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 7, 2023

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

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

2001 Market Street, Suite 3915, Unit#15
Philadelphia, Pennsylvania 19103
(Address of principal executive offices including zip code)

(267) 225-7416
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On August 7, 2023, 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

Exhibit No.	**Description**
99.1	Context Therapeutics Inc. Corporate Presentation - August 2023
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 7, 2023

Context Therapeutics Inc.

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


context
therapeutics
Advancing Medicines for Solid Tumors
Corporate Presentation
August 2023
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.

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 preclinical and 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, preclinical 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.

Lead Program: CTIM-76, a Claudin 6 x CD3 Bispecific Antibody

Opportunity	• Claudin 6 (CLDN6) is a **tumor-specific protein** that is present at high surface density across many adult cancers[1] • CLDN6 is expressed at **very low levels or absent** in normal adult tissue
Challenge	• CLDN6 antigen is **conformationally dependent,** which limits access to antibody-antigen binding and antibody development • The CLDN6 antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9, which increases the risk of off-target binding and potential side effects associated with CLDN3 (pancreas), CLDN4 (kidney, pancreas), and CLDN9 (ear, gut)
Target Validation	• TORL's TORL-1-23 ADC and BioNTech's BNT211 CAR-T cell therapy establishes **Proof of Concept**[2,3]: – Efficacy: TORL-1-23 demonstrated **75% ORR** (3/4 pts) at 2.4 mg/kg; BNT211 demonstrated **75% ORR** (6/8 pts) at DL2 – Safety: TORL-1-23 exhibited MMAE-related toxicities; BNT211 exhibited CRS that was adequately managed with anti-IL6

CTIM-76 Claudin 6 x CD3 bispecific antibody	• **Selective for CLDN6:** limited off-target effects • **Potent:** effective CLDN6-positive tumor killing at low doses • **Wide therapeutic window:** decreased risk of dangerous immune response • **IND Filing:** on track for Q1 2024

DL2 = dose level 2; **CRS** = cytokine release syndrome

1 Faber MS, et al. Bispecific claudin-6 x CD3 antibodies AACR Annual Meeting; 2021; Virtual. Abstract 1860
2 Sahin U, et al. TORL1-23: Initial results of a dose finding Phase 1 study. ASCO Annual Meeting; 2023; Chicago, IL. Abstract 3082
3 Haanen JB, et al. BNT211: A Phase I trial. ASCO Annual Meeting; 2023; Chicago, IL. Abstract 2518

Claudin-targeted Therapeutics are Gaining Momentum

$263 million raised in 2023 for early-stage programs from TORL and Alentis

TORL Biotherapeutics (Private)

$158 million Financing

Description
Funding to advance TORL-1-23, a first-in-class, clinical-stage ADC targeting Claudin 6 and other novel clinical and preclinical stage programs.

Participating Investors

Goldman Sachs, vertex VENTURES, MOORE VENTURES, DEEP TRACK CAPITAL, Bristol Myers Squibb, PERCEPTIVE ADVISORS, COWEN HEALTHCARE INVESTMENTS

Alentis Therapeutics (Private)

$105 million Financing

Description
Funding to advance clinical programs ALE.F02 and ALE.C04 – two first-in-class anti-Claudin-1 (CLDN1) antibodies for organ fibrosis and CLDN1 positive tumors.

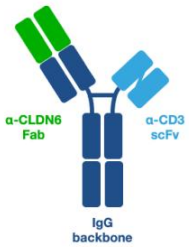
Participating Investors

RACAPITAL, novo holdings, Jeito, Schroders capital, PUREOS BIOVENTURES

Selected information presented is for illustrative purposes only

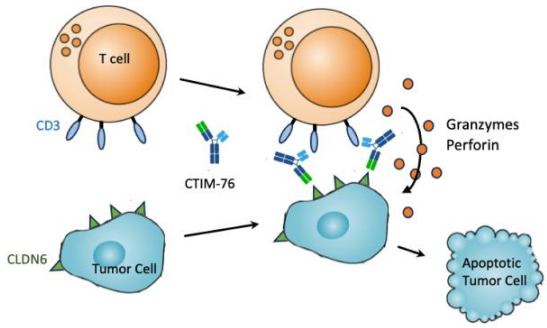
CTIM-76 Structure and Mechanism of Action

CTIM-76: Bispecific T Cell Engager



- Humanized CLDN6 and CD3 binding domains
- Half-life extended via Fc domain
- Silenced Fc domain reduces FcγR binding
- Ease of manufacturing; high purity and low aggregation

Proposed Mechanism of Action



Bispecific T-cell engager molecules bind to CD3 and CLDN6 on T cells and tumor cells, respectively, bringing them into close proximity and triggering destruction of the tumor cells

Bispecific Antibody T Cell Engagers (bsAb TCE) in Solid Tumors

2nd generation assets are addressing toxicity and dosing challenges associated with 1st generation products

Innovation Driving Clinical Success

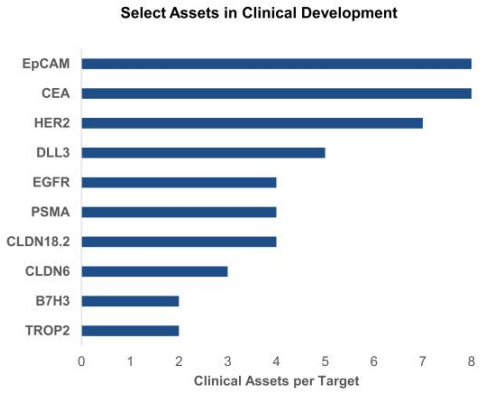
Limitations of 1st generation bsAb TCE:

1) Poor pharmacokinetics, continuous dosing
2) Cytokine release syndrome (CRS)
3) On-target/off-tumor toxicity

Advantages of 2nd generation bsAb TCE:

1) Potential for dosing every 1-3 weeks
2) Improved TCE engineering to mitigate CRS
3) Better target selection and/or enhanced avidity

Over 50 TCE in Clinical Development[1]



1 Data as of August 1, 2023


Claudin 6 (CLDN6)
Target biology and therapeutic rationale
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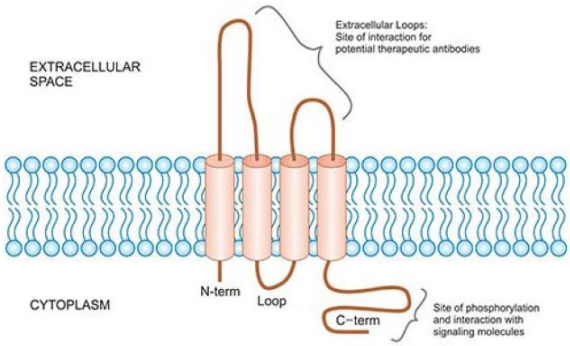
CLDN6 is an Oncofetal Protein

Oncofetal proteins are considered favorable candidates for immunotherapy

Oncofetal Characteristics of CLDN6

- Normally present at higher levels during embryonic development
- Turned off or have low levels of expression in adult tissues
- Increased expression known to occur in some tumor cells, including non-small cell lung cancer (NSCLC), ovarian, and testicular



Huan, Mol Med Reports, 2021

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:

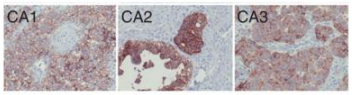
- CLDN6 prevalence
- Patient population size
- Observed clinical responses
- Eligibility for Orphan Designation

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**
Non-Small Cell Lung	201,229	110,653	6-50%[3,4,5]	**35,221**
Gastric	26,380	11,090	13-55%[8,9]	3,771
Malignant Rhabdoid	50	500	29-44%[1,2,6,7]	183
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
Small Cell Lung	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 Ushiku, 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.

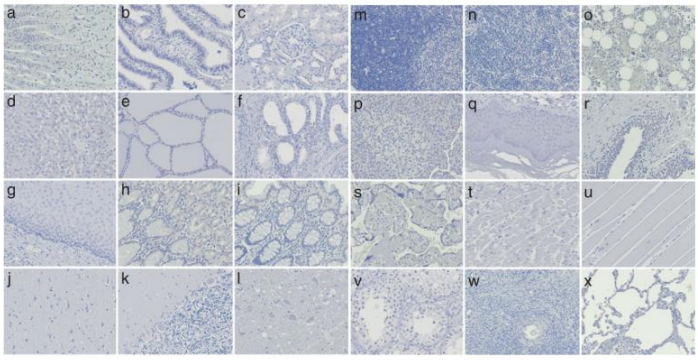
CLDN6 is Selectively Expressed on Cancer Cells

Cancer Tissue



(CA1) testicular cancer, (CA2) ovarian cancer, and (CA3) lung cancer

Normal Tissue

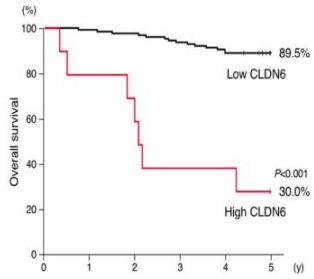


(a) adrenal gland, (b) fallopian tube, (c) kidney, (d) liver, (e) thyroid, (f) prostate, (g) esophagus, (h) stomach, (i) colon, (j) cerebrum, (k) cerebellum, (l) spinal cord. (m) thymus, (n) spleen, (o) bone marrow, (p) pancreas, (q) skin, (r) bladder, (s) placenta, (t) heart muscle, (u) striated muscle, (v) testis, (w) ovary, (x) lung

Reinhard, Science, 2020

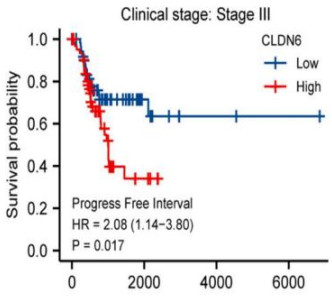
High CLDN6 Associated with a Worsened Prognosis in Cancer Patients

Endometrial Cancer[1]



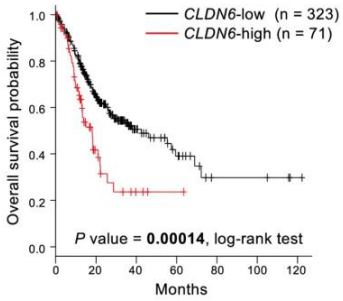
Overexpression of CLDN6 is associated with worse overall survival in endometrial cancer patients

Bladder Cancer[2]



Overexpression of CLDN6 is associated with worse overall survival and higher disease stage (more aggressive) in bladder cancer patients

Stomach Cancer[3]

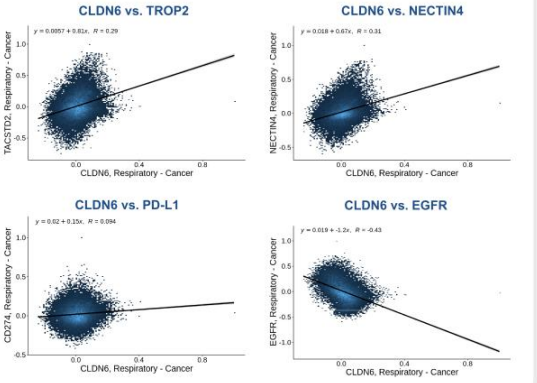


Overexpression of CLDN6 is associated with worse overall survival in stomach cancer patients

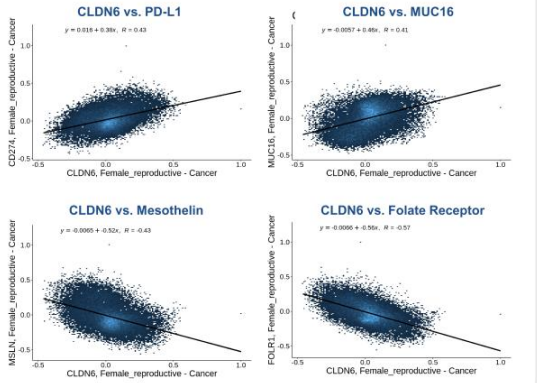
1 Kojima, Cancers, 2020
2 Zhang, Front. Cell Dev. Biol., 2021
3 Kohmoto, Gastric Cancer, 2020

CLDN6 Has Limited Overlap with Competing Drug Targets in Solid Tumors

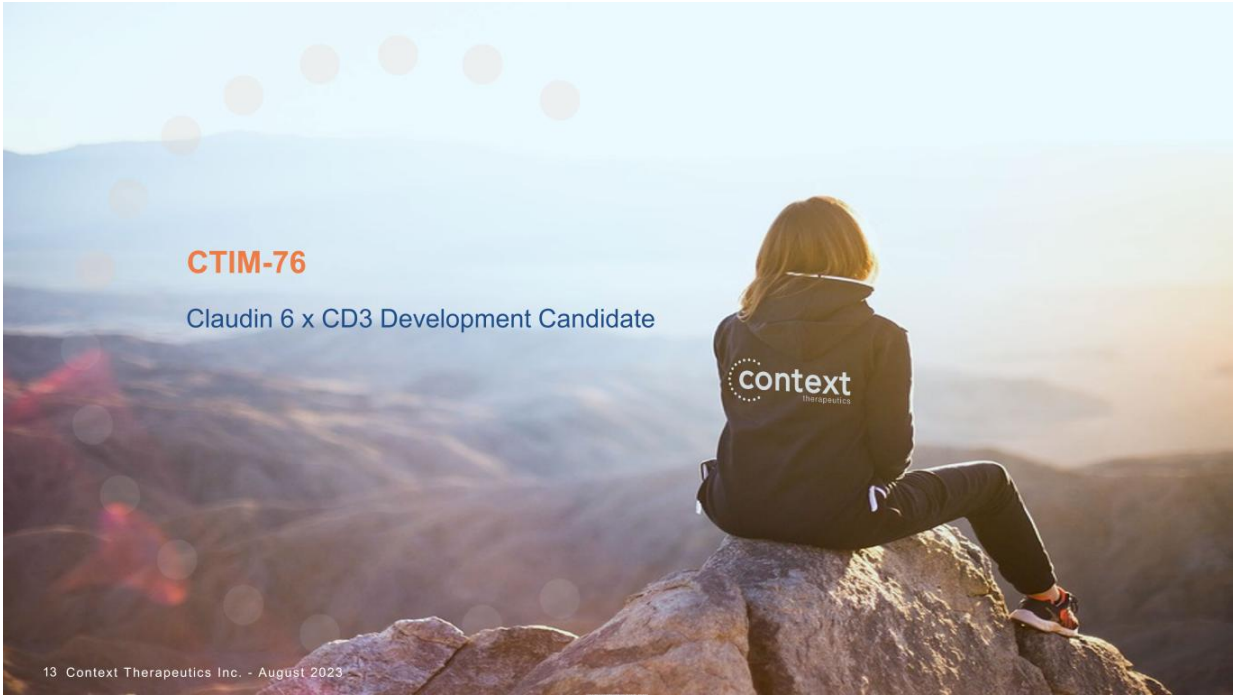
Respiratory Cancer
Limited correlation with TROP2 and Nectin-4,
no correlation with PD-L1 and EGFR



Female Reproductive Cancer
Limited correlation with PD-L1 and MUC16,
no correlation with Mesothelin and Folate Receptor Alpha



Bishop, AnalyzeR [Data Set] Accessed August 1, 2023


CTIM-76
Claudin 6 x CD3 Development Candidate
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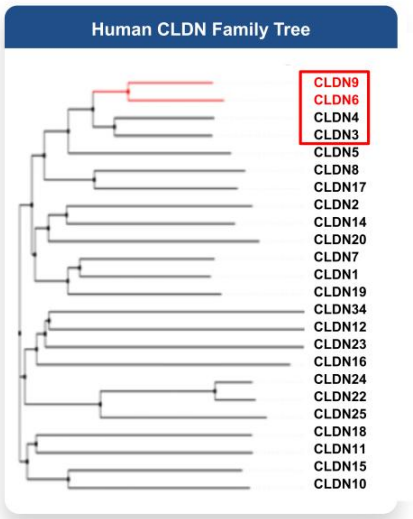
Developing a Highly Selective CLDN6 Antibody is Challenging

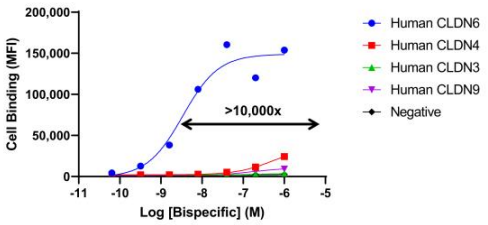


- CLDN6 antigen is **conformationally dependent**, which limits access to antibody-antigen binding
- Antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9, making CLDN6-selective binding a challenge[1]
- CLDN6 **selectivity is required** to avoid off-target liabilities identified in murine knockout studies with CLDN3 (liver, pancreas)[2], CLDN4 (kidney, pancreas)[3], and CLDN9 (ear, gastrointestinal)[4]

1 Screnci, Cancer Res, 2022
2 Tanaka, J Hepatol, 2018
3 Cordat, Physiology, 2019; Li, FEBS Open Bio, 2020
4 Nakano, PLoS Genet, 2009;

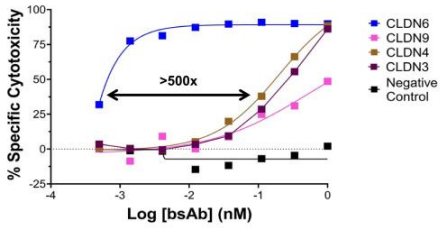
CTIM-76 Exhibits Excellent Selectivity and Potency

CLDN6 Selectivity



- CTIM-76 **CLDN6 EC50 of 3.41 nM (binding)**
- CTIM-76 **preferentially binds** to CLDN6 over CLDN3/4/9
- CLDN3/4/6/9 were transiently transfected in HEK-293F cells (4:1 Target:GFP)

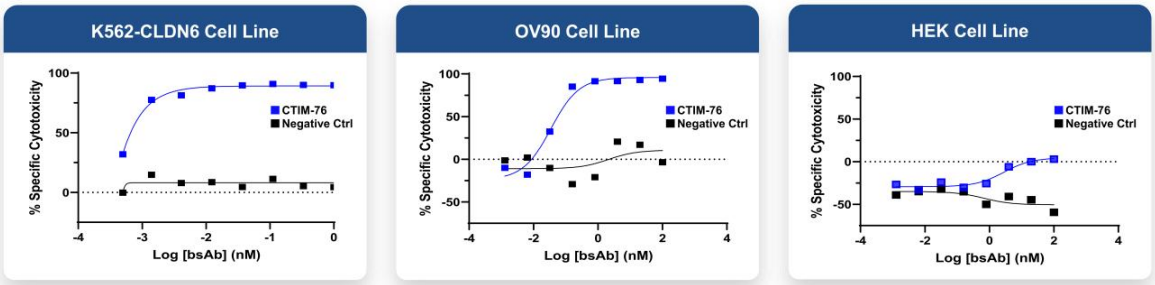
CLDN6 Potency



- Potency assay provides a better assessment than binding assays for off-target liabilities associated with CLDN3, CLDN4, or CLDN9
- CTIM-76 **CLDN6 EC50 of 0.0004 nM (cytotoxicity)**
- CTIM-76 **preferentially targets CLDN6**, with minimal binding and cytotoxicity against CLDN9-expressing cells

CTIM-76 Induces Specific Lysis

CTIM-76 showed potent and specific killing of even those cell lines with very low CLDN6 expression

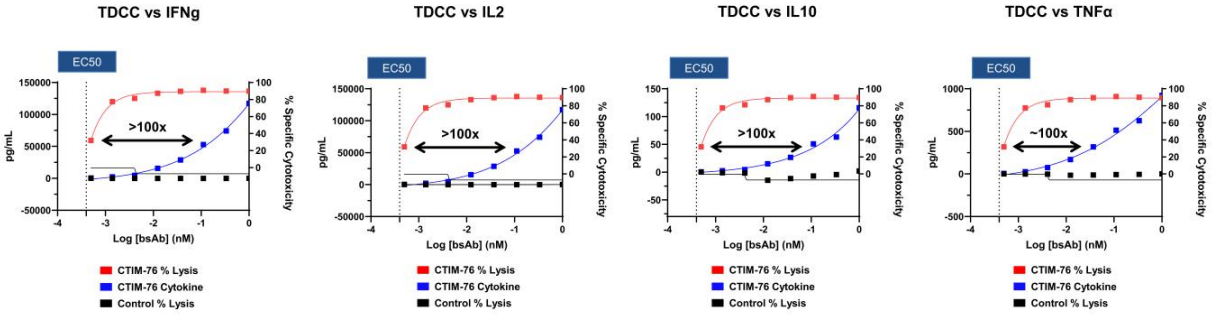


	K562-CLDN6	OV90	HEK
CLDN6 Expression	High	Medium	Low
CTIM-76 (EC50)	0.0004 nM	0.049 nM	2.79 nM

CTIM-76 Exhibits Limited Activation of Free Cytokines

- Data supports potential to dose at levels that promote cancer cell killing but have manageable levels of free cytokine production, thereby potentially reducing the risk of cytokine release syndrome
- Cytokine production evaluated in exogenous (CLDN6-K562) cell line model at 48 hours
- Cytokine production happens well above the concentration of maximal killing (TDCC EC50 = 0.0004 nM)

Comparison of T cell-dependent cellular cytotoxicity (TDCC) to Cytokine Production

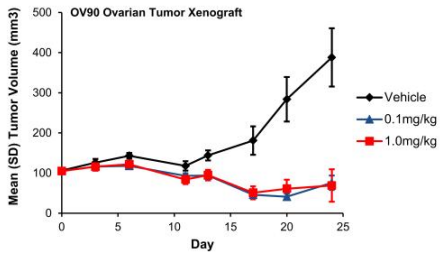


Study Design: K562 cells stably over-expressing CLDN6 and luciferase were co-cultured with human T cells at an E:T ratio of 10:1 for 48 hours. Cytotoxicity was determined by luminescence imaging.

CTIM-76 Preclinical Data

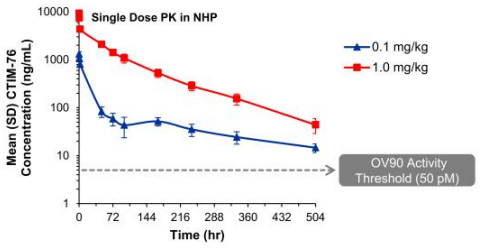
Preliminary efficacy, pharmacokinetics, and safety

Efficacy



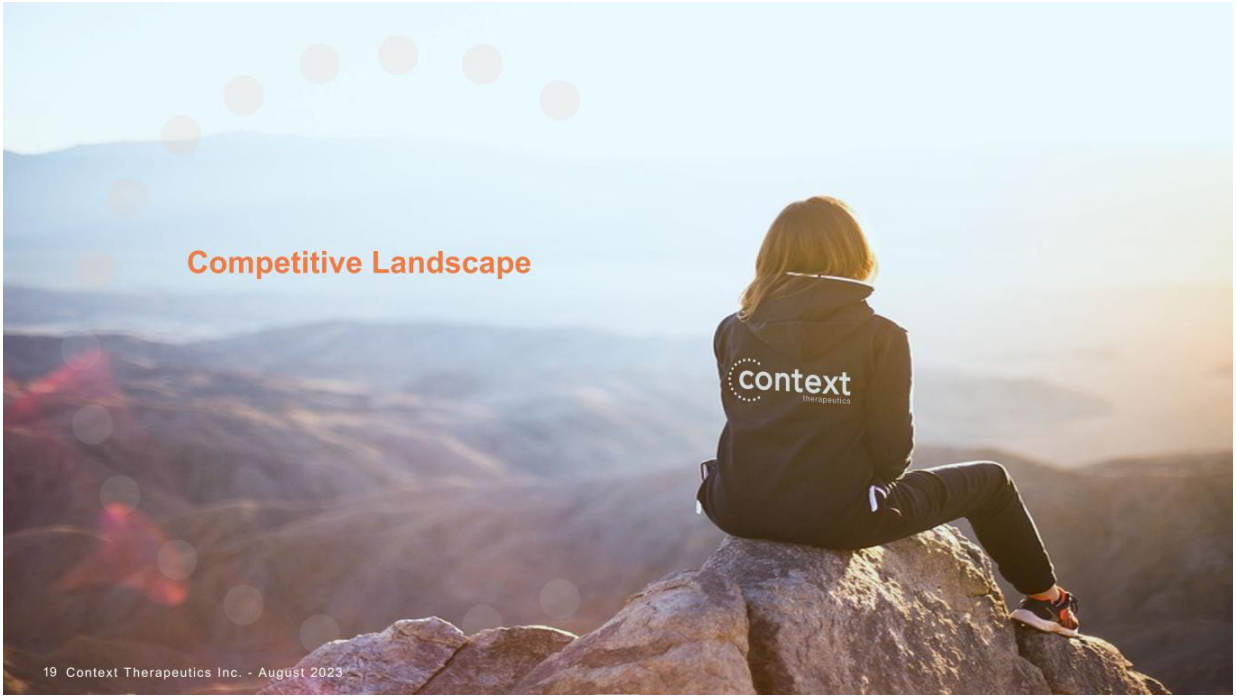
- CTIM-76 effectively engaged systemically administered human PBMC cells to promote significant tumor regression and complete responses in OV90 ovarian xenograft models in mice
- NSG-b2m knockout mice (n=10/arm) engrafted with human PBMCs and bearing advanced subcutaneous OV90 tumor xenografts (~200,000 CLDN6 copies per cell) were treated twice per week with vehicle or CTIM-76

Pharmacokinetics and Safety



- CTIM-76 in non-GLP studies in non-human primates (NHP):
  - Exhibited linear pharmacokinetics and an extended serum half-life
  - No major CRS-associated clinical symptoms or toxicity
  - Well-tolerated at physiologically relevant doses
  - CLDN3/4-related hepatobiliary effects were generally mild and self-resolved upon second treatment

NSG: NOD scid gamma immunodeficient mice; PBMC: peripheral blood mononuclear cells


Competitive Landscape
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CLDN6 Competitive Landscape[1]

1 Analysis based on current understanding of publicly available information compiled as of August 1, 2023

Phase 1 Data Presented by BioNTech and TORL Biotherapeutics at ASCO 2023

CLDN6 programs differentiated by product category, selectivity, potency, and manufacturability

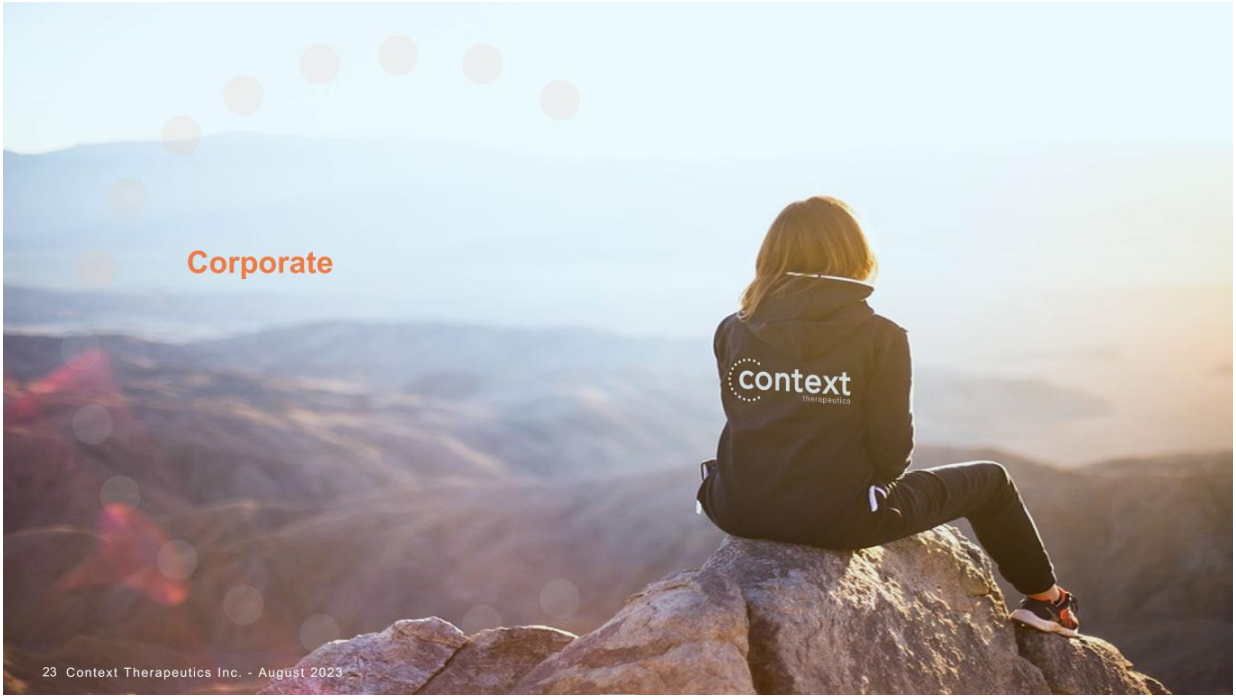
	CTIM-76	BNT211	TORL-1-23
Category	T cell Engager	CAR-T + CARVac	ADC
Mechanism of Action	T cell activation and recruitment to CLDN6+ tumor	Ex vivo T cell activation and recruitment to CLDN6+ tumor with CLDN6 antigen primer to enhance T cell persistence	Preclinical data suggests activity driven by a mix of ADCC-mediated and ADC bystander effect
Side Effects	n/a (preclinical)	Liver enzyme elevations, CRS	Alopecia, anemia, neuropathy, pneumonia
Selectivity			
Potency			
Manufacturability			

Comparison based on publicly available information and represents a non-head-to-head summary comparison
Analysis based on current understanding of publicly available information compiled as of August 1, 2023

Phase 1 Data Presented by BioNTech and TORL Biotherapeutics at ASCO 2023

	BNT211[1]	TORL-1-23[2]
Cutoff Date	March 10, 2023	May 3, 2023
Patients (n)	19 (17 evaluable)	25
Median Prior Treatments, n (range)	4 (2-9)	5 (1-10)
ORR, n (%)	Overall: (7/17) 41% Dose Level 0 or 1: 11% (1/9) Dose Level 2: 75% (6/8) Ovarian DL2: 80% (4/5)	Overall: 7/25 (28%) Ovarian: 6/19 (32%) Ovarian, 2.4mg/kg: 3/4 (75%)
SAE	Grade 3: sepsis (1 pt)	Grade 4: lymphocytopenia (1 pt) Grade 5: pneumonia (1 pt)
Treatment-Related AEs	Liver enzyme elevations	Alopecia Anemia Neuropathy Pneumonia

1 Haanen JB, et al. BNT211: A Phase I trial. ASCO Annual Meeting; 2023; Chicago, IL. Abstract 2518
2 Konecny GE, et al. TORL1-23: Initial results of a dose finding Phase 1 study. ASCO Annual Meeting; 2023; Chicago, IL. Abstract 3082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Experienced Leadership Team

Martin Lehr
CEO and Director

Praesidia Biologics · Cure Duchenne · Osage University Partners

Jennifer Minai, CPA
Chief Financial Officer

Millendo Therapeutics · parexel · EY

Chris Beck, MBA
SVP Operations

Galera Therapeutics · Shire · MERCK

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

Focus on Execution

Experienced team with deep oncology experience

Our CMO led the clinical development of multiple blockbuster drugs including Kisqali, Arimidex, and Afinitor

Our management team is supported by a Board with strong public company operating and governance experience

Investment Highlights (Nasdaq: CNTX)

Large Unmet Need

Solid Tumors

High-Value Target

Claudin 6

Near-Term Milestones

Anticipated Q1 2024 IND filing

Strong Team

Deep Domain Experience, Track Record of Success

Financial Strength

Expected Cash Runway into late 2024


context
therapeutics
Advancing Medicines
for Solid Tumors
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