

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): November 9, 2022

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

Delaware
(State of other jurisdiction of incorporation)

001-40654
(Commission File Number)

86-3738787
(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 November 9, 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 99.1 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 9.01. Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Context Therapeutics Inc. Corporate Presentation - November 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: November 9, 2022

Context Therapeutics Inc.

By: /s/ Martin A. Lehr

Name: Martin A. Lehr

Title: Chief Executive Officer



Advancing Medicines for Female Cancers

Corporate Presentation

November 2022



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.

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Important Notice and Disclaimers

Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions.

This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied. While the Company believes its internal research is reliable, such research has not been verified by any independent source. All the scientific and clinical data presented within this presentation are – by definition prior to completion of the clinical trial and a clinical study report – preliminary in nature and subject to further quality checks including customary source data verification.

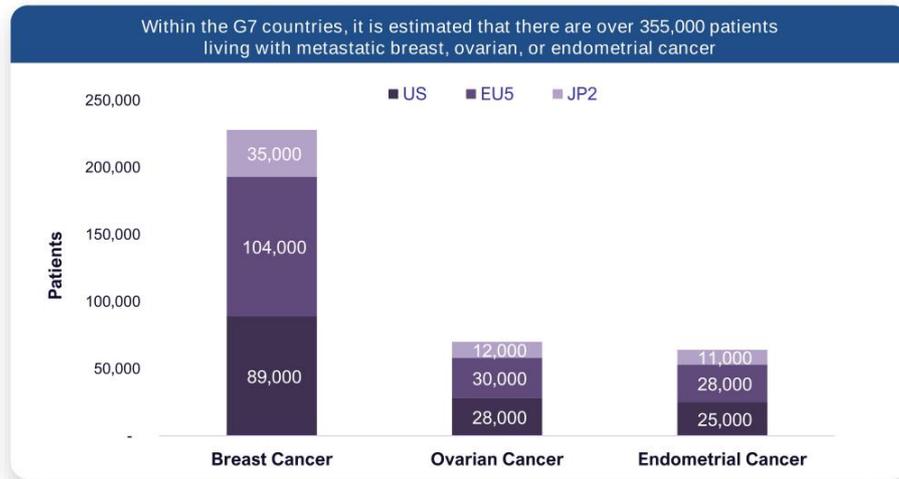
The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

Context Therapeutics Overview

Focus on Women's Oncology	<ul style="list-style-type: none"> • Unmet clinical need in breast, ovarian, and endometrial cancers
ONA-XR oral PR antagonist	<ul style="list-style-type: none"> • ONA-XR is a novel, potentially first-in-class progesterone receptor (PR) antagonist • Endometrial Phase 2 trial initial data reports 4-month PFS rate of 77%¹ • In November 2022, initiated Phase 1b/2 ELONA trial. On track for Phase 1b data in Q4 2023 • 2L/3L metastatic breast cancer initial data to be presented in December 2022
CLDN6 x CD3 bispecific antibody	<ul style="list-style-type: none"> • Claudin 6 (CLDN6) is uniquely expressed in certain adult and pediatric cancers • Developing a highly selective CLDN6 x CD3 bispecific antibody • On track for Candidate selection in Q4 2022 and IND submission in Q1 2024
Cash Guidance	<ul style="list-style-type: none"> • Expected cash runway into Q1 2024

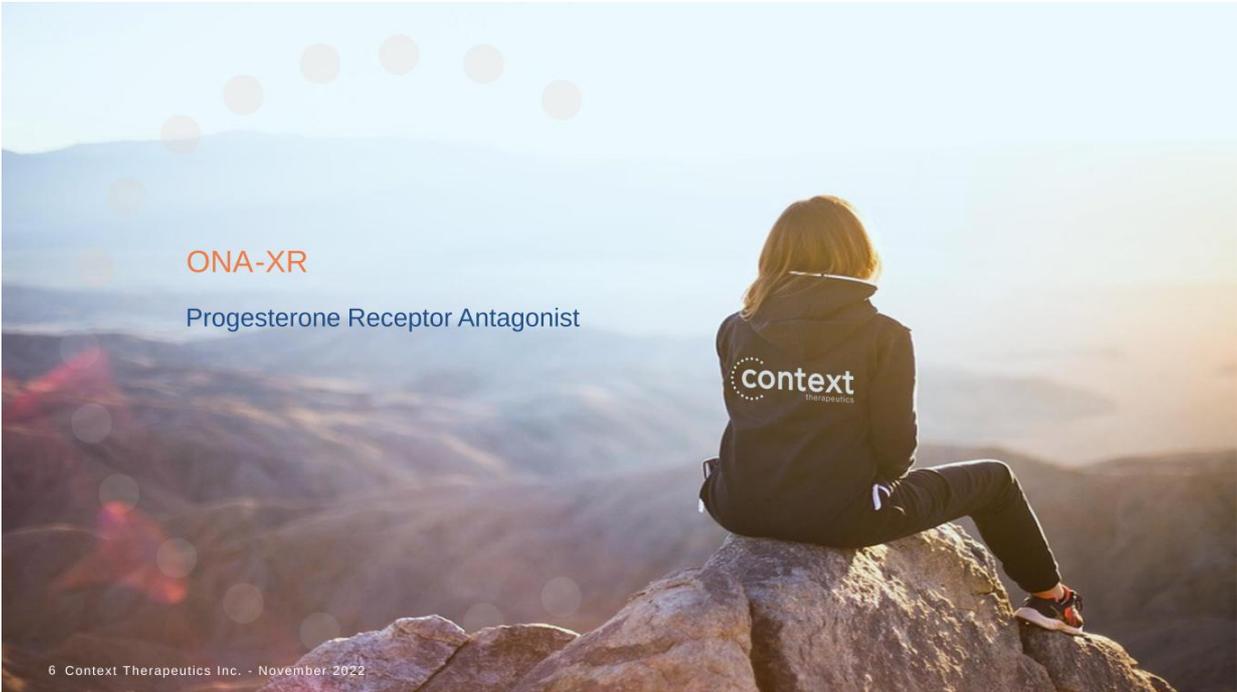
Unmet Need in Female Cancers

Prevalence of Metastatic Female Cancers in EU5, Japan, and US



Pipeline

Cancer	Clinical Indication	Preclinical	Phase 1 Clinical	Phase 2 Clinical	Milestones
ONA-XR (PR antagonist) ¹					
Breast Cancer	2L/3L ER+,PR+,HER2- Combination w/ elacestrant	Phase 1b/2 ELONA Trial			Initiate Q4 2022 Phase 1b data Q4 2023 <input checked="" type="checkbox"/>
	2L/3L ER+,PR+,HER2- Combination w/ fulvestrant	*Phase 2 SMILE Trial			Initial data Dec 2022
Endometrial Cancer	Recurrent PR+ Endometrioid Combination w/ anastrozole	*Phase 2 Trial			Initial data Q4 2022 Data update mid-2023 <input checked="" type="checkbox"/>
Ovarian Cancer	Recurrent PR+ Granulosa Cell Tumor Combination w/ anastrozole	*Phase 2 Trial			Initial data Q4 2022 Data update mid-2023 <input checked="" type="checkbox"/>
CLDN6xCD3 bispecific antibody					
	CLDN6-positive cancers				Candidate selection Q4 2022 IND submission Q1 2024



ONA-XR

Progesterone Receptor Antagonist

Onapristone Extended Release (ONA-XR)

Mechanism of Action	<ul style="list-style-type: none"> Onapristone (ONA) 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 PR antagonist that blocks both ligand-dependent and ligand-independent PR activation¹
Dosing and Administration	<ul style="list-style-type: none"> ONA-XR is an extended-release (XR) tablet form of onapristone (ONA) 50 mg administered orally twice per day
Clinical Data With Immediate Release Formulation	<ul style="list-style-type: none"> 56% overall response rate (ORR) in patients with advanced or metastatic 1L ER+,PR+,HER2- breast cancer² Immediate release formulation associated with liver enzyme elevations^{3,4}
Clinical Data With Extended Release Formulation ^{5,6}	<ul style="list-style-type: none"> Extended release formulation mitigates liver enzyme elevations; no treatment-related severe adverse events to date Preliminary 4-month progression free survival (PFS) rate of 77% in ongoing Phase 2 endometrial cancer trial
Intellectual Property	<ul style="list-style-type: none"> IP protection through at least 2034 assuming no additional patent filings or patent term extensions ONA-XR is a New Chemical Entity (NCE)

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1 Huang, Mol Can Res, 2019

2 Robertson et al., J Eur Cancer, 1999

3 Cottu et al., PLOS One, 2019

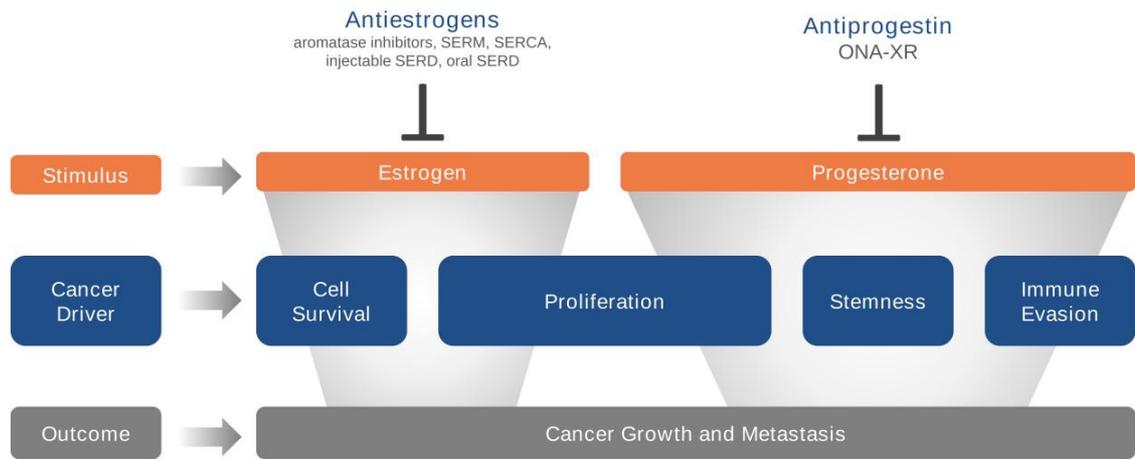
4 Lewis et al., Drug Safety, 2020

5 Data referenced as of September 30, 2022

6 As assessed by study Investigator

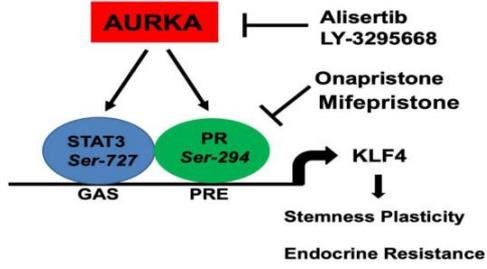
Mechanism of Action

Blocking cancer growth by combining antiestrogen and antiprogestin therapies



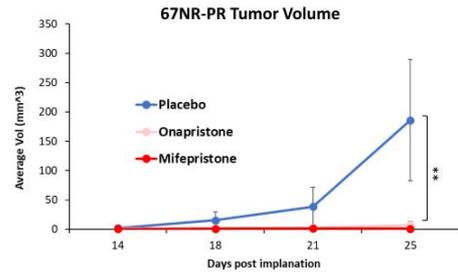
PR Regulates Cancer Drivers of Stemness and Immune Evasion

PR Promotes Cancer Cell Stemness and Metastases¹



- Cancer plasticity and endocrine therapy resistance is mediated through AURKA phosphorylation of S727-STAT3 and S294-PR transcription factors that favors their co-recruitment in the promoter region of KLF4 stemness reprogramming gene

PR Restricts Immune Recognition of Cancer Cells²



- Antiprogesterins onapristone and mifepristone inhibited tumor growth in syngeneic (67NR-PR) tumor model in BALB/C mice
- Antiprogesterins had limited tumor growth inhibition in immune-deficient (NOD/SCID) mice (data not shown)

Completed Clinical Trials

Summary of select clinical trials evaluating onapristone with IR or XR formulation

Onapristone Treatment	Stage	Patients (n)	Clinical Indication	Prior Treatments Median (range)	Biomarker	Data
IR (100 mg QD)	Ph 2	19	Breast Cancer First line (1L) advanced or metastatic	Hormone naïve		56% ORR ¹ 67% CBR 14.0 month PFS
IR (100 mg QD)	Ph 2	101	Breast Cancer Second line (2L) advanced or metastatic	1 (1-2)		10% ORR ² 48% CBR 4.0 month PFS
XR (50 mg BID)	Ph 2	14	Granulosa Cell Tumor of Ovary Advanced or Metastatic	4 (2-17)	PR+	35% CBR ³ 12 month PFS rate of 20%
XR (10-50 mg BID)	Ph 1	13	Ovarian Cancer Advanced or Metastatic	4 (2-10)	PR+	8% ORR ⁴ 6 month PFS rate of 31%
XR (10-50 mg BID)	Ph 1	20	Breast Cancer Advanced or Metastatic	9 (2-14)	PR+	25% DCR ⁴ 6 month PFS rate of 15%

¹⁰ Context Therapeutics Inc. - November 2022

IR = immediate release; XR = extended release
¹ Robertson, Eur J Cancer, 1999
² Jonat, Endocrine Therapy of Breast Cancer, 2002

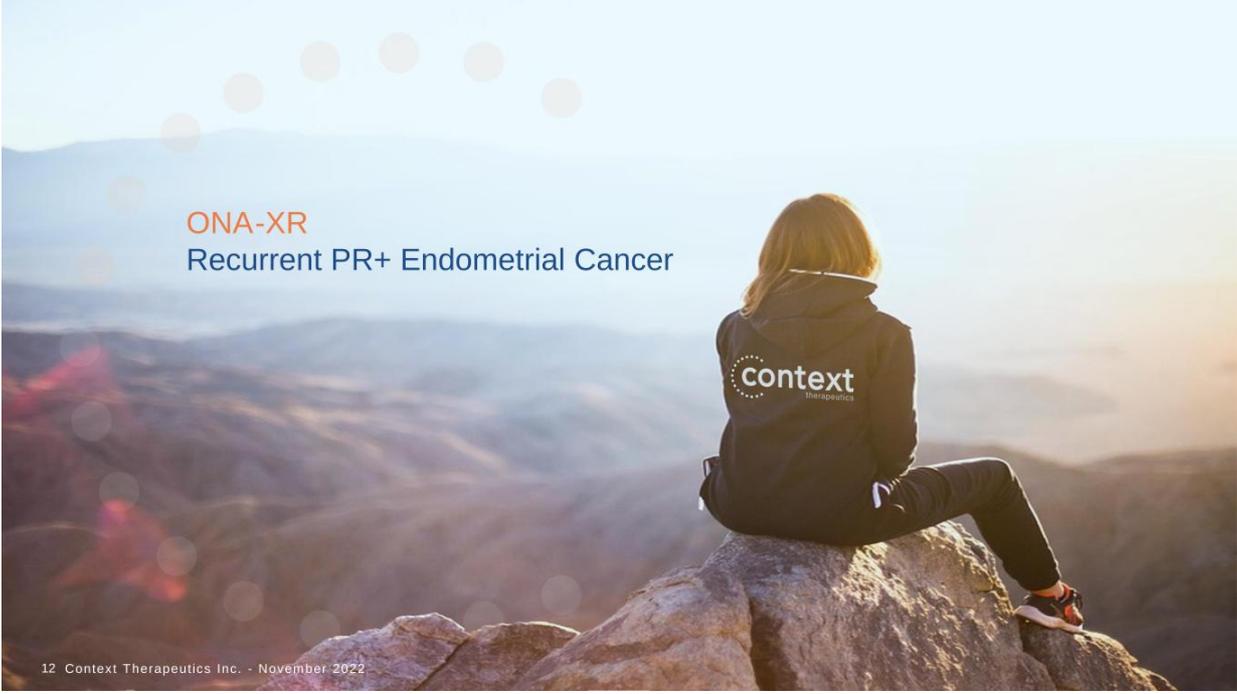
³ Grisham, ASCO Annual Meeting 2022
⁴ Cottu, PLoS One, 2018

Key Ongoing Clinical Trials

Treatment	Stage	Patients (n)	Clinical Indication	Biomarker	Key Inclusion and Exclusion Criteria	Collaborator	Data Update ¹
ONA-XR + Anastrozole	Ph 2	25	Endometrial Cancer	PR+	<ul style="list-style-type: none"> Must have received at least one prior treatment with a platinum/taxane chemotherapy 		<ul style="list-style-type: none"> 12 patients enrolled 4-month PFS rate of 77% No treatment-related SAE
ONA-XR + Anastrozole	Ph 2	25	Granulosa Cell Tumor of the Ovary	PR+	<ul style="list-style-type: none"> Must have received at least one prior chemotherapy regimen 		<ul style="list-style-type: none"> 14 patients enrolled No treatment-related SAE
ONA-XR + Fulvestrant	Ph 2	39	Breast Cancer (2L/3L) SMILE Trial	PR+	<ul style="list-style-type: none"> Must have received prior CDK4/6 inhibitor therapy One line of prior chemotherapy in metastatic setting allowed 		
ONA-XR + Elacestrant	Ph 1b/2	67	Breast Cancer (2L/3L) ELONA Trial	PR+	<ul style="list-style-type: none"> Must have received prior CDK4/6 inhibitor therapy ≥50% patients with ESR1 mutant No prior chemotherapy in metastatic setting 		

¹¹ Context Therapeutics Inc. - November 2022

¹ Data cut off as of September 30, 2022; preliminary raw data



ONA-XR
Recurrent PR+ Endometrial Cancer

Endometrial Cancer

- Endometrial cancer is the 4th most common cancer in women
 - Endometrial cancer is on the rise and is linked to obesity^{1,2}
 - ~13,000 patient deaths per year in the US³
 - Market is projected to grow from \$1.5bn in 2020 to \$5.1bn in 2029⁵
- Hormone signaling is a driver of endometrial cancer
 - Endometrial cancer is thought to be caused by excess hormone production that leads to endometrial hyperplasia and cancer
- Chemotherapy and surgery remain first line treatments
 - Primary treatment includes surgical removal of uterus, ovaries, and fallopian tubes followed by platinum/taxane chemotherapy
 - PD-1 antibodies (Keytruda, Jemperli) were recently approved in MSI-H and dMMR genetic subpopulations post-chemotherapy (~13-30% of population)⁵
 - Lenvima + Keytruda combination therapy is approved post-chemotherapy, however, tolerability can be challenging for patients⁶
- Antiestrogen therapy is currently used off-label
 - Hormonal therapy is an alternative treatment for patients who wish to preserve their fertility, and for those with metastatic or recurrent disease without curative options



~14,000 patients have recurrent endometrial cancer that cannot be fully removed via surgery²

34%

Of endometrial cancer patients are PR+⁴

¹ American Cancer Society, Endometrial Cancer Risk Factors. (accessed Nov. 4, 2022)

² Epic Oncology (incidence, 1st/ 2nd line treated); epic Oncology physician survey 2019

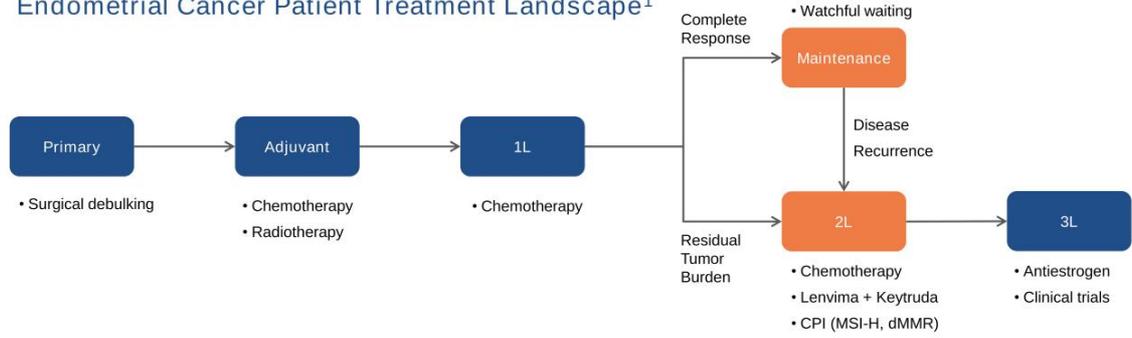
³ Nation Cancer Institute, Endometrial Cancer Incidence Rising in the US and Worldwide (accessed Nov. 4, 2022)

⁴ Høgdall, Oncol Rep, 2007

⁵ Vinuesa and Webster, Nat Rev Drug Disc, 2022

⁶ Makker, NEJM, 2022

Endometrial Cancer Patient Treatment Landscape¹



1L First Line (1L)

- Standard of Care (SOC) is carboplatin + paclitaxel
- mPFS of ~12 months

2L Second Line (2L)

- Treatment goal is disease stabilization for 4-6 months
- Lenvima + Keytruda poor tolerability associated with high discontinuation rate in patients

M Maintenance Line

- No approved therapies
- Treatment goal is disease stabilization for ≥4 months and to provide a high quality of life

3L Third Line (3L)

- Limited treatment options

Potential Target Indications for ONA-XR

ONA-XR + Anastrozole in PR+ Endometrial Cancer¹

- Ongoing Phase 2 Trial
 - Investigator-initiated, open label, multi-center, trial evaluating ONA-XR 50 mg BID in combination with the antiestrogen anastrozole 1 mg QD administered orally to treat women with ER+/PR+ endometrial adenocarcinoma who have received at least one prior platinum/taxane-based chemotherapy regimen
 - Co-primary endpoints: 4-month PFS and ORR
 - Secondary endpoints: DCR, DoR, safety, and quality of life
- Efficacy
 - The study has enrolled 12 of 25 planned patients
 - 9 patients have completed at least one month of treatment
 - 4-month PFS rate was 77%
 - 12-month PFS rate was 33%
 - 7 patients remain on the trial
- Safety
 - There have been no treatment-related serious adverse events reported
- Updated data anticipated in mid-2023

Benchmarking Against Single Agents

	ONA-XR + Anastrozole	ONA-XR	Anastrozole
Trial	Schilder (ongoing) ¹	Cottu 2018 ²	PARAGON 2019 ³
Patients (n)	12 (9 evaluable)	12	54
Lines of Prior Chemotherapy, n (%)			
1	8 (66)	4 (33)	50 (93)
≥2	4 (33)	8 (66)	4 (7)
Treatment free interval (TFI) ≥6 months, n (%)	4 (33)	1 (8)	36 (70)
4-month PFS rate, n (%)	7 (77)	4 (33)	ND
12-month PFS rate, n (%)	3 (33)	1 (8)	4 (7)
mPFS (95% CI), months	NE	2.0 (1.7-5.3)	2.7 (1.9-4.5)
Side Effects	Well tolerated	Well tolerated	Well tolerated

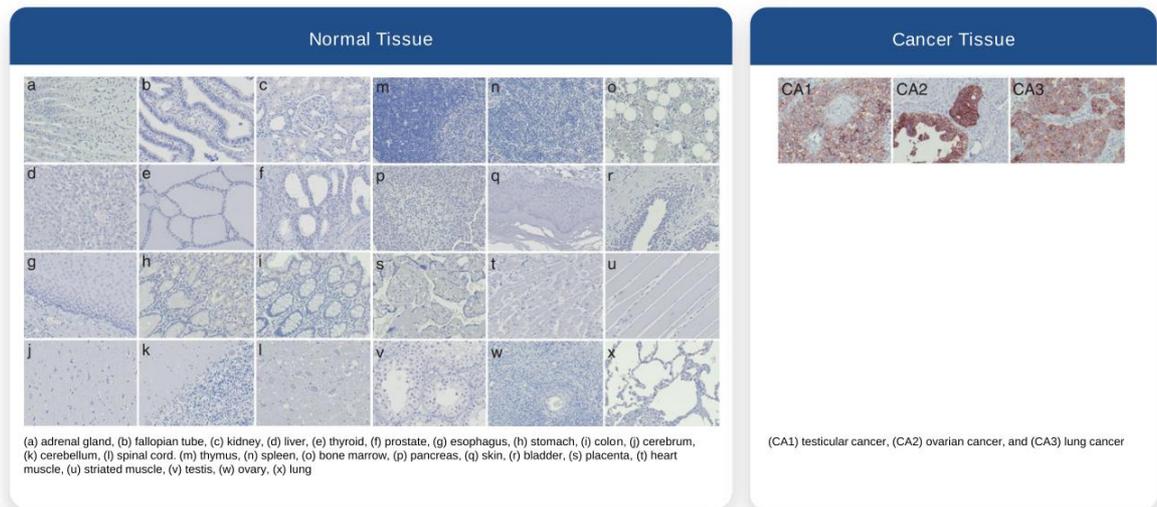


CLDN6xCD3
Bispecific Antibody Program

Claudin 6 (CLDN6) is an Emerging Oncology Target

Opportunity	<ul style="list-style-type: none"> • CLDN6 is a tumor-specific protein that is present at high surface density across adult and pediatric cancers¹ • CLDN6 is expressed at very low levels or absent from normal adult tissue
Challenge	<ul style="list-style-type: none"> • CLDN6 antigen is conformationally-dependent, which limits the utility of traditional antibody discovery approaches • Antigen binding region is highly conserved with CLDN3, CLDN4, and CLDN9 • CLDN6 selectivity is required to avoid off-target liabilities identified in murine knockout studies with CLDN3 (pancreas), CLDN4 (kidney, pancreas), and CLDN9 (ear, gut)
Target Validation	<ul style="list-style-type: none"> • BNT211 CAR-T establishes Proof of Concept²: <ul style="list-style-type: none"> – Novel CAR-T + mRNA vaccine evaluated in Phase 1 dose-escalation study in CLDN6+ solid tumors – 50% response rate (ORR) in second dosing cohort
Unmet Need	<ul style="list-style-type: none"> • Selectivity: preferentially target CLDN6 over other CLDN proteins • Potency: specific lysis of CLDN6+ cancer cells over normal cells • Safety: activation of cytotoxic T cells without concomitant activation of free cytokines • Manufacturability: scalable process

CLDN6 is Selectively Expressed on Cancer Cells



CLDN6 Has the Potential to Reach a Large Patient Population

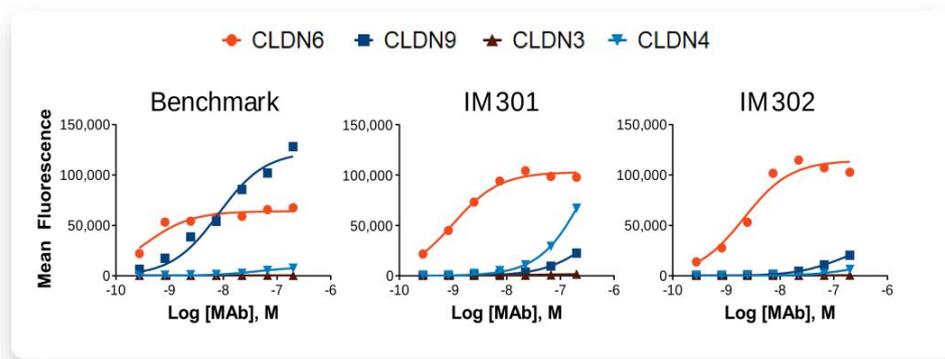
~62,500 patients per year in the US only in Relapse/Refractory Setting

Initial indications of interest based on:

- CLDN6 prevalence
- Patient population size
- Observed clinical responses
- Eligibility for Orphan or Rare Pediatric Designation

Selected Cancer indications	Incidence	R/R Incidence	CLDN6 Positive	Patient Population Based on R/R Incidence
Testicular	9,910	400	95% ¹	380
Ovarian	19,900	12,800	54-55% ^{1,2}	6,982
NSCLC	201,229	110,653	6-50% ^{3,4,5}	35,221
Malignant Rhabdoid	50	500	29-44% ^{1,2,6,7}	183
Gastric	26,380	11,090	13-55% ^{8,9}	3,771
Breast	290,600	43,800	2-41% ^{1,10,11}	9,417
Endometrial	65,900	12,500	20-31% ^{1,12,13}	3,188
Glioma	19,000	10,000	21% ⁸	2,100
Bladder	81,180	17,100	2-8% ^{1,13}	855
SCLC	35,511	19,527	2% ¹	391

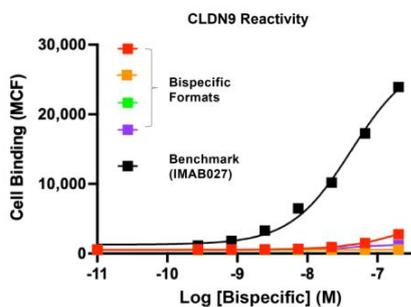
¹ Reinhard, Science, 2020; ² Wang, Diagn Pathol., 2013; ³ Gao, Oncol Lett., 2013; ⁴ Kohmoto, Gastric Cancer, 2020; ⁵ Lin, Diagn Pathol., 2013; ⁶ Micke, Intl J Cancer, 2014; ⁷ Soini, Pol J Path, 2022; ⁸ Antonelli, Brain Pathol., 2011; ⁹ Sullivan, Am J Surg Pathol., 2012; ¹⁰ Jia, Intl J Clin Exp Pathol., 2019; ¹¹ Yafang, J Breast Cancer, 2011; ¹² Kojima, Cancers, 2020; ¹³ Ushku, Histopath., 2012
 Incidences based on public estimates, Relapsed/refractory (R/R) or last-line patient population approximated by annual mortality; CLDN6 target prevalence is based on IHC or RNAseq from published reports. Patient population derived from midpoint of CLDN6 positive population multiplied by R/R incident population.

Context Antibodies Display High Selectivity for CLDN6¹

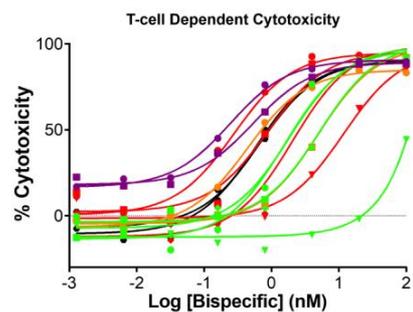
Key Takeaways

- Benchmark (IMAB027/ASP1650; Astellas/Ganymed) exhibits off-target binding to CLDN9
- 1st generation Context mAb (IM301, IM302) exhibit high CLDN6 selectivity
- 2nd generation Context mAb exhibit even greater CLDN6 selectivity than IM301 and IM302 (data not shown)

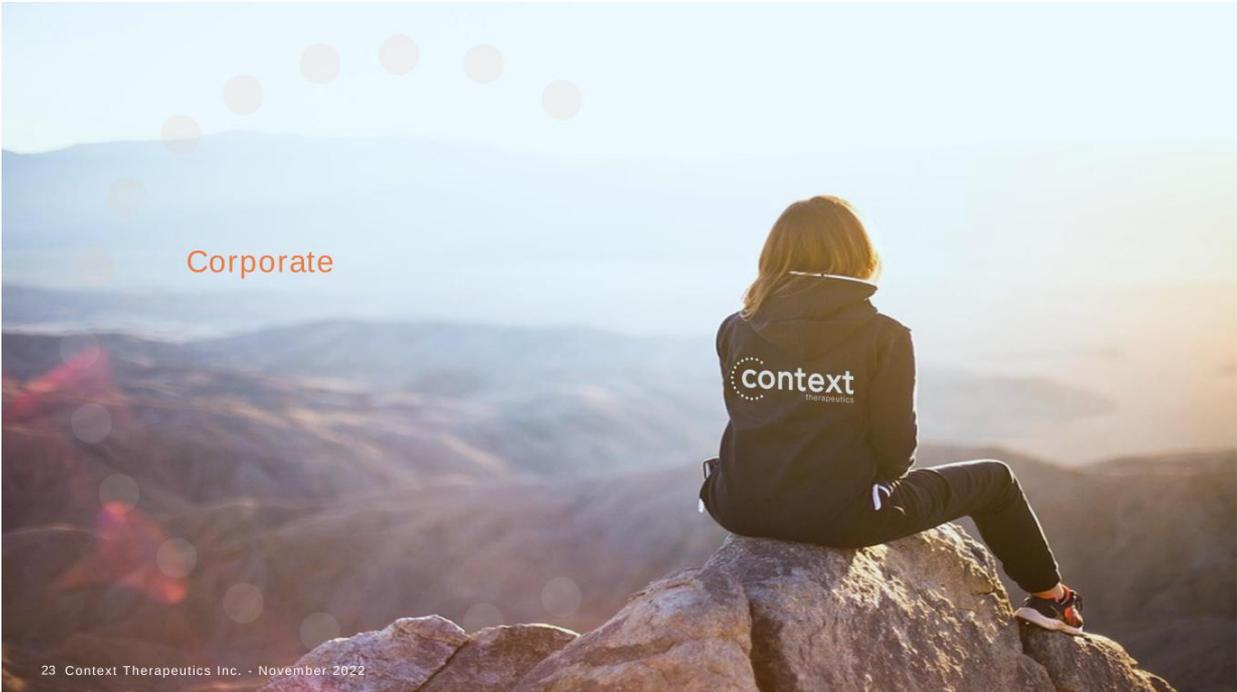
Development of Selective and Potent CLDN6 Bispecific Antibodies

Bispecific antibodies retain high CLDN6 specificity¹

- A diverse set of bispecific formats were evaluated, represented by a different color (red, orange, green, purple)
- Binding to CLDN9 was not affected by Context bispecific format and was markedly lower compared to IMAB027 (black)

Bispecifics induce robust T-cell dependent cytotoxicity¹

- A diverse set of bispecific formats and derivatives thereof effectively induced T-cell dependent cell killing in OV90 ovarian tumor cells
- Certain bispecific formats (green) and derivatives thereof were less potent (purple) than others



Corporate

Experienced Leadership Team



Martin Lehr
CEO and Director



Jennifer Minai, CPA
Chief Financial Officer



Chris Beck, MBA
SVP Operations



Alex Levit, Esq
Chief Legal Officer



Tarek Sahmoud, MD, PhD
Chief Medical Officer



Priya Marreddy, MS
VP Clinical Operations



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 Key Anticipated Milestones

ONA-XR	1H 2022	2H 2022	2023	2024
Breast – AACR preclinical update				
Breast – ELONA trial initiation				
Endometrial – Phase 2 initial data				
Granulosa Cell – Phase 2 initial data				
Breast – SMILE trial initial Phase 2 data				
Breast – ELONA trial Phase 1b data				

Claudin 6	1H 2022	2H 2022	2023	2024
Candidate selection				
IND submission				

Investment Highlights



**Large
Unmet Need**
Female Cancers



**High-Value
Targets**
Progesterone
Receptor and
Claudin 6



**Near-Term
Milestones**
Multiple Data
Readouts in
Q4 2022



**Strong
Team**
Deep Domain
Experience, Track
Record of Success



**Financial
Strength**
Expected Cash
Runway into
Q1 2024



ADVANCING MEDICINES
FOR FEMALE CANCERS

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