2 clinical trials → Announced Phase 1b/2 clinical trial with Menarini Group to evaluate elacestrant (oral SERD) plus ONA-XR
CLDN6 x CD3 bispecific antibody	→ Claudin 6 (CLDN6) is uniquely expressed in gynecologic, testicular, lung, and gastric cancers → Developing a highly selective CLDN6 x CD3 bispecific antibody → On track to announce Development Candidate in Q4 2022

(1) Chiebowski, JAMA, 2010; Daniel, Oncogene, 2015

Pipeline

Cancer	Clinical Indication	Research	Phase 1	Phase 2	Phase 3	Upcoming Milestones	FDA Fast Track
ONA-XR (PR antagonist)[1]							
Breast Cancer	1L ER+,PR+,HER2- ctDNA^{high}			Phase 1b/2 Trial		• Phase 1b data Mid 2023	
	2L/3L ER+,PR+,HER2- Combination w/ elacestrant			Phase 1b/2 Trial		• Initiate Q4 2022	
	2L/3L ER+,PR+,HER2- Combination w/ fulvestrant			Phase 2 Trial		• Preliminary data Q4 2022	
Ovarian Cancer	Recurrent PR+ Granulosa Cell			Phase 2 Trial		• Preliminary data Q4 2022	✓
Endometrial Cancer	Recurrent PR+ Endometrioid			Phase 2 Trial		• Preliminary data Q4 2022	
CLDN6xCD3 bispecific antibody							
	Ovarian & Endometrial Cancer					• Candidate selection Q4 2022	

(1) Tyligand Biosciences Ltd licensed rights to ONA-XR in China, HK, Macau

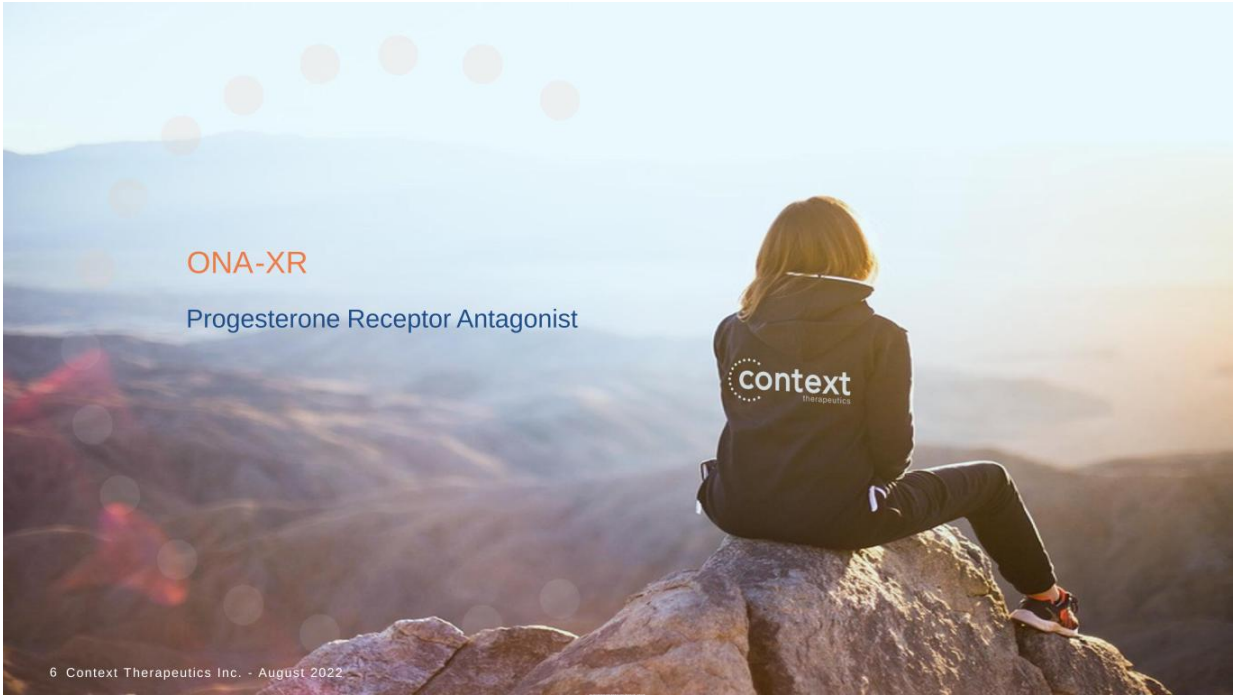
Progress Since IPO and Follow-on Use of Proceeds

Recent Announcements

- ONA-XR
  - Q3 2022: clinical trial collaboration with Menarini Group to evaluate elacestrant, an oral Selective Estrogen Receptor Degrader (SERD), plus ONA-XR
  - Q2 2022: three presentations at AACR highlighting potential of ONA-XR beyond anti-estrogen combination therapy
  - Q4 2021: window of opportunity trial data identifies markers of response and endocrine sensitivity
- CLDN6xCD3
  - Q2 2022: two presentations at AACR highlighting bispecific selectivity and T cell-mediated cytotoxicity

Upcoming 2022 Milestones

- ONA-XR
  - Initiate Phase 1b/2 combination trial with elacestrant
  - Prelim. data from Phase 2 trial in mBCa (post-CDK)
  - Prelim. data from Phase 2 trial in endometrial cancer
  - Prelim. data from Phase 2 trial in ovarian cancer
- CLDN6xCD3
  - Nominate development candidate

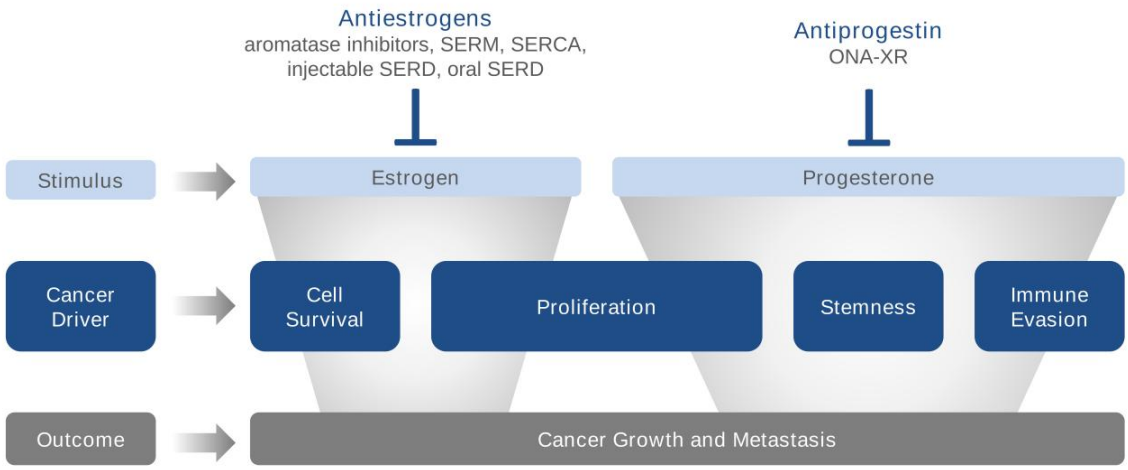

ONA-XR
Progesterone Receptor Antagonist
context
therapeutics

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 administered orally twice per day
Ongoing and Planned Clinical Trials	→ Drive enrollment in four ongoing clinical trials → Initiate Phase 1b/2 combination clinical trial to evaluate elacestrant (oral SERD) plus ONA-XR
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 Clinical Trials

Breast Cancer Treatment Line	Context Trial Design	Clinical Collaborator	Treatment	Trial Status	PR+ Patients (US)[1]	Medical Need
Adjuvant (after primary disease treatment)	Window of Opportunity	SOLTI	ONA-XR	Completed; Data presented at SABCS '21	>>250,000	Enhance antiestrogen potency
First-Line Metastatic	1L ER+,PR+,HER2- (ctDNA^{high})	Memorial Sloan Kettering Cancer Center	ONA-XR + Palbociclib + Letrozole	Enrolling patients	~56k	Treat patients who are at high risk of early progression
Second / Third Line Metastatic	2L/3L ER+,PR+,HER2- (post-CDK4/6i)	MENARINI group	ONA-XR + Elacestrant	Q4 initiation	~35k	Improve response rate and progression free survival
Second / Third Line Metastatic	2L/3L ER+,PR+,HER2- (post-CDK4/6i)	Carbone Cancer Center, University of Wisconsin School of Medicine and Public Health	ONA-XR + Fulvestrant	Enrolling patients	~35k	Improve response rate and progression free survival

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

(1) Secondary epidemiologic estimates, 2020 estimates

ONA-XR Evaluation in Gynecologic Clinical Trials

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

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

(1) Secondary epidemiologic estimates, 2020 estimates


Elacestrant + ONA-XR
Combination Clinical Trial
Clinical Trial Collaboration with Menarini Group
context
therapeutics
11 Context Therapeutics Inc. - August 2022

Rationale for Clinical Trial Collaboration

Clinical Trial Collaboration and Supply Agreement

- Phase 1b/2 study of ELacestrant in combination with ONApristone in patients with advanced or metastatic ER+,PR+,HER2- breast cancer (ELONA trial)
- Context will sponsor the clinical trial and Menarini Group will supply elacestrant at no cost
- Context and Menarini will form a Joint Development Committee to review the clinical trial results

MENARINI group

- Elacestrant is the first oral SERD to show positive Ph 3 top line results[1]
- Submitted NDA in June 2022

Elacestrant + ONA-XR

- Potential to enhance elacestrant clinical activity in metastatic breast cancer
- Establish clinical proof of concept for ONA-XR combination therapy with oral SERD class

context therapeutics

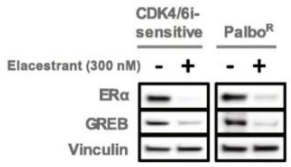
- ONA-XR is the most complete PR antagonist in clinical development[2]
- ONA-XR tolerability profile makes it a potentially ideal combination agent[3]
- Desire to clinically validate combination of ONA-XR with new oral SERDs

(1) "Positive EMERALD Trial Results for Elacestrant Presented at San Antonio Breast Cancer Symposium 2021." Menarini Group, 8 Dec. 2021. Press release
(2) Afhuppe, J. Steroid Biochem. Mol. Biol. 2009, 105; Afhuppe, J. Steroid Biochem. Mol. Biol. 2010, 45
(3) Lewis, J. Drug Safety 2020

Elacestrant: Potential to be 1st FDA Approved Oral SERD

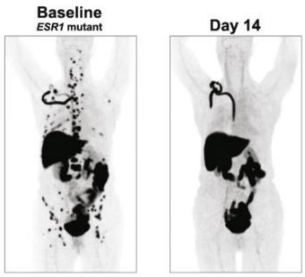
Strong efficacy/safety data across clinical trials

Selective ER Degrader[1] (SERD)



- Highly potent and selective oral SERD
- Active in models of treatment resistance

Positive PD Response[2]



- Selective for estrogen receptor
- Target engagement retained in ESR1 mutant

Ph 3 (EMERALD) Results[3]

	Elacestrant	Control
PFS	2.79 months	1.19 months
	HR=0.697; P = 0.0018	
PFS ESR1 mut	3.78 months	1.87 months
	HR=0.546; P=0.0005	
TEAE leading to discontinuation	6.3%	4.4%

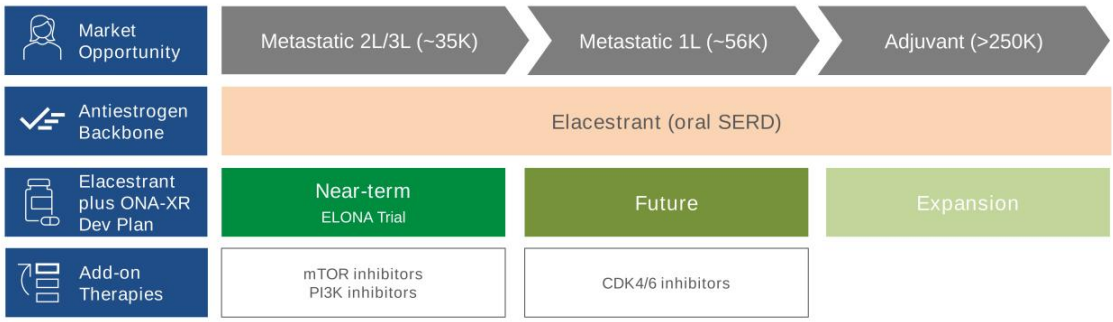
- Trial met both primary endpoints (PFS, PFS ESR1)
- First oral SERD to demonstrate higher efficacy than fulvestrant in a pivotal trial
- Well tolerated
- Can become standard of care in CDK4/6 inhibitor-resistant population

(1) Patel et al., Breast Cancer Research, 2019
(2) Jager et al., Breast Cancer Research, 2020
(3) Bardia, SABCS, 2021

Elacestrant + ONA-XR: Potential to Improve the Treatment of Breast Cancer

- Elacestrant is first oral SERD to show positive top line results in a Phase 3 clinical trial[1,2]
- If approved, elacestrant has the potential to become the antiestrogen standard of care
- When used in combination, ONA-XR may enhance elacestrant clinical activity both in ESR1 mutant and general population

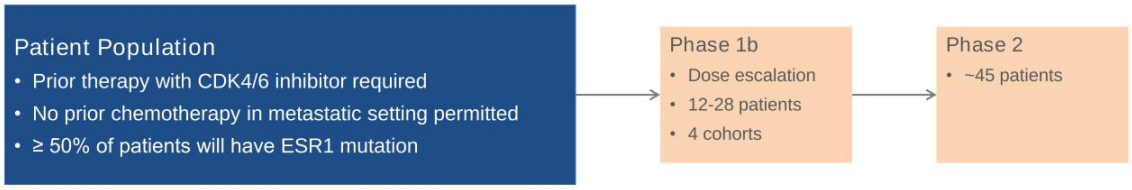
ER+,PR+,HER2- Breast Cancer Treatment Landscape in United States[3]

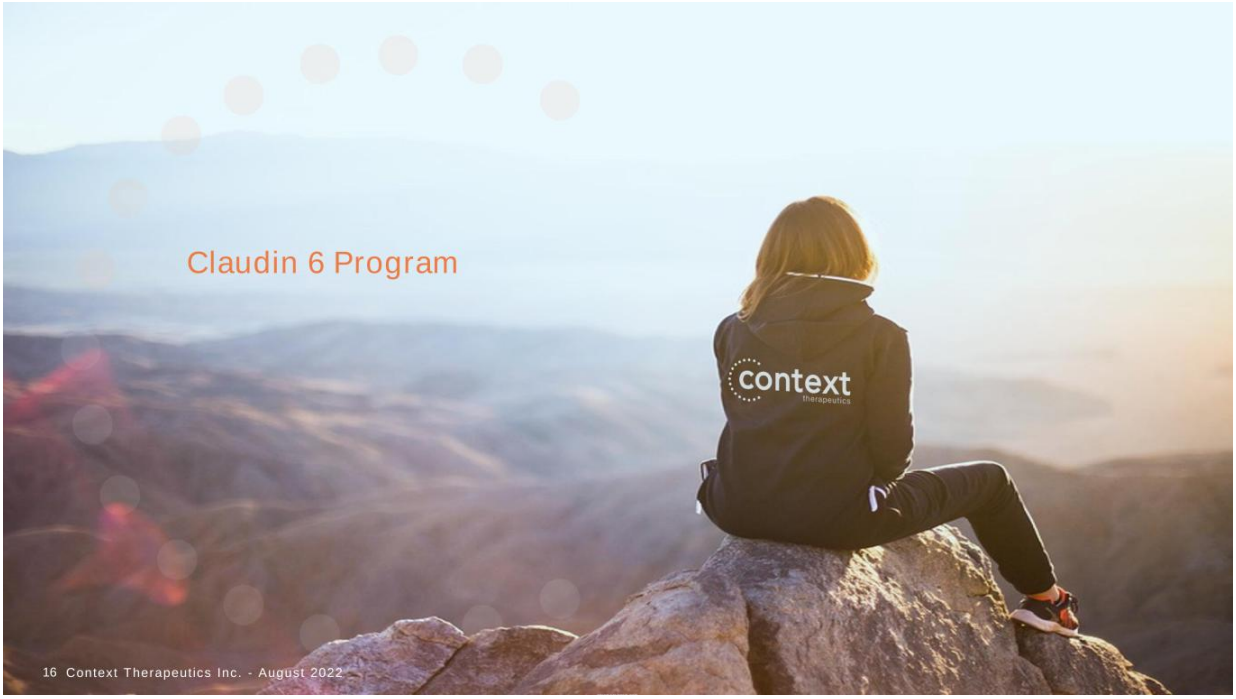


(1) Bardia et al, Results of EMERALD phase 3 trial. 2021 SABCS. Abstract GS2-02. Presented December 8, 2021
(2) "Positive EMERALD Trial Results for Elacestrant Presented at San Antonio Breast Cancer Symposium 2021." Menarini Group, 8 Dec. 2021. Press release.
(3) Source: secondary epidemiologic estimates, 2020 estimates

Phase 1b/2 (ELONA Trial) – Designed to Evaluate Combination Efficacy and Tolerability

- Indication: ER+,PR+,HER2- advanced or metastatic breast cancer
- Study: Phase 1b (n=12-28) / Phase 2 (n=45)
- Primary Endpoint: overall response rate (ORR)
- Secondary Endpoint: progression free survival (PFS), clinical benefit rate (CBR)
- Sites: US only, 16-19 sites




Claudin 6 Program
context
therapeutics

Claudin 6 (CLDN6) is an Exciting, Emerging Oncology Target

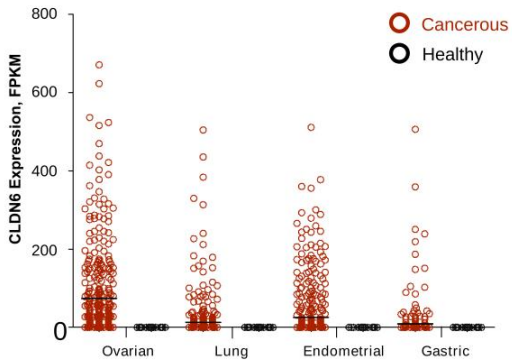
Claudins are major components of tight junctions that maintain cell polarity and intercellular adhesion.

CLDN6 is a tumor-specific protein in adults that is present in gynecologic cancers, as well as lung, gastric, and testicular cancer.

A competing CLDN6-targeting approach, BNT211, achieved a 43% ORR in an early Ph 1 study. Lipase activity was a noted side effect.[1]

High CLDN6 selectivity is required to avoid potential off target toxicities associated with CLDN3 (liver), CLDN4 (pancreas), and CLDN9 (ear, stomach).

CLDN6 is Highly Expressed in Select Solid Tumors[2]



1 Haanen JB, Mackensen A, Koenecke C, et al. CT002 - BNT211: A Phase I trial to evaluate safety and efficacy of CLDN6 CAR-T cells and CARVac-mediated in vivo expansion in patients with CLDN6-positive advanced solid tumors. Presented at: American Association for Cancer Research Annual Meeting; April 8-13, 2022; New Orleans, LA. Abstract CT002.
2 Cancer RNAseq data from The Cancer Genome Atlas (TCGA). Normal tissue RNAseq data from the Genotype-Tissue Expression (GTEx)project

Claudin 18.2 versus Claudin 6

A more advanced Claudin-targeting approach, Claudin 18.2, provides a relevant comparison for Claudin 6

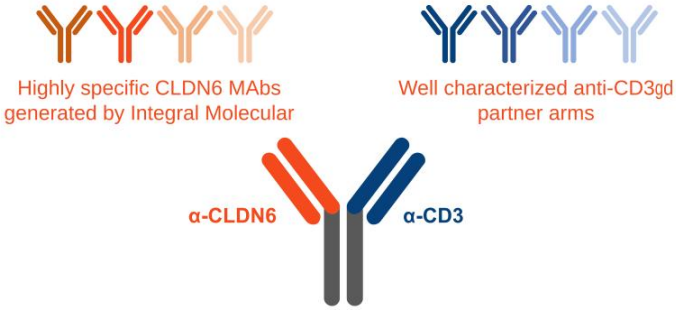
	Claudin 18.2	Claudin 6
Most advanced program	Phase 3	Phase 1
Competition (clinical)	20+ programs	4 programs
Targeting approaches	ADC, bispecific, CAR-T, mAb	ADC, bispecific, CAR-T
Protein expression in normal adult tissue	Gastric (differentiated)	Not expressed
Biomarker prevalence in solid tumors[1,2]	Gastric (70%) Pancreatic (16%)	Testicular (>95%) Ovarian (55%) Endometrial (31%) Lung (16%) Gastric (13%) Bladder (2%) Breast (2%)

1) Pellino A, Brignola S, Riello E, et al. Association of CLDN18 protein expression with clinicopathological features and prognosis in advanced gastric and gastroesophageal junction adenocarcinomas. J Pers Med (Epub) 10-26-2021.
2) Reinhard K, Rengstl B, Oehm P, et al . An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors. Science. 2020 Jan 24;367(6476):446-453.

CLDN6xCD3 Bispecific Antibody Program

We have developed a library of CLDN6xCD3 bispecifics

- Explored a range of bispecific frameworks, CLDN6 sequences, and CD3 sequences
- Comparator bispecifics generated for benchmarking

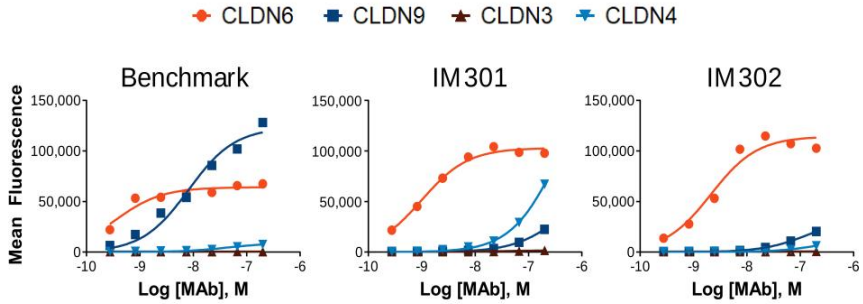


Rucker et al., Development of CLDN6 bispecific antibodies for treatment of ovarian cancer, AACR 2022

Our Antibodies Display High Selectivity for CLDN6

Key Takeaways

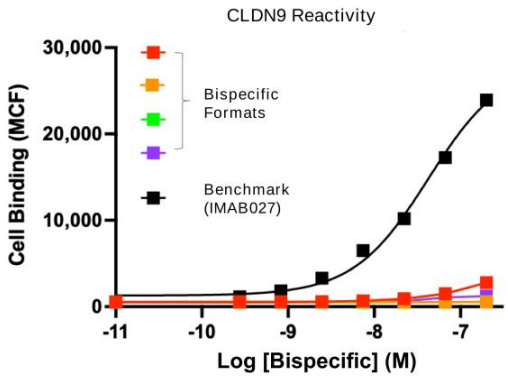
- Benchmark (IMAB027) exhibits off target binding to CLDN9
- 1st generation Context mAb (IM301, IM302) exhibit high CLDN6 selectivity
- 2nd generation Context mAb (data not shown) exhibit even greater CLDN6 selectivity than IM301 and IM302



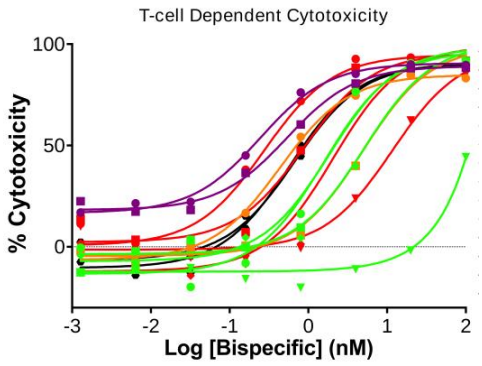
Benchmark = IMAB027
Rucker et al., Development of CLDN6 bispecific antibodies for treatment of ovarian cancer, AACR 2022

CLDN6xCD3 Bispecific Antibody Library

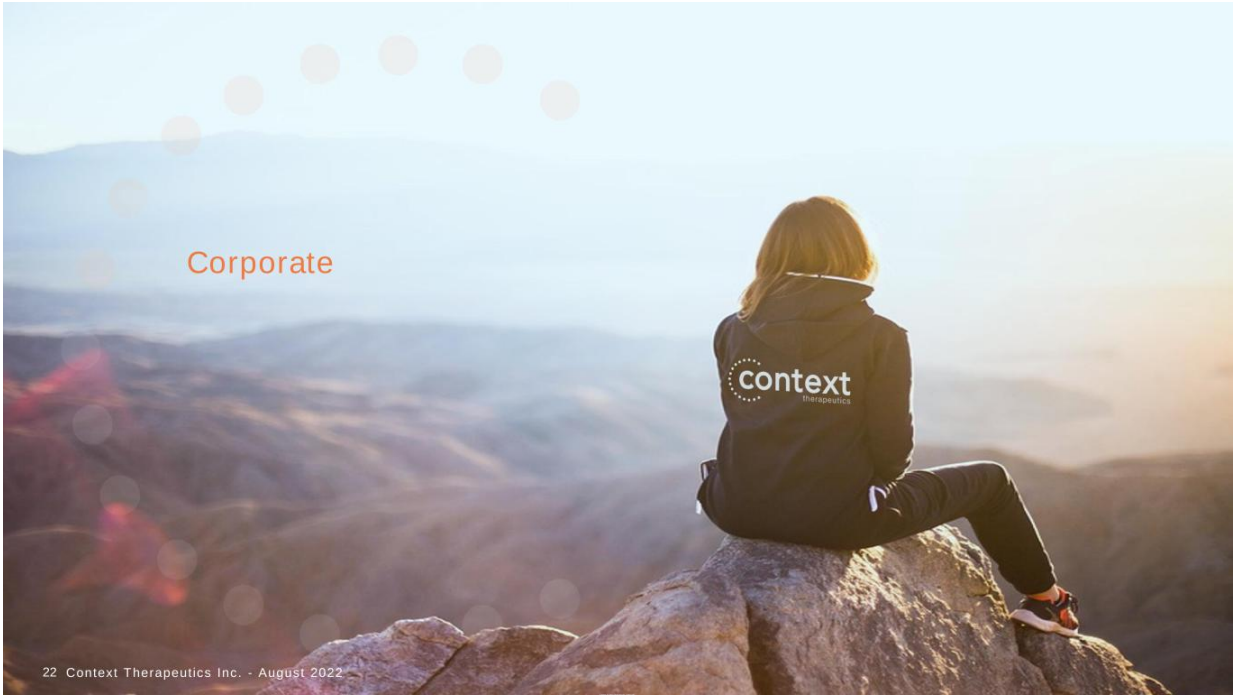
Bispecific antibodies retain high CLDN6 specificity



Bispecifics induce robust T-cell dependent cytotoxicity



Rucker et al., Development of CLDN6 bispecific antibodies for treatment of ovarian cancer, AACR 2022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Experienced Team

Martin Lehr
CEO and Director

Praesidia Biologics · Cure Duchenne · OSAGE University Partners

Jennifer Minai, CPA
Chief Financial Officer

Millendo Therapeutics · parexel · EY

Evan Dick, PhD
SVP R&D

aclaris Therapeutics · Ceptaris Therapeutics · Ception Therapeutics

Alex Levit, Esq
Chief Legal Officer

optinose · teva · ReedSmith

Tarek Sahmoud, MD, PhD
Chief Medical Officer

Novartis · H3 Biomedicine · Celgene

Priya Marreddy, MS
VP Clinical Operations

Spark Therapeutics · teva · PRA Health Sciences

Chris Beck, MBA
SVP Operations

Galera Therapeutics · Shire · MERCK

Mark Fletcher, PhD
VP R&D

hikma. · QUALITEST · Ligand

Focus on Execution

- Experienced team with deep oncology experience
- 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

Recent and Upcoming Milestones

ONA-XR	Q4 2021	1H 2022	2H 2022	2023
Breast – Window of Opportunity data presentation	✓			
Breast – AACR preclinical update		✓		
Breast – Oral SERD clinical trial collaboration			✓	
Endometrial – Phase 2 trial update			●	
Granulosa Cell – Combination Phase 2 trial update			●	
Breast – 2L/3L (post-CDK4/6) Phase 2 trial update			●	
Breast – 1L (ctDNA enriched) Phase 1b trial update				●

Claudin 6	Q4 2021	1H 2022	2H 2022	2023
AACR preclinical update		✓		
Development candidate Selection			●	

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 Q4 2023


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