

Filed pursuant to Rule 433 of the Securities Act of 1933  
Issuer Free Writing Prospectus dated July 12, 2021  
Relating to the Preliminary Prospectus dated July 1, 2021  
Registration Statement File No. 333-256572



## Advancing Medicines For Female Cancers

Context Therapeutics Inc.

## 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.

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The Company has filed with the SEC a registration statement (File No. 333-256572) including a preliminary prospectus for the offering to which this presentation relates, but such registration statement has not been declared effective.

Before you invest, you should read the preliminary prospectus in that registration statement, including the "Risk Factors" set forth therein, and the documents filed as exhibits to the registration statement for more complete information about the Company and the offering. You may access these documents for free by visiting EDGAR on the SEC website at [www.sec.gov](http://www.sec.gov).

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Copies of the preliminary prospectus may be obtained for free by visiting EDGAR on the SEC web site at [www.sec.gov](http://www.sec.gov) or by contacting ThinkEquity, a Division of Fordham Financial Mgmt., Inc., 17 State Street, 22nd Floor, New York, NY 10004, by telephone at (877) 436-3673 or by email at [prospectus@think-equity.com](mailto:prospectus@think-equity.com).



## Offering Summary

<b>Issuer</b>	Context Therapeutics Inc.
<b>Listing</b>	CNTX (NASDAQ Capital Markets)
<b>Proposed Aggregate Offering<sup>(1)</sup></b>	\$19,500,000
<b>Price Range</b>	\$12.00-\$14.00 per share
<b>Shares Offered</b>	1,500,000
<b>Pre-IPO Common Shares Outstanding as converted<sup>(2)</sup></b>	5,376,716
<b>Use of Proceeds</b>	Advancing clinical development of ONA-XR, our lead PR antagonist for PR+ solid tumors, preclinical advancement of Claudin 6 bispecific, R&D working capital, general corporate
<b>Sole Book-Runner</b>	ThinkEquity, a division of Fordham Financial Management, Inc.

(1) Anticipated gross proceeds are assuming a \$13.00 initial public offering price, which is the midpoint of the price range included on the cover page of the preliminary prospectus and the sale of 1,500,000 shares of common stock.

(2) Common stock share total is as of July 1, 2021, after giving pro forma effect to the conversion of all outstanding shares of preferred stock and the conversion of certain warrants immediately prior to the completion of the initial public offering.



- Clinical-stage women's oncology company headquartered in Philadelphia, PA
- Lead program is in Phase 2 development for female hormone-dependent cancers
- Up to 70% of breast, ovarian, and endometrial cancers are hormone-dependent
- Management and advisors have been associated with the development of several FDA approved products (Kisqali<sup>®</sup>, Arimidex<sup>®</sup>) for female, hormone-dependent cancers



**Women's Oncology  
Company**



**Large Market  
With Significant  
Unmet Need**



**Lead Program in  
Phase 2  
Development**

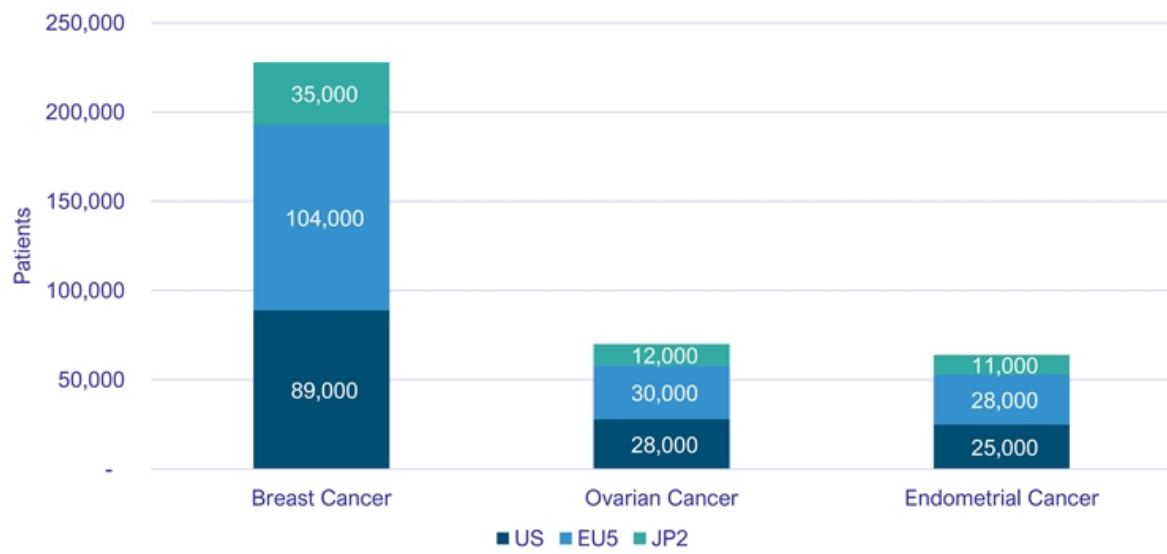


**Experienced  
Team**



## Lead Product ONA-XR Targets Female Hormone-Dependent Cancers

Prevalence of Metastatic Female Hormone-Dependent Cancers in EU5, Japan, and US



## Management



**Martin Lehr**  
CEO and Director

- Independent Director, Praesidia Biologics
- Director, CureDuchenne Ventures
- Senior Associate, Osage University Partners



**Tarek Sahnoud, MD, PhD**  
Chief Medical Officer

- President, OncoStrategy LLC
- CMO, H3 Biomedicines
- SVP, Celgene
- SVP, Novartis Oncology



**Evan Dick, PhD**  
SVP R&D

- SVP, Aclaris Therapeutics
- SVP, Ralexar Therapeutics
- SVP, Ceptaris Therapeutics
- SVP, Ception Therapeutics



**Jennifer Evans Stacey, Esq**  
Independent Director

- GC, Wistar Institute
- GC, Antares Pharmaceuticals
- GC, Auxilium Pharmaceuticals



**Richard Berman, JD, MBA**  
Chairman and Independent Director

- Director, Cryoport (SCYRX), BioVie (SBIV)
- Fmr CEO, Easylink
- SVP, Bankers Trust



**Bill Rencher, PhD**  
Head of CMC and Regulatory

- President, Drug Development Solutions LLC
- Senior Director, Fulcrum Pharma Dev
- Director, CONRAD Program
- Assoc. Director, Schering Plough



**Eileen Kittrick, CPA**  
Controller

- Controller, Genova Group
- Sr Dir, Siegfried Group
- Auditor, Lindquist & Joyce



**Alex Levit, Esq**  
Chief Legal Officer

- Deputy GC, OptiNose
- Associate GC, Teva
- Associate, Reed Smith



**Linda West**  
Independent Director

- Director, Galera Therapeutics (SGRTX)
- CFO, multiple DuPont business units
- General Auditor, DuPont

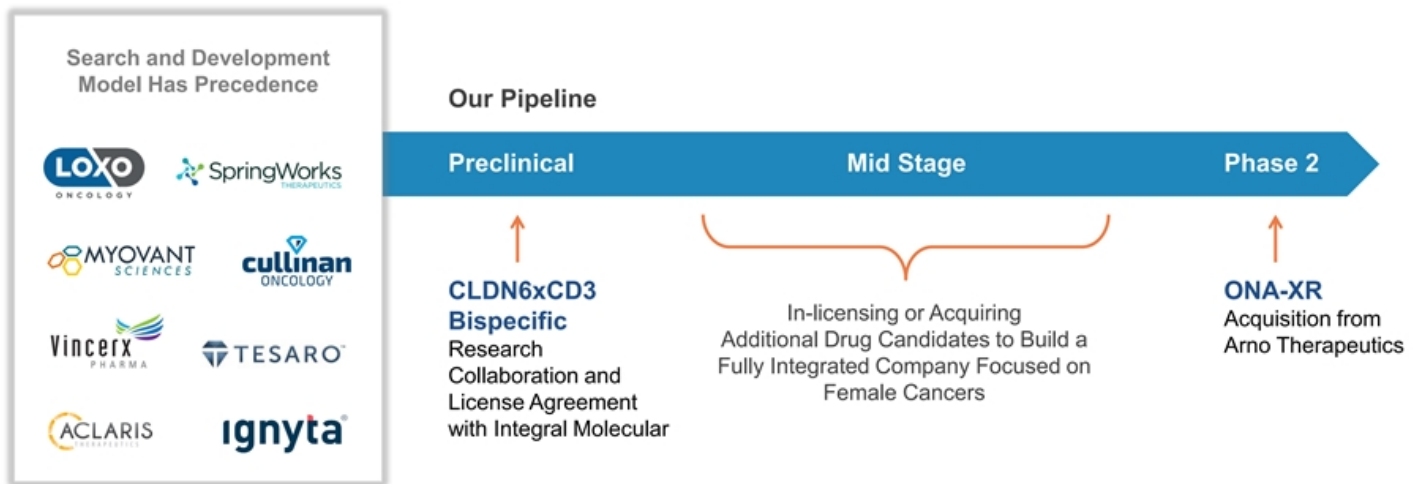


**Philip Kantoff, MD**  
Independent Director

- Chief of Medicine, Memorial Sloan Kettering Cancer Center
- Chair, Clinical Research, Dana Farber Cancer Center
- Chair, SAB, Prostate Cancer Foundation



## How We Will Advance Medicines for Female Cancers



## Search and Development Operating Model





## Pipeline

Cancer	Clinical Indication	Research	Phase 1	Phase 2	Phase 3	Upcoming Milestones	FDA Fast Track
<b>ONA-XR (PR antagonist)<sup>1</sup></b>							
Breast Cancer	1L ER+,PR+,HER2- ctDNA <sup>high</sup>	Phase 1b/2 Trial				<ul style="list-style-type: none"> <li>First patient Mid 2021</li> <li>Proof of concept data 2022</li> </ul>	
	2L/3L ER+,PR+,HER2- Post-CDK4/6 inhibitor	Phase 2 Trial				<ul style="list-style-type: none"> <li>First patient Mid 2021</li> <li>Proof of concept data 2022</li> </ul>	
Ovarian Cancer	Recurrent PR+ Granulosa Cell	Phase 2 Trial				<ul style="list-style-type: none"> <li>Clinical update 1H 2021</li> </ul>	
Endometrial Cancer	Recurrent PR+ Endometrioid	Phase 2 Trial				<ul style="list-style-type: none"> <li>First patient Q2 2021</li> </ul>	
<b>CLDN6xCD3 bispecific antibody</b>							
	Ovarian & Endometrial Cancer					<ul style="list-style-type: none"> <li>IND enabling studies 2022</li> </ul>	



# ONA-XR

Progesterone Receptor Antagonist



## ONA-XR: Oral PR Antagonist for ER+,PR+,HER2- Breast Cancer

- Up to 70% of breast cancer patients have hormone-dependent disease referred to as ER+,PR+,HER2-
- For these patients, estrogen deprivation (via anti-estrogen) therapy is the core treatment modality
- Anti-estrogen resistance leads to poor treatment response in later treatment lines
- Unmet need for a new therapy that can overcome anti-estrogen resistance

High-Risk	Primary Disease	Adjuvant Therapy	Metastatic Breast Cancer		
Mammographic Monitoring	Surgery + Chemotherapy and/or Radiation	Antiestrogen	1 <sup>st</sup> Line Letrozole + CDK4/6	2 <sup>nd</sup> Line Fulvestrant or Fulvestrant + Alpelisib	3 <sup>rd</sup> Line Chemotherapy or Palliative Care

- 24 month PFS
- 20-25% ORR

- 2-7 month PFS
- < 15% ORR

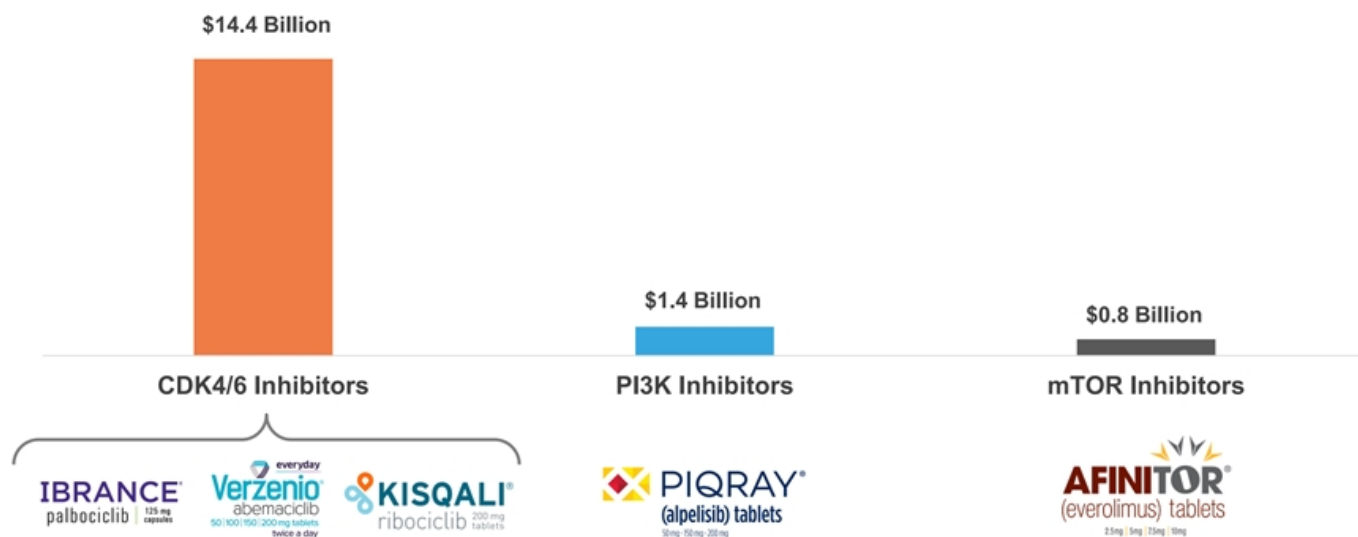
ONA-XR may decrease mammographic density and decrease risk of developing breast cancer

ONA-XR may enhance activity of antiestrogens

ONA-XR may enhance activity of antiestrogens and reduce the need for chemotherapy



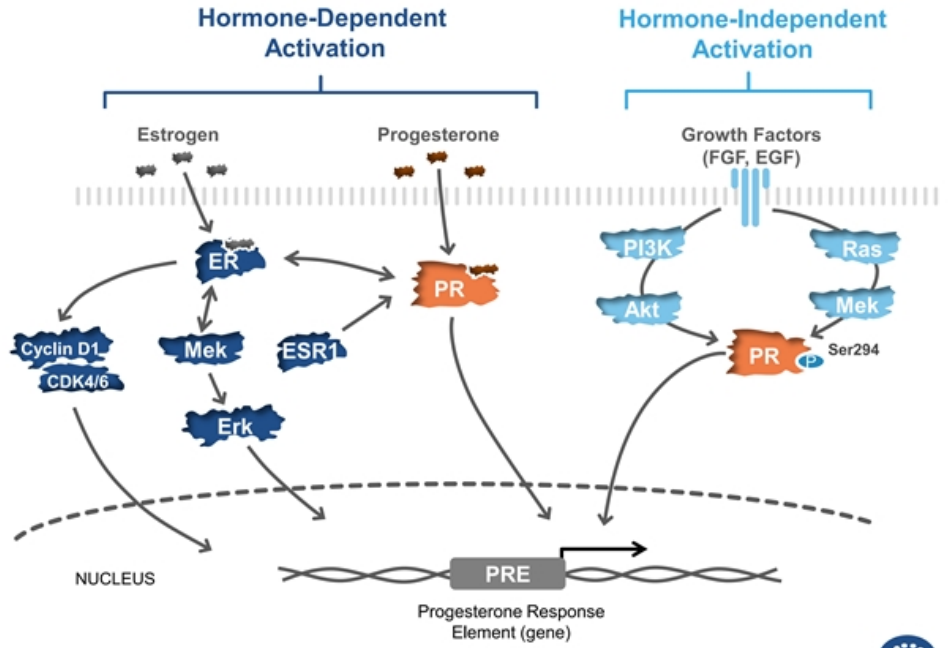
## Vast Market Opportunity for ONA-XR in Hormone-Driven Breast Cancer



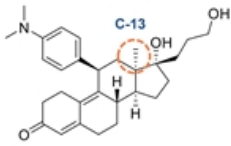
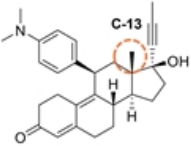
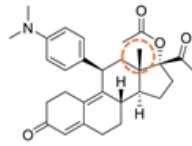
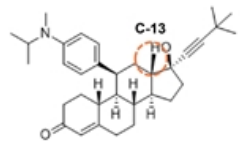
# ONA-XR Works by Blocking PR Activation of Cancer Signaling Pathways

## How Onapristone Works

- Onapristone prevents progesterone receptor (PR) dimerization and nuclear translocation
- Onapristone is the only PR antagonist to block both progesterone and growth-factor mediated activation of PR





## ONA-XR is a Full PR Antagonist

	Full Antagonist	MIFEPRISTONE (Korlym™)	ULIPRISTAL ACETATE (Esmya™)	ORIC-101 (Oric Pharmaceuticals)
PR Classification	Full Antagonist	Partial Antagonist	Partial Antagonist	Partial Antagonist
Configuration	3-Dimensional	Flat	Flat	Flat
Chemical Structure				
Selectivity PR / AR PR / GR	<b>32</b> <b>47</b>	4 2	5 2	n.d. 0.3
Side Effects	<b>Fatigue</b>	abdominal pain, uterine cramping, nausea, vomiting, and diarrhea	headache, nausea, feeling tired, and abdominal pain	cortisolemia, nausea
Response Rate 1L mBCa	<b>56%</b>	10%	n.a.	n.a.



## Clinical Activity Supported by Prior Studies with Immediate Release (IR) Formulation

Antiprogesterin	Clinical Indication	Response	Positives	Limitations
<b>Onapristone Immediate Release (ONA-IR)<sup>1</sup></b> 100mg QD	1L (first line) Breast Cancer Locally Advanced or Metastatic	56% ORR <sup>2</sup> 67% CBR 17.5-month DoR 14-month PFS	 Monotherapy activity	Signs of transient liver enzyme elevations
<b>Onapristone Immediate Release (ONA-IR)</b> 100mg QD	2L (second line) Breast Cancer Metastatic	10% ORR <sup>3</sup> 48% CBR	 Monotherapy activity	Lack of selection for PR+ patients may underrepresent true clinical effect

(1) ONA-IR is not FDA approved and no longer in clinical development  
 (2) Robertson 1999  
 (3) Jonat 2002



## Our Strategy to Improve Clinical Outcomes from ONA-IR Studies



**Extended-Release Formulation (ONA-XR)**  
to improve safety



**Utilize PR Biomarker**  
for patient selection



**Incorporate New Diagnostic Technologies**  
to predict response for use in future trials





## Clinical Development Plan in Breast Cancer

Treatment Line	Estimated Market Size (US)*	Standard of Care (SOC)	Unmet Need	Context Trial	Trial Status
<b>Adjuvant</b> (after Primary Disease)	>>250,000	Antiestrogen	Enhance Antiestrogen potency; decrease progression to TNBC	Window of Opportunity <sup>1</sup>	Enrollment Completed; Data Anticipated Q4 2021
<b>First-Line Metastatic</b>	75,000	Antiestrogen + CDK4/6i	Identify and treat 20% of patients who are at high risk of early relapse	1L ER+,PR+,HER2-(ctDNA <sup>high</sup> ) <sup>2</sup>	Study Open
<b>Second / Third Line Metastatic</b>	35,000	Fulvestrant or Fulvestrant + PI3Ka	Weak tumor response to current SOC	2L/3L ER+,PR+,HER2-(post-CDK4/6i) <sup>3</sup>	Study Open

**Our Trials are Each Designed to Address a Specific Clinical Unmet Need**



## Additional Clinical Opportunity in Gynecologic Cancers

Cancer	Estimated Market Size (US)*	Standard of Care (SOC)	Unmet Need	Context Trial	Trial Status
Recurrent Endometrial	25,000	Lenvima + Keytruda	Limited treatment options after recurrence	Combination with Anastrozole in PR+ patients <sup>1</sup>	Study Open
Recurrent Granulosa Cell Tumor of Ovary	5,000	Physician's Choice	No FDA approved products in recurrent setting	Combination with Anastrozole in PR+ patients <sup>2</sup>	Monotherapy Phase Complete; Combination Study Open

### Progesterone Receptor is an Emerging Target in Gynecologic Cancers



## Summary

### ONA-XR



- ONA-XR is an oral, full progesterone receptor (PR) antagonist
- PR is a validated clinical target in breast cancer, emerging target in gynecologic cancers
- IP protection through 2034, assuming no additional patent filings

### Large Market Opportunity



- Hormone driven cancer (breast, ovarian, endometrial) are large and growing markets
- Unmet need to address resistance to antiestrogens and new products

### Near-Term Value Creation



- Multiple Phase 2 studies across PR+ breast, ovarian, and endometrial cancers
- Utilization of novel diagnostic technologies provides early readout of clinical activity



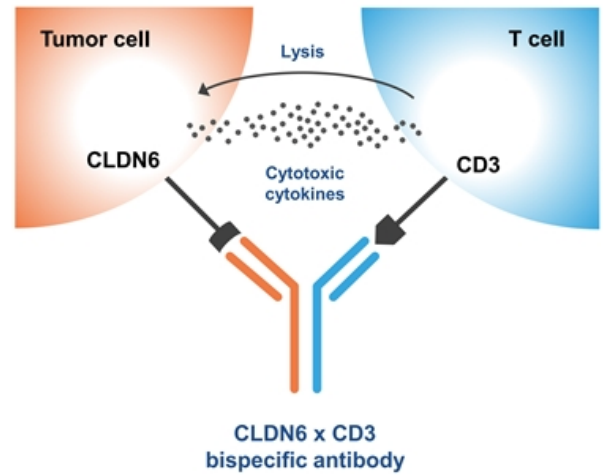
## Claudin 6 Program



## CLDN6 x CD3 Bispecific Antibody

*Designed to Recruit Cytotoxic T-cells to Claudin 6-expressing Tumors*

- Unique Drug Target**  
 Claudin 6 (CLDN6) is an oncofetal membrane protein target expressed in multiple hormone-dependent cancers and absent from healthy adult tissues
- Target Cross-Reactivity is Major Challenge**  
 CLDN6 is structurally similar to CLDN9, which is required for normal hearing and maintaining the gut epithelial barrier<sup>1,2</sup>
- Overcomes Cross-Reactivity Challenge**  
 Several global pharmaceutical companies are developing anti-CLDN6 antibodies, but due to close structural homologies with other claudins, especially CLDN9, to our knowledge there are no highly selective inhibitors of CLDN6 in clinical development



## Competitive Landscape

Competition differentiated by stage, drug format, and Claudin 6 selectivity

	Context	BioNTech	Abbvie
<b>Program</b>	Confidential	BNT211 BNT142	SC-004
<b>Antibody Format</b>	CLDN6xCD3 Bispecific	CLDN6 CAR-T, CLDN6xCD3 (bi(sFc))	CLDN6/9 ADC
<b>Stage</b>	Preclinical	Phase 1, Phase 1	Phase 2
<b>Status</b>	Active	Active <sup>i</sup>	Deprioritized <sup>ii</sup>
<b>Selectivity CLDN6:9</b>	<b>&gt;100x</b>	<b>7x</b>	<b>1x</b>

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



## Summary



Precision Medicines Meets Immunotherapy



Claudin 6 is Enriched in Multiple Cancers



Opportunity to be 1<sup>st</sup>/2<sup>nd</sup> in Market Based on Current Competition



Entering IND Enabling Studies in 2022






Corporate





## Anticipated Use of Proceeds: ~\$15.9 million<sup>1</sup>

	Activity	Description	Capital Allocation <sup>2</sup>
	<b>Clinical Development</b>	ONA-XR development, including our three ongoing Phase 2 trials, our ongoing Phase 1b/2 trial and our two ongoing Phase 0 trials	~\$7.4 million
	<b>Preclinical Development</b>	CLDN6xCD3 bsAb development	~\$3.5 million
	<b>General Corporate and Working Capital</b>	Corporate expenses	~\$5.0 million

<sup>1</sup> Anticipated net proceeds are assuming a \$13.00 initial public offering price, which is the midpoint of the price range included on the cover page of the preliminary prospectus and the sale of 1,500,000 shares of common stock, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

<sup>2</sup> Our expected use of proceeds represents our intentions based upon our current plans and business conditions. However, we cannot predict with certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above.



## Cap Table

Capitalization <b>Common Stock<sup>(1)</sup></b>	<b>5,376,716</b>
-----	
<b>Options<sup>(2)</sup></b>	<b>436,437</b>
-----	
<b>Fully Diluted Common</b>	<b>5,813,153</b>
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## Valuation

Valuation drivers are blended values from the following:

### **ONA-XR**

Multiple Phase 2 trial readouts

### **Claudin 6**

Precision medicine meets immunotherapy

### **Search and Development**

Opportunistic pipeline expansion

### **Experienced Team**

Multiple FDA approvals in female cancers

(1) Common stock share total is as of July 1, 2021, after giving pro forma effect to the conversion of all outstanding shares of preferred stock and the conversion of certain warrants immediately prior to the completion of the initial public offering.

(2) Shares of common stock subject to options is as of July 1, 2021. The weighted average exercise price of such options is \$2.69 per share.



## Partnerships



### Worldwide Exclusive License to CDLN6 Antibody in Bispecific Format

- Integral Molecular to design and optimize CLDN6 x CD3 bispecific antibody
- Context to fund all development and commercial activities
- Integral received upfront payment and is eligible to receive future milestones and royalties



### CMC Partnership and Out-licensing of Rights to ONA-XR in Greater China

- Tyligand to design and optimize a novel onapristone manufacturing process
- Tyligand receives license to ONA-XR in Greater China

### Value-Creating Partnerships






Expands Pipeline

Capital Efficient

Mutually Beneficial Economics



## Investment Highlights

Large Unmet Need		Female Cancers
High Value Targets		Progesterone Receptor and Claudin 6
Lead Product Candidate		ONA-XR Being Evaluated in Multiple Phase 2 Trials
Strong Team		Deep Domain Experience, Track Record of Success
Near-Term Milestones		Multiple Data Readouts in 2022





Advancing Medicines  
for Female Cancers

## Appendix



## Abbreviations

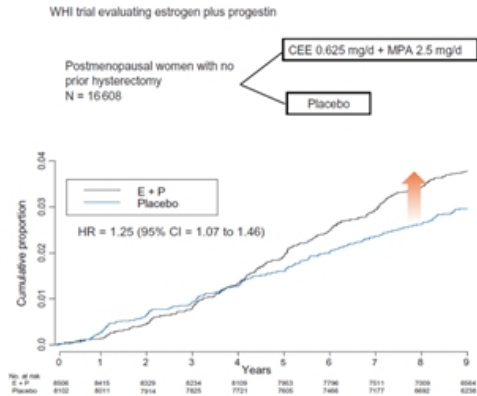
<b>AR</b>	Androgen Receptor
<b>ctDNA</b>	Circulating tumor DNA
<b>ER</b>	Estrogen receptor
<b>ESR1</b>	Estrogen receptor 1 gene
<b>Ful</b>	Fulvestrant
<b>GR</b>	Glucocorticoid Receptor
<b>MAPK</b>	Mitogen activated protein kinase
<b>mBCa</b>	Metastatic breast cancer
<b>ONA-IR</b>	Onapristone immediate release
<b>ONA-XR</b>	Onapristone extended release
<b>ORR</b>	Overall response rate
<b>PFS</b>	Progression free survival
<b>PR</b>	Progesterone receptor
<b>PR+</b>	Progesterone receptor positive
<b>SERD</b>	Selective estrogen receptor degrader
<b>SoC</b>	Standard of Care
<b>WT</b>	Wild type



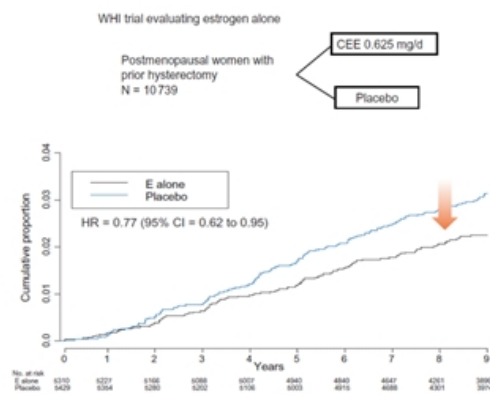
## Epidemiologic Evidence: Progesterone Increases Breast Cancer Risk

Progesterone promotes oncogenic progression and maintenance of stem cells, creating a reservoir of pre-malignant cells to seed metastasis. Initial evidence for this tumorigenic role is derived from longitudinal studies of the use of hormone replacement therapy in menopausal women. These studies determined that estrogen was correlated with a 23% decrease in cancer risk, whereas progesterone was correlated with a 25% increase in cancer risk (Horwitz 2008, Anderson 2012). **The conclusion of this finding is that blocking progesterone function via anti-progestin therapy may be beneficial in cancer patients.**

### Estrogen + Progestin HRT 25% increase cancer risk

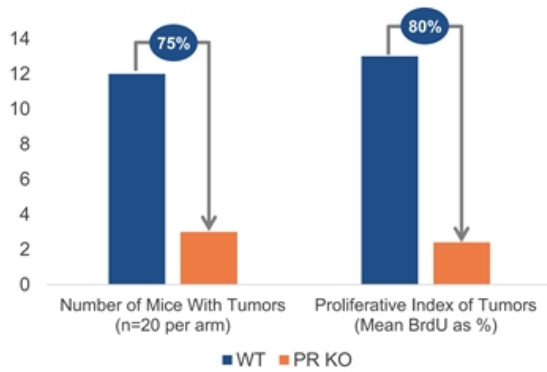


### Estrogen HRT 23% decrease cancer risk

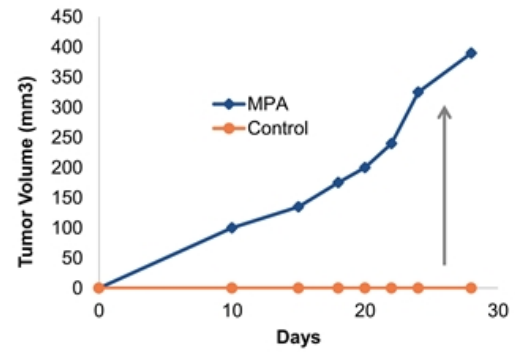




## Target Validation: In Vivo Models



**Progesterone Receptor Knockout (PR KO) Inhibits Tumors**  
Carcinogen treated, 7,12 dimethylbenz(a)anthracene (DMBA), pituitary-isografted mice, there was a marked reduction in mammary tumor incidence at week 44 in PRKO mice as compared with isogenic wild types (WT).  
(Adapted from Lydon)



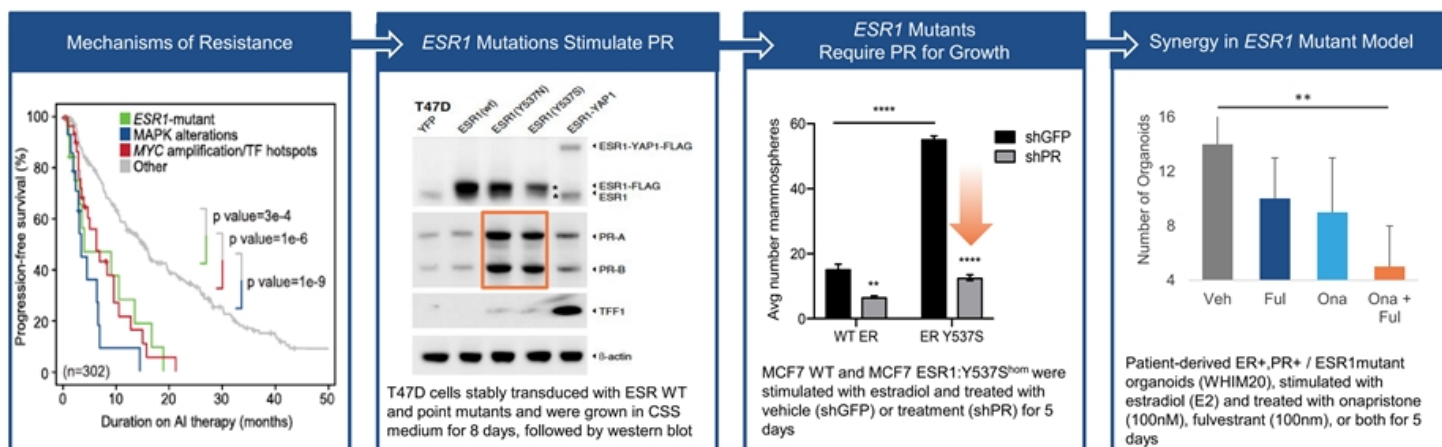
**Progesterone Stimulates Tumors**  
Progesterin-induced mammary carcinomas were subcutaneously transplanted into the flank of female BALB/c mice treated or non-treated with synthetic progesterone - medroxyprogesterone acetate (MPA).  
(Adapted from Lanari)

## Progesterone Receptor Regulates Tumor Growth



## ONA-XR Active in Hard-to-Treat *ESR1* Mutations

- 20-35% of ER+,PR+,HER2- metastatic breast tumors are *ESR1* mutated (hyperactive estrogen receptor)<sup>1,2</sup>
- Estrogen receptor mutations are associated with resistance to anti-estrogen + CDK4/6i therapy<sup>1,2</sup>
- *ESR1* mutations stimulate PR expression and induce PR activity<sup>3</sup>



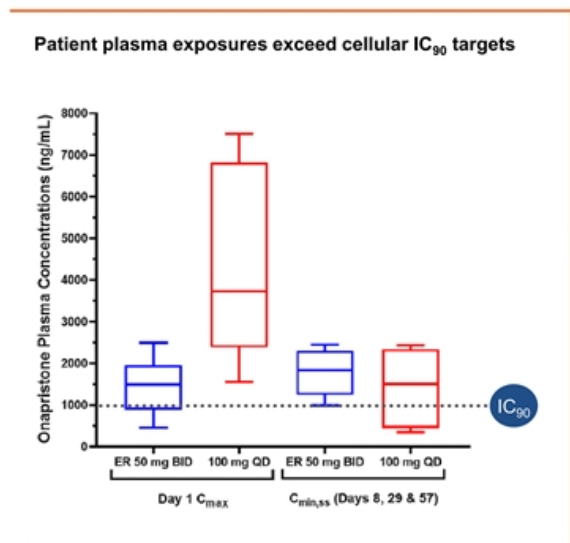
## Onapristone Clinical Experience

Antiprogestin	Stage	Patients (n)	Clinical Indication	Prior Treatments Median (Range)	Biomarker	Data	Reference
Onapristone IR (100mg QD)	Phase 2	19	Breast Cancer Locally Advanced or Metastatic	Hormone naïve		56% ORR, 17.5-month DoR 67% CBR 14.0 month PFS	Robertson 1999
Onapristone IR (100mg QD)	Phase 2	101	Breast Cancer Metastatic	1 (1-2)		10% ORR 48% CBR 4.0 month PFS	Jonat 2002
Onapristone XR (50mg BID)	Phase 2	14	Granulosa Cell Tumor of Ovary Metastatic	4 (2-17)	PR+	*57% DCR *21% 6-month PFS	Ongoing
Onapristone IR (10 - 50mg BID) ±Abiraterone	Phase 1b/2	36	Castrate Resistant Prostate Cancer Active progression on Abiraterone	2 (1-4)	PR+	ONA-XR (10-50 mg) 2.8 month PFS ONA-XR (50 mg) + Abiraterone 4.4 month PFS	Jayaram 2017
Onapristone XR (10 - 50mg BID)	Phase 1	20	Breast Cancer Metastatic	9 (2-14)	PR+	25% DCR 15% 6-month PFS	Cottu 2018
Onapristone XR (10 - 50mg BID)	Phase 1	13	Ovarian Cancer Metastatic	4 (2-10)	PR+	8% ORR 31% 6-month PFS	Cottu 2018



## Safety: ONA-XR Has Improved Tolerability Over ONA-IR

### ONA-XR Has Lower C<sub>max</sub> and Equivalent C<sub>min</sub> Compared to ONA-IR<sup>(1)</sup>



### ONA-XR Significantly Reduced Rate of Liver Enzyme Elevations<sup>(1)</sup>

Study	Robertson 1999	Jayaram 2017, Cottu 2018
<b>Drug</b>	Onapristone IR	ONA-XR
<b>Dose</b>	100 mg QD	10-50 mg BID
<b>Patients (n)</b>	19	88
<b>Liver Related TEAE (all grades); n (%)</b>		
ALT increased	12 (63.2)	↓ 9 (10.2)
Blood ALP increased	7 (36.8)	↓ 6 (6.8)
Blood bilirubin increased	4 (21.1)	↓ 3 (3.4)
GGT increased	10 (52.6)	↓ 14 (15.9)
ALT > 3X and bilirubin > 2X with ALP > 2X	0 (0.0)	↔ 0 (0.0)



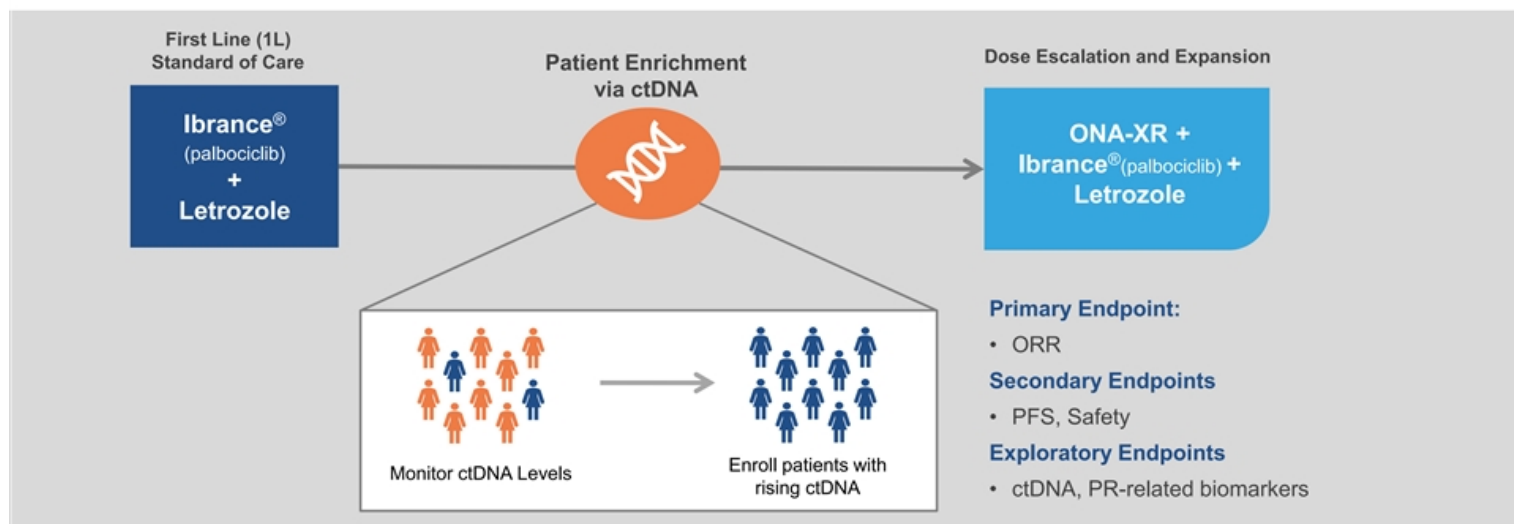
## ONA-XR: Summary of Cumulative Serious Adverse Events\*

System Organ Class Preferred Term	Overall (N=128) n (%)	10mg BID (N=16) n (%)	20mg BID (N=18) n (%)	30mg BID (N=15) n (%)	40mg BID (N=14) n (%)	50mg BID (N=47) n (%)*	100mg QD (N=6) n (%)
<b>Any Serious TEAE</b>	<b>34 (27)</b>	<b>7 (44)</b>	<b>7 (39)</b>	<b>6 (40)</b>	<b>3 (21)</b>	<b>9 (19)</b>	<b>1 (17)</b>
Ascites	2 (2)	0	0	0	1 (7)	1 (2)	0
Vomiting	2 (2)	0	1 (6)	1 (7)	0	0	0
Chest pain	2 (2)	0	1 (6)	0	1 (7)	0	0
Pneumonia	2 (2)	0	0	2 (13)	0	0	0
Femur fracture	2 (2)	0	0	1 (7)	0	1 (2)	0
Anemia	1 (1)	0	0	0	0	0	1 (17)
Atrial fibrillation	1 (1)	0	0	0	0	1 (2)	0
Syncope	1 (1)	0	0	0	0	1 (2)	0
Retinal artery occlusion	1 (1)	0	1 (6)	0	0	0	0
Abdominal pain upper	1 (1)	1 (6)	0	0	0	0	0
Upper gastrointestinal hemorrhage	1 (1)	0	0	1 (7)	0	0	0
Volvulus	1 (1)	0	0	0	0	1 (2)	0
Death	1 (1)	0	0	0	0	1 (2)	0
Pyrexia	1 (1)	0	1 (6)	0	0	0	0
Portal vein thrombosis	1 (1)	1 (6)	0	0	0	0	0
Abdominal wall abscess	1 (1)	1 (6)	0	0	0	0	0
Post procedural cellulitis	1 (1)	0	0	0	1 (7)	0	0
Pyelonephritis	1 (1)	0	0	0	0	0	1 (17)
Sepsis	1 (1)	0	0	0	0	1 (2)	0
Aspartate aminotransferase increased	1 (1)	1 (6)	0	0	0	0	0
Hypercalcaemia	1 (1)	0	0	0	1 (7)	0	0
Hyperkalaemia	1 (1)	0	0	0	1 (7)	0	0
Hyponatraemia	1 (1)	0	0	0	1 (7)	0	0
Hydronephrosis	1 (1)	0	0	0	0	0	1 (17)
Urinary retention	1 (1)	0	0	1 (7)	0	0	0



## First Line Metastatic Breast Cancer<sup>1</sup>

Phase 1b/2 Adaptive Trial utilizing ctDNA for Selection of Patients Who Are at High Risk of Early Relapse

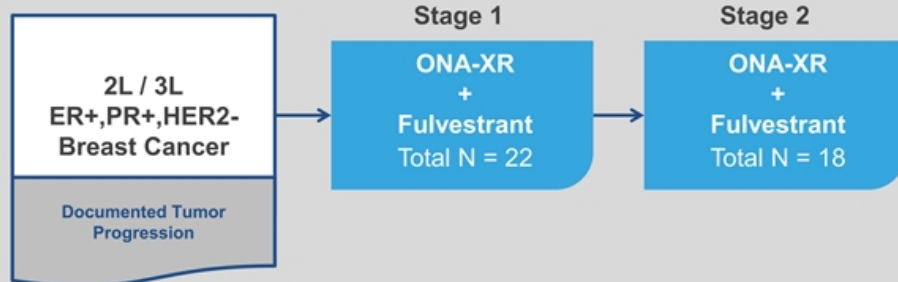


Potential Whitespace Opportunity Within 1L HR+,HER2- mBCa



## Second / Third Line Metastatic Breast Cancer<sup>1</sup>

Phase 2 Trial Evaluating Complete Hormone Blockade in Women Who Progressed on Prior Therapy in the Metastatic Setting



### Endpoints:

- Primary: ORR
- Secondary: ctDNA, PFS, safety



### Subgroup Analysis

- *ESR1* and *PIK3CA* mutations
- PR-related biomarkers

Intended to Establish Combination Synergy After Failure of CDK4/6 and/or PI3K $\alpha$  Inhibitors



## Pharmacodynamic Studies

Study	Target Deliverables
 <p><sup>1</sup>Radiolabeled Progesterone (<sup>18</sup>F-FFNP PET) Uptake in Tumors</p>	<ul style="list-style-type: none"> <li>• Target engagement</li> <li>• Confirmation of recommended phase 2 dose (RP2D)</li> <li>• Drug distribution</li> </ul>
 <p><sup>2</sup>Window of Opportunity in primary breast cancer</p>	<ul style="list-style-type: none"> <li>• On-target drug effects</li> </ul>

## Studies Seek to Confirm Target Engagement and On-target Drug Effects





## Onapristone Intellectual Property

- Will be considered a New Chemical Entity (NCE)
- Eligible for regulatory exclusivity in all territories worldwide, outside of China\*
- ANDA challenge would have to provide bioequivalence to ONA-XR
- Issued patents in the US and Japan around extended-release formulation with expiration date in 2034 + PTE
- Polymorph patent applications offer potential protection through 2034 + PTE

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### Patent Family 1

- Issued in US, Japan, Canada
- Pending prosecution in other major territories
- Covering methods and compositions of ONA-XR

### Patent Family 2

- Issued in US
- Pending prosecution in other major territories
- Covering onapristone polymorphs

