

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): September 27, 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 September 27, 2022, the Company issued a press release updating its expected cash runway and anticipated milestones for its products under development. 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 September 27, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Context Therapeutics Inc., dated September 27, 2022
99.2	Context Therapeutics Inc. Corporate Presentation - September 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: September 27, 2022

Context Therapeutics Inc.

By: /s/ Martin A. Lehr

Name: Martin A. Lehr

Title: Chief Executive Officer



Context Therapeutics® Amends Cash Guidance, Extends Runway into Q1 2024

Company to focus resources on advancing ONA-XR ELONA Phase 1b/2 clinical trial and on advancing CLDN6xCD3 bispecific antibody toward IND

PHILADELPHIA, PA— September 27, 2022—Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a women’s oncology company developing novel treatments for breast and gynecological cancers, today announced updated cash guidance to extend its runway into Q1 2024.

The company plans to defer noncritical R&D activities, reduce future overhead and infrastructure expenditures, and prioritize its onapristone extended release (ONA-XR) ELONA Phase 1b/2 clinical trial and Claudin 6 (CLDN6) program.

“Context has been fortunate to collaborate with two tremendous organizations – The Menarini Group and Integral Molecular. We believe these collaborations have broadened the therapeutic potential for ONA-XR through the ELONA trial and accelerated the development of a new treatment modality to address CLDN6 positive tumors,” said Martin Lehr, CEO of Context Therapeutics. “In light of the challenging current investment climate for biotechnology, we are streamlining the organization’s resources with the intent to take the Company through the execution of the Phase 1b portion of the ELONA trial and the advancement of our CLDN6xCD3 bispecific antibody program to an Investigational New Drug Application (IND).”

The ELONA Phase 1b/2 clinical trial is evaluating ONA-XR, an oral progesterone receptor (PR) antagonist, in combination with Menarini’s elacestrant in estrogen receptor positive (ER+), PR+, HER2- metastatic breast cancer (mBCa) patients who have previously been treated with a CDK4/6 inhibitor. An IND amendment filed specifically for this trial was submitted to the U.S. Food and Drug Administration in September 2022. The Company remains on track to initiate the ELONA clinical trial in Q4 2022 and to report Phase 1b data in Q4 2023. Context retains worldwide rights for ONA-XR, other than the rights it out-licensed for Greater China.

Context anticipates the nomination of a CLDN6xCD3 bispecific monoclonal antibody (BsMAB) development candidate from the organization’s research collaboration with Integral Molecular in Q4 2022. An IND submission is planned in Q1 2024. Context retains worldwide rights to certain CLDN6 antibody patents in the field of bispecific antibodies.

In addition, Context will continue to provide access to ONA-XR through the Company’s ongoing Investigator-Sponsored Trials (ISTs) and anticipates sharing preliminary data from its Phase 2 clinical trials in granulosa cell tumors and endometrial cancer in November 2022, and from its Phase 2 clinical trial in breast cancer in December 2022.

“We’re fortunate to have ISTs that can continue to explore the potential of ONA-XR while we focus on derisking and moving our near-term priority programs forward,” said Lehr. “We’re thinking long-term; Context is committed to improving the lives of women with cancer and we believe that these thoughtful and future-focused changes best position us to be nimble during the current market challenges. We continue to concentrate on fully realizing the value of our collaborations and pipeline.”

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 1/2 clinical 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) having sufficient cash to fund our operations into the first quarter 2024, (ii) the expectation to report preliminary data from certain of our currently ongoing clinical trials in November and December 2022, (iii) the expectation to select a development candidate for our CLDN6xCD3 program in the fourth quarter of 2022, (iv) the expectation to initiate the combination study of ONA-XR and elacestrant in the fourth quarter of 2022 and to report Phase 1b data in the fourth quarter of 2023, (v) the intent to streamline the organization's resources to take the Company through the execution of the Phase 1b portion of the ELONA trial and the advancement of our CLDN6xCD3 bispecific program to an IND, (vi) the expectation to have an IND submission for our CLDN6xCD3 bispecific in the first quarter of 2024, (vii) the results of our clinical trials, (viii) the potential benefits of the product candidates, (ix) the likelihood data will support future development, and (x) 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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Advancing Medicines for Female Cancers

Corporate Presentation
September 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.

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.

Context Therapeutics Overview

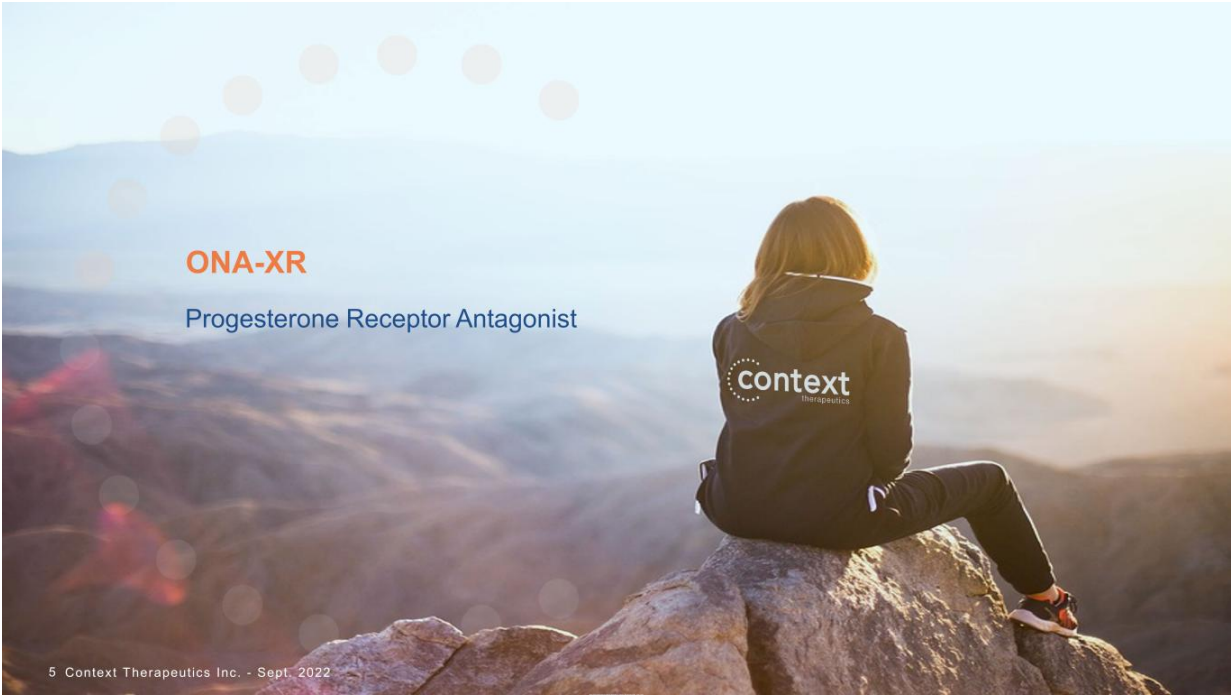
Focus on Women's Oncology	→ Unmet clinical need in breast, ovarian, and endometrial cancers
ONA-XR <i>oral PR antagonist</i>	→ ONA-XR is novel, potentially first-in-class progesterone receptor (PR) antagonist → Q4 2022 expected initiation of Phase 1b/2 ELONA trial to evaluate elacestrant (oral SERD) plus ONA-XR → Q4 2022 expected preliminary data from three ongoing Investigator-Sponsored Trials (IST)
CLDN6 x CD3 <i>bispecific antibody</i>	→ 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	→ Expected cash runway into Q1 2024

Pipeline

Cancer	Clinical Indication	Research	Phase 1	Phase 2	Phase 3	Key Anticipated Milestones	FDA Fast Track
ONA-XR (PR antagonist)¹							
Breast Cancer	2L/3L ER+,PR+,HER2- Combination w/ elacestrant		Phase 1b/2 ELONA Trial			<ul style="list-style-type: none"> Initiate Q4 2022 Phase 1b data Q4 2023 	
	2L/3L ER+,PR+,HER2- Combination w/ fulvestrant		*Phase 1b/2 SMILE Trial			<ul style="list-style-type: none"> Preliminary data Q4 2022 	
Ovarian Cancer	Recurrent PR+ Granulosa Cell Combination w/ anastrozole		*Phase 2 Trial			<ul style="list-style-type: none"> Preliminary data Q4 2022 	<input checked="" type="checkbox"/>
Endometrial Cancer	Recurrent PR+ Endometrioid Combination w/ anastrozole		*Phase 2 Trial			<ul style="list-style-type: none"> Preliminary data Q4 2022 	
CLDN6xCD3 bispecific antibody							
	Ovarian & Endometrial Cancer					<ul style="list-style-type: none"> Candidate selection Q4 2022 IND submission Q1 2024 	

⁴ Context Therapeutics Inc. - Sept. 2022

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



ONA-XR

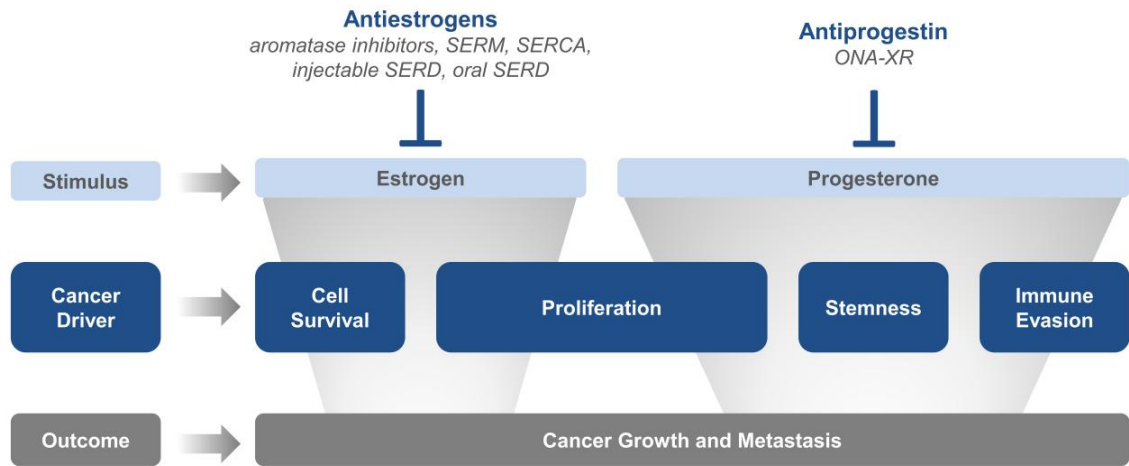
Progesterone Receptor Antagonist

Onapristone Extended Release (ONA-XR)





Mechanism of Action	<ul style="list-style-type: none"> → 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
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
Historical Clinical Data	<ul style="list-style-type: none"> → Onapristone generated a 56% ORR and a 17.5 DoR in patients with advanced or metastatic 1L ER+,PR+,HER2- breast cancer; however, transient liver enzyme elevations were noted¹ → ONA-XR was developed to mitigate the risk of liver enzyme elevations^{2,3}
Ongoing and Planned Clinical Trials	<ul style="list-style-type: none"> → Over 150 patients dosed to date with no cases of drug-related liver enzyme elevations → Support ongoing Investigator-Sponsored Trials (ISTs) → Initiate Phase 1b/2 combination clinical trial to evaluate elacestrant (oral SERD) plus ONA-XR
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)

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 INNOVATIVE BREAST CANCER RESEARCH	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 2022 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

ONA-XR Evaluation in Gynecologic Clinical Trials

Cancer	Context Trial Design	Clinical Collaborator	Trial Status	PR+ Patients (US) ¹	Standard of Care (SOC)	Medical Need
Recurrent Endometrial	Combination with anastrozole in PR+ patients	 Jefferson <small>UNIVERSITY OF SOUTHWEST PHOENIX MEDICAL COLLEGE</small>	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



**Elacestrant + ONA-XR
Combination Clinical Trial**

Clinical Trial Collaboration with Menarini

Rationale for Clinical Trial Collaboration

Clinical Trial Collaboration and Supply Agreement

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



Elacestrant + ONA-XR



- Elacestrant is the first oral SERD to show positive Ph 3 top line results¹
- Priority Review and assigned a PDUFA date of February 17, 2023

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

- ONA-XR is the most complete PR antagonist in clinical development²
- ONA-XR tolerability profile makes it a potentially ideal combination agent³
- Desire to clinically validate combination of ONA-XR with new oral SERDs

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

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

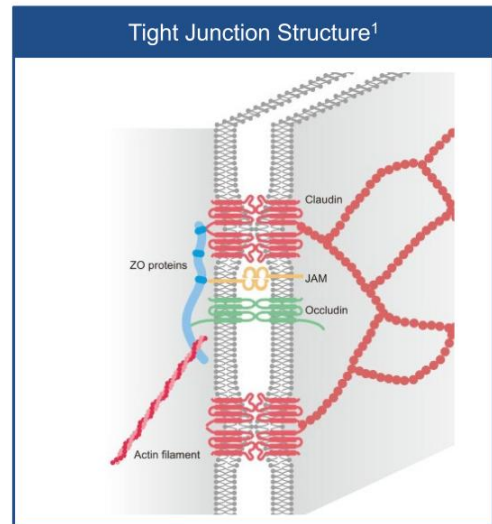




**CLDN6xCD3
Bispecific Antibody Program**

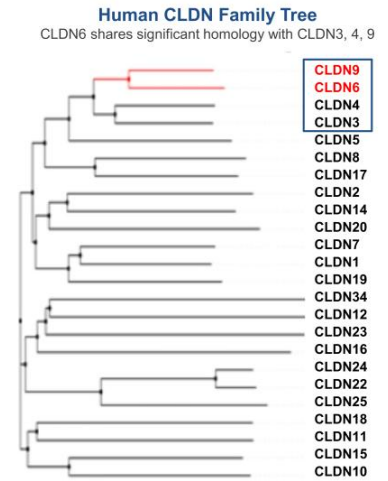
Claudin (CLDN) Proteins

- Tight junctions (TJ) regulate cell barrier and permeability
- CLDN proteins constitute a structural core of TJ, along with junction adhesion molecule (JAM) and occludin
- Over 20 CLDN proteins have been characterized
- Dysregulation of CLDN protein expression and function occurs in multiple diseases, including cancer



Many CLDN Proteins are Associated with Disease

CLDN	Disease	Reference
CLDN 1	Colitis, skin permeability	Bhat 2016, Furuse 2001
CLDN 2	Colorectal cancer, IBD	Barrett 2020, Dhawan 2011
CLDN 3	Psoriasis, ovarian cancer	Sikora 2019, Oh 2021
CLDN 4	Diabetes, ovarian cancer	Li 2014, Stewart 2006
CLDN 5	Cerebral edema, depression	Menard 2017, Matsumoto-Okazaki 2012
CLDN 6	Multiple cancers	Antonelli 2011, Reinhard 2020, Ushiku 2012
CLDN 7	Colon cancer	Xu 2021
CLDN 9	Hearing loss	Nakano 2009, Ramzan 2021
CLDN 11	Myelin dysfunction	Maheras 2018, Riedhammer 2021
CLDN 14	Kidney stones, hearing loss	Thorleifsson 2009, Wilcox 2001
CLDN 15	Celiac disease	Schumann 2012
CLDN 16	Hypercalcinuria	Simon 1999
CLDN 17	Renal dysfunction	Adil 2022
CLDN 18.2	Gastric cancer	Nimi 2001
CLDN 19	Renal dysfunction, vision loss	Adil 2022, Wang 2019



CLDN6 is an Emerging Oncology Target



CLDN6 is a **tumor-specific protein** that is present at high surface density across adult and pediatric cancers¹



CLDN6 selectivity is required to avoid off-target liabilities identified in murine knockout studies with CLDN3 (pancreas), CLDN4 (kidney, pancreas), and CLDN9 (ear, gut)



BioNTech's BNT211 establishes **Proof of Concept** for CLDN6 immunotherapy:

- 5 of 10 (50% ORR) patients who received BNT211 (CLDN6 CAR-T) + CARVac (CLDN6 mRNA vaccine) showed a partial response in an ongoing Ph 1 study in CLDN6+ solid tumors
- Elevated transaminase and lipase were noted side effects²

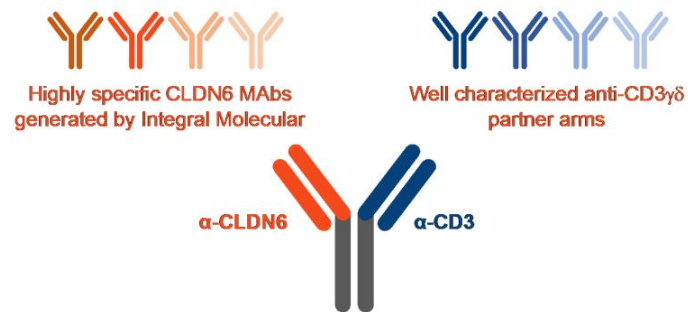
CLDN6 Prevalence in Cancer

Cancer	Prevalence (IHC, RNAseq)	Reference
Testicular	95%	Reinhard 2020
Ovarian	54-55%	Reinhard 2020, Wang 2013
Gastric	13-55%	Gao 2013, Kohmoto 2020, Lin 2013
NSCLC	6.5-50%	Micke 2014, Reinhard 2020, Soini 2022, Wang 2015
Malignant Rhabdoid (AT/RT and non-CNS)	29-44%	Antonelli 2011, Sullivan 2012
Breast	2-41%	Jia 2019, Reinhard 2020, Yafang 2011
Endometrial	20-31%	Kojima 2020, Reinhard 2020, Ushiku 2012
Glioma	21%	Antonelli 2011
Bladder	2-8%	Reinhard 2020, Ushiku 2012
SCLC	2%	Reinhard 2020

CLDN6xCD3 Bispecific Antibody Program

We have developed a library of CLDN6xCD3 bispecifics

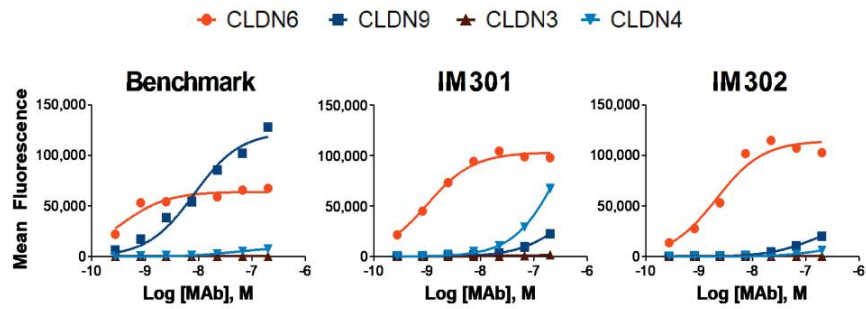
- Explored a range of bispecific frameworks, CLDN6 sequences, and CD3 sequences
- Comparator bispecifics generated for benchmarking
- Candidate selection on track for Q4 2022



Our Antibodies Display High Selectivity for CLDN6

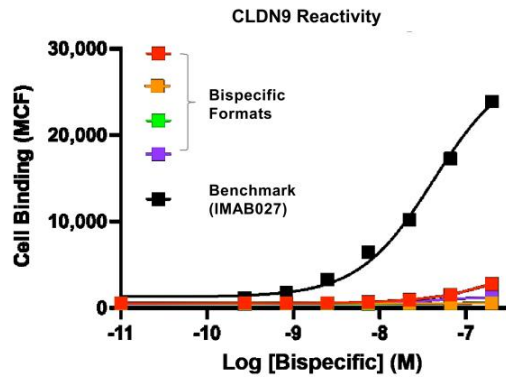
Key Takeaways

- 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

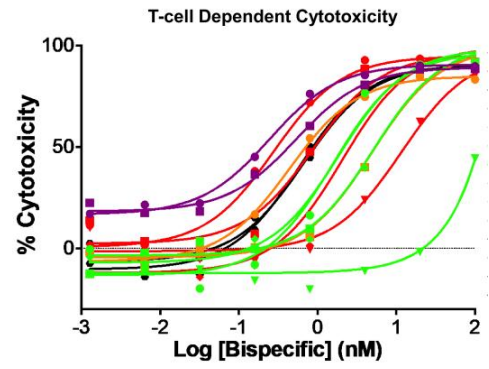


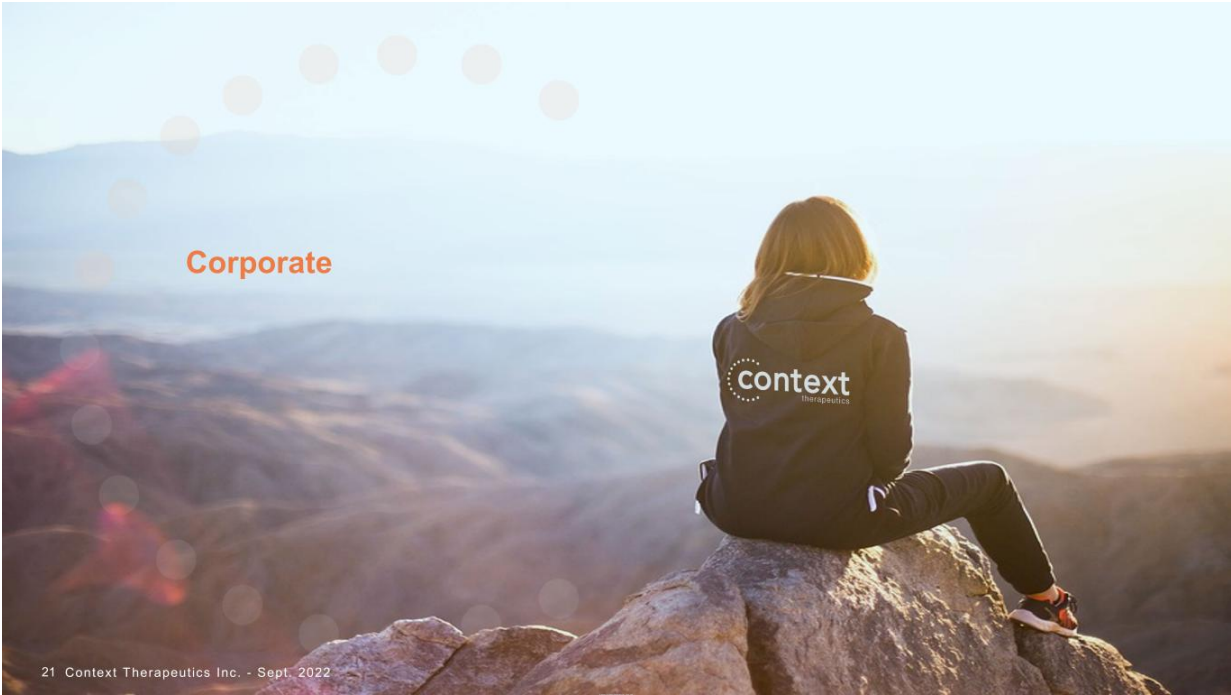
CLDN6xCD3 Bispecific Antibody Library

Bispecific antibodies retain high CLDN6 specificity



Bispecifics induce robust T-cell dependent cytotoxicity





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 Sahnoud, 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				
Breast – ELONA trial Phase 1b data				
Breast – 2L/3L (post-CDK4/6) Phase 2 preliminary data				
Endometrial – Phase 2 preliminary data				
Granulosa Cell – Phase 2 preliminary 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



BRINGING CHANGE FOR
FEMALE CANCERS

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